

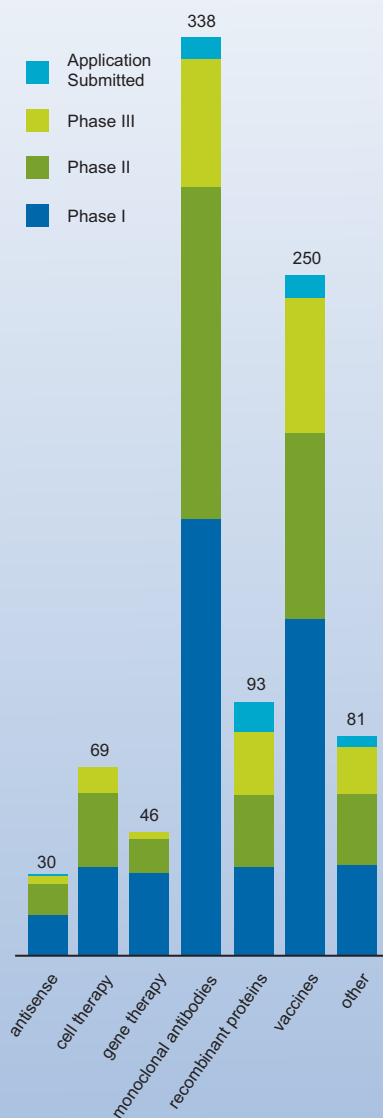
MEDICINES IN DEVELOPMENT

# Biologics

PRESENTED BY AMERICA'S BIOPHARMACEUTICAL RESEARCH COMPANIES

## Biologics Research Pushing Frontiers of Science With More Than 900 Medicines and Vaccines in Development

### Biologics In Development By Product Category and Development Phase



In the human body there are **12 trillion cells**, **200,000 proteins** and **25,000 genes**



America's biopharmaceutical research companies are developing 907 biologics targeting more than 100 diseases. Biologics are developed through biological processes using living cells or organisms.

This report lists biologics in human clinical trials or under review by the U.S. Food and Drug Administration (FDA). A link to the sponsor company's web site provides more detailed information on the science and technologies behind each potential product. The 907 medicines and vaccines in development include:

- 338 cancer therapeutics that target several different types of solid tumors, leukemia and lymphoma. Monoclonal antibodies account for 170 of the 338 products in development.
- 176 candidates in development for an array of infectious diseases, including 134 vaccines.
- 71 medicines for autoimmune diseases, such as lupus, multiple sclerosis and rheumatoid arthritis.

- 58 treatments for cardiovascular diseases, such as congestive heart failure and stroke.
- Other diseases include diabetes, digestive disorders, genetic disorders, neurologic and respiratory disorders.

Definitions for selected product categories and diseases can be found on page 86.

For information on the history and future of biologics research, the science behind the medicines, and a discussion of issues critical to continued discovery and development of these cutting-edge medicines, please see *Biologic Medicines in Development 2013—Overview*.

The medicines in this report reflect the new ways America's biopharmaceutical research companies are attacking disease through biotechnology. The 907 medicines and vaccines in development promise to push the frontiers of science and bring new treatments to patients for our more challenging diseases.

## AUTOIMMUNE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase*
ABT-122	AbbVie <i>North Chicago, IL</i>	mAb	rheumatoid arthritis	Phase I <a href="http://abbvie.com">abbvie.com</a>
<b>Actemra®</b> tocilizumab	Genentech <i>South San Francisco, CA</i> Roche <i>Nutley, NJ</i>	mAb	early rheumatoid arthritis	Phase III <a href="http://gene.com">gene.com</a>
			systemic sclerosis	Phase II <a href="http://gene.com">gene.com</a>
AGS-009	Argos Therapeutics <i>Durham, NC</i>	mAb	systemic lupus erythematosus (SLE)	Phase I <a href="http://argostherapeutics.com">argostherapeutics.com</a>
alemtuzumab	Genzyme <i>Cambridge, MA</i>	mAb	relapsing-remitting multiple sclerosis (Fast Track)	application submitted <a href="http://genzyme.com">genzyme.com</a>
<b>Alferon N Injection®</b> interferon-alpha-n3 subcutaneous	Hemispherx Bioscience <i>Philadelphia, PA</i>	interferon	multiple sclerosis	Phase II <a href="http://hemispherx.net">hemispherx.net</a>
AMG 557/MEDI-5872	Amgen <i>Thousand Oaks, CA</i> AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	mAb	SLE	Phase I <a href="http://amgen.com">amgen.com</a> <a href="http://astrazeneca.com">astrazeneca.com</a> <a href="http://medimmune.com">medimmune.com</a>
AMG 729	Amgen <i>Thousand Oaks, CA</i>	mAb	autoimmune diseases	Phase I <a href="http://amgen.com">amgen.com</a>
AMG 811	Amgen <i>Thousand Oaks, CA</i>	mAb	discoid lupus erythematosus, SLE	Phase I <a href="http://amgen.com">amgen.com</a>
anti-IL17 mAb (RG7624)	Genentech <i>South San Francisco, CA</i>	mAb	autoimmune disorders	Phase I <a href="http://gene.com">gene.com</a>
anti-LINGO (BIIB033)	Biogen Idec <i>Weston, MA</i>	mAb	multiple sclerosis (see also eye)	Phase II <a href="http://biogenidec.com">biogenidec.com</a>
ARX424 (PEGylated interferon beta-1a)	Ambrx <i>La Jolla, CA</i>	interferon	multiple sclerosis	Phase I <a href="http://ambrx.com">ambrx.com</a>
atacept (TACI-Ig)	EMD Serono <i>Rockland, MA</i>	recombinant fusion protein	SLE	Phase II/III <a href="http://emdserono.com">emdserono.com</a>

\*For more information about a specific medicine or company in the report, please click on the provided link.

## AUTOIMMUNE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
ATX-MS-1467	EMD Serono <i>Rockland, MA</i>	peptide vaccine	multiple sclerosis	Phase I emdserono.com
AZ01 (long-acting pegylated interferon beta)	Allozyne <i>Seattle, WA</i>	interferon	multiple sclerosis	Phase I allozyne.com
<b>Benlysta®</b> belimumab (subcutaneous)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	mAb	SLE (see also blood, transplantation)	Phase III gsk.com
			systemic scleroderma	gsk.com
BHT-3009	Bayhill Therapeutics <i>Palo Alto, CA</i>	DNA vaccine	multiple sclerosis	Phase II bayhilltx.com
BI-695500 (rituximab biosimilar)	Boehringer-Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	mAb	rheumatoid arthritis	Phase III boehringer-ingelheim.com
BI-695501 (adalimumab biosimilar)	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	mAb	rheumatoid arthritis	Phase I boehringer-ingelheim.com
BIIB017 (PEG-interferon beta-1a)	Biogen Idec <i>Weston, MA</i>	interferon	relapsing multiple sclerosis (Fast Track)	Phase III biogenidec.com
BT-061	AbbVie <i>North Chicago, IL</i> Biotest <i>Dreieich, Germany</i>	mAb	rheumatoid arthritis (see also skin)	Phase II abbvie.com biotest.de
<b>Cimzia®</b> certolizumab pegol	UCB <i>Smyrna, GA</i>	mAb	ankylosing spondylitis, juvenile rheumatoid arthritis (see also musculoskeletal)	Phase III ucb.com
clazakizumab (anti-IL6)	Bristol-Myers Squibb <i>Princeton, NJ</i> Alder Biopharmaceuticals <i>Bothell, WA</i>	mAb	rheumatoid arthritis (see also digestive, musculoskeletal)	Phase II bms.com alderbio.com
CNTO-136 (sirukumab)	Janssen Biotech <i>Horsham, PA</i>	mAb	rheumatoid arthritis (see also other)	Phase III janssenbiotech.com
CNTO-1959	Janssen Biotech <i>Horsham, PA</i>	mAb	rheumatoid arthritis (see also skin)	Phase II janssenbiotech.com

## AUTOIMMUNE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
daclizumab	AbbVie North Chicago, IL Biogen Idec Weston, MA	mAb	multiple sclerosis (relapsing forms)	Phase III abbvie.com biogenidec.com
epratuzumab	Immunomedics Morris Plains, NJ UCB Smyrna, GA	mAb	SLE (Fast Track)	Phase III immunomedics.com ucb.com
GSK1223249 (NOGO-A mAb)	GlaxoSmithKline Rsch. Triangle Park, NC	mAb	multiple sclerosis (see also neurologic)	Phase I gsk.com
<b>Humira</b> <sup>®</sup> adalimumab	AbbVie North Chicago, IL	mAb	rheumatoid arthritis (combination therapy) (see also digestive, eye, musculoskeletal, skin, other)	Phase III abbvie.com
<b>Ilaris</b> <sup>®</sup> canakinumab (Orphan Drug)	Novartis Pharmaceuticals East Hanover, NJ	mAb	systemic juvenile idiopathic arthritis (see also cardiovascular, diabetes, musculoskeletal)	Phase III novartis.com
ISIS-CRP <sub>Rx</sub>	Isis Pharmaceuticals Carlsbad, CA	antisense	rheumatoid arthritis (see also cardiovascular)	Phase II isispharm.com
mavrilimumab	AstraZeneca Wilmington, DE MedImmune Gaithersburg, MD	mAb	rheumatoid arthritis	Phase II astrazeneca.com medimmune.com
MEDI-546 (anti-IFN-alphaR mAb)	AstraZeneca Wilmington, DE MedImmune Gaithersburg, MD	mAb	SLE	Phase II astrazeneca.com medimmune.com
MEDI-551 (anti-CD19 mAb)	AstraZeneca Wilmington, DE MedImmune Gaithersburg, MD	mAb	scleroderma (see also cancer)	Phase I astrazeneca.com medimmune.com
MEDI-570 (anti-ICOS mAb)	AstraZeneca Wilmington, DE MedImmune Gaithersburg, MD	mAb	SLE	Phase I astrazeneca.com medimmune.com

## AUTOIMMUNE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
<b>NeuroVax™</b> (IR208)	Immune Response Biopharma <i>New York, NY</i>	peptide vaccine	multiple sclerosis	Phase II immuneresponsebio pharma.com
NN8209 (anti-C5aR-151 mAb)	Novo Nordisk <i>Princeton, NJ</i>	mAb	rheumatoid arthritis	Phase II novonordisk.com
NN8210 (anti-C5aR-215 mAb)	Novo Nordisk <i>Princeton, NJ</i>	mAb	rheumatoid arthritis	Phase I novonordisk.com
NN8226 (anti-IL-20 mAb)	Novo Nordisk <i>Princeton, NJ</i>	mAb	rheumatoid arthritis	Phase II novonordisk.com
NN8765 (anti-NKG2 mAb)	Novo Nordisk <i>Princeton, NJ</i>	mAb	rheumatoid arthritis	Phase I novonordisk.com
NN8828 (anti-IL-21 mAb)	Novo Nordisk <i>Princeton, NJ</i>	mAb	rheumatoid arthritis	Phase II novonordisk.com
			SLE	Phase I novonordisk.com
<b>Nplate™</b> romiplostim (Orphan Drug)	Amgen <i>Thousand Oaks, CA</i>	recombinant fusion protein	immune thrombocytopenic purpura in children (see also cancer)	Phase III amgen.com
NU-100 (interferon beta-1b)	Nuron Biotech <i>Exton, PA</i>	recombinant interferon	multiple sclerosis	Phase III nuronbiotech.com
ocrelizumab (anti-CD20 mAb)	Biogen Idec <i>Weston, MA</i> Genentech <i>South San Francisco, CA</i> Roche <i>Nutley, NJ</i>	mAb	primary-progressive multiple sclerosis	Phase III biogenidec.com gene.com
			relapsing-remitting multiple sclerosis	Phase III biogenidec.com gene.com
ofatumumab (subcutaneous)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	mAb	multiple sclerosis, rheumatoid arthritis	Phase II gsk.com
olokizumab	UCB <i>Smyrna, GA</i>	mAb	rheumatoid arthritis	Phase II ucb.com
<b>Orencia®</b> abatacept	Bristol-Myers Squibb <i>Princeton, NJ</i>	recombinant fusion protein	early rheumatoid arthritis (see also musculoskeletal, other)	Phase III bms.com

## AUTOIMMUNE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
otelixizumab (anti-CD3 mAb)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	mAb	rheumatoid arthritis	Phase I gsk.com
ozoralizumab (ATN-103)	Ablynx <i>Ghent, Belgium</i>	mAb	rheumatoid arthritis	Phase II completed ablynx.com
pateclizumab (anti-LT alpha mAb)	Genentech <i>South San Francisco, CA</i>	mAb	rheumatoid arthritis	Phase II gene.com
PD-360324	Pfizer <i>New York, NY</i>	mAb	cutaneous lupus erythematosus	Phase I pfizer.com
PDA-001 (cenplacel-L)	Celgene Cellular Therapeutics <i>Summit, NJ</i>	stem cell therapy	rheumatoid arthritis (see also digestive)	Phase II celgene.com
			multiple sclerosis, sarcoidosis	Phase I celgene.com
PF-04236921	Pfizer <i>New York, NY</i>	mAb	SLE (see also digestive)	Phase II pfizer.com
			rheumatoid arthritis	Phase I pfizer.com
PF-05280586 (rituximab biosimilar)	Pfizer <i>New York, NY</i>	mAb	rheumatoid arthritis	Phase I/II pfizer.com
plovamer acetate (second-generation peptide copolymer)	EMD Serono <i>Rockland, MA</i>	peptide	multiple sclerosis	Phase I emdserono.com
<b>Prolia</b> <sup>®</sup> denosumab	Amgen <i>Thousand Oaks, CA</i>	mAb	rheumatoid arthritis (see also musculoskeletal)	Phase II amgen.com
<b>RAVAX</b> <sup>™</sup> rheumatoid arthritis vaccine	Immune Response BioPharma <i>New York, NY</i>	vaccine	rheumatoid arthritis	Phase III immuneresponsebio pharma.com
rontalizumab (RG7415)	Genentech <i>South San Francisco, CA</i>	mAb	SLE	Phase II gene.com
SAN-300 (anti-VLA-1 antibody)	Santarus <i>San Diego, CA</i>	mAb	rheumatoid arthritis	Phase I santarus.com

## AUTOIMMUNE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
SAR113244 (anti-CXCR5 mAb)	Sanofi US <i>Bridgewater, NJ</i>	mAb	SLE	Phase I sanofi.com
sarilumab (SAR153191)	Regeneron Pharmaceuticals <i>Tarrytown, NY</i> Sanofi US <i>Bridgewater, NJ</i>	mAb	rheumatoid arthritis	Phase III regeneron.com sanofi.com
secukinumab (AIN457)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	ankylosing spondylitis, rheumatoid arthritis (see also eye, musculoskeletal, skin)	Phase III novartis.com
			multiple sclerosis	Phase II novartis.com
sifalimumab (anti-IFN-alpha mAb)	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	mAb	SLE	Phase II astrazeneca.com medimmune.com
<b>Simponi</b> <sup>®</sup> golimumab (Orphan Drug)	Janssen Biotech <i>Horsham, PA</i>	mAb	rheumatoid arthritis (intravenous) (see also digestive)	application submitted janssenbiotech.com
			juvenile rheumatoid arthritis (subcutaneous)	Phase III janssenbiotech.com
			sarcoidosis (subcutaneous)	Phase II completed janssenbiotech.com
<b>Soliris</b> <sup>®</sup> eculizumab (Orphan Drug)	Alexion Pharmaceuticals <i>Cheshire, CT</i>	mAb	severe or refractory myasthenia gravis (see also eye, infectious, transplantation)	Phase II alxn.com
<b>Stelara</b> <sup>®</sup> ustekinumab	Janssen Biotech <i>Horsham, PA</i>	mAb	rheumatoid arthritis, sarcoidosis (see also digestive, musculoskeletal, other)	Phase II janssenbiotech.com
tabalumab (BAFF inhibitor)	Eli Lilly <i>Indianapolis, IN</i>	mAb	SLE (see also cancer)	Phase III lilly.com
<b>Tcelna</b> <sup>™</sup> imilecleucel-T	Opexa Therapeutics <i>The Woodlands, TX</i>	cell therapy vaccine	multiple sclerosis (Fast Track)	Phase II opexatherapeutics.com
<b>Tysabri</b> <sup>®</sup> natalizumab	Biogen Idec <i>Weston, MA</i>	mAb	secondary-progressive multiple sclerosis	Phase III biogenidec.com

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Product Name	Sponsor	Product Category	Indication	Development Phase
veltuzumab (IMMU-106)	Immunomedics <i>Morris Plains, NJ</i> Takeda Pharmaceuticals USA <i>Deerfield, IL</i>	mAb	immune thrombocytopenic purpura, rheumatoid arthritis (see also cancer)	Phase II immunomedics.com takeda.com
VX15	Teva Pharmaceuticals <i>Tikva, Israel</i> Vaccinex <i>Rochester, NY</i>	mAb	multiple sclerosis (see also cancer)	Phase I tevapharm.com vaccinex.com
<b>XmAb®5871</b> (anti-CD19 mAb)	Xencor <i>Monrovia, CA</i>	mAb	autoimmune disorders	Phase I xencor.com

## BLOOD DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
ACE-536	Acceleron Pharma <i>Cambridge, MA</i> Celgene <i>Summit, NJ</i>	recombinant fusion protein	anemia	Phase I acceleronpharma.com celgene.com
ALXN1102/ALXN1103	Alexion Pharmaceuticals <i>Cheshire, CT</i>	recombinant fusion protein	paroxysmal nocturnal hemoglobinuria	Phase I alxn.com
AMT-060 (Orphan Drug)	uniQure <i>Amsterdam, The Netherlands</i> St. Jude Children's Research Hospital <i>Memphis, TN</i>	gene therapy	hemophilia B	Phase I/II uniqure.com
ART123 (recombinant human thrombomodulin alpha)	Asahi Kasei Pharma America <i>Waltham, MA</i>	recombinant protein	disseminated intravascular coagulation	Phase III akpamerica.com
AskBio009	Asklepios BioPharmaceutical <i>Chapel Hill, NC</i> Baxter International <i>Deerfield, IL</i>	gene therapy	hemophilia B	Phase I/II askbio.com baxter.com
<b>ATryn®</b> antithrombin alfa (Orphan Drug)	GTC Biotherapeutics <i>Framingham, MA</i>	recombinant protein	heparin resistance in patients undergoing CABG surgery	Phase III gtc-bio.com



## BLOOD DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
BAX-111 (recombinant von Willebrand factor) (Orphan Drug)	Baxter International <i>Deerfield, IL</i>	recombinant protein	von Willebrand disease	Phase III baxter.com
BAX-326 (rFIX) (Orphan Drug)	Baxter International <i>Deerfield, IL</i>	recombinant protein	hemophilia B	application submitted baxter.com
BAX-817 (rFVIIa)	Baxter International <i>Deerfield, IL</i>	recombinant protein	hemophilia A, hemophilia B	Phase I/II baxter.com
BAX-855 (rFVIII)	Baxter International <i>Deerfield, IL</i>	recombinant protein	hemophilia A	Phase I baxter.com
BAY 86-6150 (rFVIIa)	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	recombinant protein	hemophilia A, hemophilia B	Phase II/III bayerpharma.com
BAY 94-9027 (rFVIII)	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	recombinant protein	hemophilia A	Phase II/III bayerpharma.com
<b>Benlysta</b> <sup>®</sup> belimumab (oral)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	mAb	vasculitis (see also autoimmune, transplantation)	Phase I completed gsk.com
beta-globin gene therapy (lentiglobin)	bluebird bio <i>Cambridge, MA</i> INSERM <i>Paris, France</i>	gene therapy	beta-thalassemia, sickle cell anemia	Phase I/II bluebirdbio.com
BI-655075	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	mAb	blood coagulation disorders	Phase I boehringer-ingelheim.com
CSL-627 (rVIII-SC)	CSL Behring <i>King of Prussia, PA</i>	recombinant protein	hemophilia A	Phase I cslbehring.com
CSL-654 (rIX-FP) (Orphan Drug)	CSL Behring <i>King of Prussia, PA</i>	recombinant fusion protein	hemophilia B	Phase II/III cslbehring.com
CSL-689 (rVIIa-FP) (Orphan Drug)	CSL Behring <i>King of Prussia, PA</i>	recombinant fusion protein	hemophilia A, hemophilia B	Phase I cslbehring.com

## BLOOD DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
CYT107 (interleukin-7)	Cytheris <i>Rockville, MD</i>	recombinant interleukin	idiopathic CD4-positive lymphocytopenia (see also cancer, infectious, transplantation)	Phase I/II cytheris.com
epoetin alfa biosimilar	Hospira <i>Lake Forest, IL</i>	recombinant erythropoietin	anemia	Phase III hospira.com
erythropoietin gene therapy	Medgenics <i>San Francisco, CA</i>	gene therapy	anemia	Phase II medgenics.com
factor VIII/ von Willebrand factor	CSL Behring <i>King of Prussia, PA</i>	recombinant protein	hemophilia A, von Willebrand disease	Phase III cslbehring.com
ferroportin mAb	Eli Lilly <i>Indianapolis, IN</i>	mAb	anemia	Phase I lilly.com
hepcidin mAb	Eli Lilly <i>Indianapolis, IN</i>	mAb	anemia	Phase I lilly.com
HM10760A	Hanmi Pharmaceutical <i>Seoul, South Korea</i>	long-acting erythropoietin	anemia	Phase I hanmipharm.com
human recombinant factor VIII	Octapharma USA <i>Hoboken, NJ</i>	recombinant protein	hemophilia A	Phase II octapharma.com
IB1001 (recombinant factor IX biosimilar)	Inspiration Biopharmaceuticals <i>Cambridge, MA</i> Ipsen <i>Paris, France</i>	recombinant protein	hemophilia B	application submitted inspirationbio.com
ISIS-FXI <sub>Rx</sub>	Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	clotting disorders	Phase II isispharm.com
NAV™ therapeutic	ReGenX Biosciences <i>Washington, DC</i>	gene therapy	hemophilia B (see also genetic)	Phase I/II regenxbio.com
NiCord® umbilical cord blood stem cell therapy	Gamida Cell <i>Jerusalem, Israel</i>	stem cell therapy	sickle cell anemia (see also cancer)	Phase I/II gamida-cell.com
NN1841 (rFXIII)	Novo Nordisk <i>Princeton, NJ</i>	recombinant protein	congenital factor XIII deficiency	application submitted novonordisk.com
NN7008 (turoctocog alfa)	Novo Nordisk <i>Princeton, NJ</i>	recombinant protein	hemophilia A	application submitted novonordisk.com

## BLOOD DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
NN7088 (N8-GP, rFVIII glycopegylated)	Novo Nordisk <i>Princeton, NJ</i>	recombinant protein	hemophilia A	Phase III novonordisk.com
NN7999 (N9-GP, rFIX glycopegylated)	Novo Nordisk <i>Princeton, NJ</i>	recombinant protein	hemophilia B	Phase III novonordisk.com
OBI-1 (recombinant porcine factor VIII) (Orphan Drug)	Inspiration Biopharmaceuticals <i>Cambridge, MA</i> Ipsen <i>Paris, France</i>	recombinant protein	hemophilia A (Fast Track)	Phase III inspirationbio.com
PF-05280602 (rhFVIIa)	Catalyst Biosciences <i>South San Francisco, CA</i> Pfizer <i>New York, NY</i>	recombinant protein	hemophilia	Phase I catalystbiosciences.com pfizer.com
PRT4445 (FXa inhibitor antidote)	Portola Pharmaceuticals <i>South San Francisco, CA</i>	recombinant protein	hemorrhage	Phase II portola.com
recombinant factor VIII-Fc (Orphan Drug)	Biogen Idec <i>Weston, MA</i>	recombinant fusion protein	hemophilia A (Fast Track)	Phase III biogenidec.com
recombinant factor IX-Fc (Orphan Drug)	Biogen Idec <i>Weston, MA</i>	recombinant fusion protein	hemophilia B (Fast Track) ----- hemophilia B in children (Fast Track)	application submitted biogenidec.com ----- Phase III biogenidec.com
SelG1	Selexys Pharmaceuticals <i>Oklahoma City, OK</i>	mAb	sickle cell anemia	Phase I completed selexys.com
sotatercept (ACE-011)	Accelaron Pharma <i>Cambridge, MA</i> Celgene <i>Summit, NJ</i>	recombinant fusion protein	anemia in patients with end-stage renal disease (see also cancer)	Phase II accelaronpharma.com celgene.com
TT-173	Thrombotargets <i>Durham, NC</i>	recombinant protein	blood coagulation disorders	Phase I thrombotargets.com
<b>Wilate®</b> von Willebrand factor/ coagulation factor VIII complex (human)	Octapharma USA <i>Hoboken, NJ</i>	recombinant protein	surgical blood loss	Phase III octapharma.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
8H9 mAb	United Therapeutics <i>Silver Spring, MD</i>	mAb	metastatic brain cancer	Phase I unither.com
212-Pb-TCMC-trastuzumab	AREVA Med <i>Bethesda, MD</i>	mAb	HER2-positive cancer metastasized to the abdominal region	Phase I arevamed.com
AbGn-7	AbGenomics International <i>Los Altos, CA</i>	mAb	solid tumors	Phase I
ABIO-0501 (TALL-104)	Abiogen Pharma <i>Pisa, Italy</i>	cell therapy	chronic myeloid leukemia (CML)	Phase II abiogen.it
ABT-806	AbbVie <i>North Chicago, IL</i>	mAb	solid tumors	Phase I abbvie.com
Actimab-A (M195 mAb)	Actinium Pharmaceuticals <i>New York, NY</i>	mAb	acute myeloid leukemia (AML)	Phase I/II actiniumpharmaceuticals.com
<b>Adcetris®</b> brentuximab vedotin (Orphan Drug)	Seattle Genetics <i>Bothell, WA</i>	mAb	cutaneous T-cell lymphoma, front-line Hodgkin lymphoma, post-transplant Hodgkin lymphoma relapse prevention	Phase III seattlegenetics.com
			non-Hodgkin lymphoma, non-lymphoma malignancies, CD30-positive hematologic malignancies, CD30-positive T-cell lymphoma	Phase II seattlegenetics.com
AD-IL-12	ZIOPHARM Oncology <i>New York, NY</i>	gene therapy	malignant melanoma	Phase I/II ziopharm.com
ADI-PEG-20	Polaris Pharmaceuticals <i>San Diego, CA</i>	pegylated protein	liver cancer	Phase III polarispharma.com
			malignant melanoma, mesothelioma, small-cell lung cancer (SCLC)	Phase II polarispharma.com
ADX-HPV	Advaxis <i>Princeton, NJ</i>	vaccine	cervical cancer, cervical intraepithelial neoplasia	Phase II advaxis.com
AE08	Antigen Express <i>Worcester, MA</i>	peptide vaccine	malignant melanoma	Phase I antigenexpress.com
AE37	Antigen Express <i>Worcester, MA</i>	peptide vaccine	breast cancer	Phase II antigenexpress.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
AGS-003	Argos Therapeutics <i>Durham, NC</i>	personalized dendritic cell vaccine	metastatic renal cancer (Fast Track)	Phase III argostherapeutics.com
ALD-151	Cytomedix <i>Gaithersburg, MD</i> Duke University <i>Durham, NC</i>	stem cell therapy	leukemia	Phase I completed cytomedix.com
<b>AlloStim™</b> cancer vaccine	Immunovative Therapies <i>Shoham, Israel</i>	cell vaccine	hematological malignancies, solid tumors	Phase I/II immunovative.co.il
<b>Allovectin®</b> velimogene aliplasmid (Orphan Drug)	Vical <i>San Diego, CA</i>	DNA immunotherapeutic	malignant melanoma (Fast Track)	Phase III vical.com
ALN-VSP	Alnylam Pharmaceuticals <i>Cambridge, MA</i>	RNA interference	liver cancer, liver metastases	Phase I alnylam.com
ALT-801	Altor BioScience <i>Miramar, FL</i>	recombinant fusion protein	AML, bladder cancer, malignant melanoma, multiple myeloma	Phase I/II altorbioscience.com
ALT-836	Altor BioScience <i>Miramar, FL</i> Genentech <i>South San Francisco, CA</i>	mAb	cancer (see also respiratory)	Phase I/II altorbioscience.com gene.com
AME-133v	MENTRIK Biotech <i>Dallas, TX</i>	mAb	non-Hodgkin lymphoma	Phase II mentrik.com
AMG 386	Amgen <i>Thousand Oaks, CA</i>	recombinant fusion protein	fallopian tube cancer, ovarian cancer, peritoneal cancer ----- breast cancer, colorectal cancer, gastric cancer, liver cancer, esophageal cancer, renal cancer	Phase III amgen.com ----- Phase II amgen.com
AMG 780	Amgen <i>Thousand Oaks, CA</i>	antibody	solid tumors	Phase I amgen.com
AMG 820	Amgen <i>Thousand Oaks, CA</i>	mAb	solid tumors	Phase I amgen.com
AMG 888 (U3-1287)	Amgen <i>Thousand Oaks, CA</i> U3 Pharma <i>Martinsried, Germany</i>	mAb	non-small-cell lung cancer (NSCLC)	Phase II amgen.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
antibody-drug conjugate (RG7600)	Genentech South San Francisco, CA	mAb	ovarian cancer, pancreatic cancer	Phase I gene.com
anti-CD3-anti-HER2/neu-activated T-cells	TransTarget Hillsborough, CA Barbara Ann Karmanos Cancer Institute Detroit, MI	cell therapy	metastatic breast cancer	Phase II
anti-CD22 ADC (RG7593)	Genentech South San Francisco, CA Seattle Genetics Bothell, WA	mAb	diffuse large B-cell lymphoma, non-Hodgkin lymphoma	Phase II gene.com
			chronic lymphocytic leukemia (CLL)	Phase I gene.com
anti-CD45 mAb	Actinium Pharmaceuticals New York, NY	mAb	AML	Phase I actiniumpharmaceuticals.com
anti-CD79b ADC (RG7596)	Genentech South San Francisco, CA Seattle Genetics Bothell, WA	mAb	diffuse large B-cell lymphoma, non-Hodgkin lymphoma	Phase II gene.com
			CLL	Phase I gene.com
anti-CXCR4	Bristol-Myers Squibb Princeton, NJ	mAb	hematological malignancies	Phase I bms.com
anti-EGFL7 mAb (RG7414)	Genentech South San Francisco, CA	mAb	metastatic colorectal cancer, NSCLC	Phase II gene.com
			solid tumors	Phase I gene.com
anti-FGFR3 mAb (RG7444)	Genentech South San Francisco, CA	mAb	solid tumors	Phase I gene.com
anti-HER3/EGFR DAF mAb (RG7597)	Genentech South San Francisco, CA	mAb	colorectal cancer, head and neck cancer	Phase II gene.com
anti-PD-L1	Bristol-Myers Squibb Princeton, NJ	mAb	cancer (see also infectious)	Phase I bms.com
anti-PD-L1 mAb (RG7446)	Genentech South San Francisco, CA	mAb	melanoma, solid tumors	Phase I gene.com
anti-STEAP1 ADC (RG7450)	Genentech South San Francisco, CA Seattle Genetics Bothell, WA	mAb	prostate cancer	Phase I gene.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
APN301 (hu14.18-IL2)	Apeiron Biologics <i>Vienna, Austria</i>	mAb	malignant melanoma, neuroblastoma in children	Phase II completed apeiron-biologics.com
<b>Archexin™</b> RX-0201 (Orphan Drug)	Rexahn Pharmaceuticals <i>Rockville, MD</i>	antisense	pancreatic cancer	Phase II rexahn.com
<b>Arzerra®</b> ofatumumab (Orphan Drug)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	mAb	CLL (first-line therapy), diffuse large B-cell lymphoma, follicular lymphoma	Phase III gsk.com
ASC-101 (Orphan Drug)	America Stem Cell <i>Carlsbad, CA</i>	stem cell therapy	myeloablation associated with hematological malignancies	Phase I/II americastemcell.com
ASG-5ME	Agensys <i>Santa Monica, CA</i> Seattle Genetics <i>Bothell, WA</i>	mAb-drug conjugate	pancreatic cancer, castration-resistant prostate cancer	Phase I agensys.com seattlegenetics.com
ASG-22ME	Agensys <i>Santa Monica, CA</i> Seattle Genetics <i>Bothell, WA</i>	mAb-drug conjugate	solid tumors	Phase I agensys.com seattlegenetics.com
autologous stem cell therapy	California Stem Cell <i>Irvine, CA</i>	stem cell therapy	malignant melanoma	Phase II californiastemcell.com
AV-203	AVEO Oncology <i>Cambridge, MA</i>	mAb	solid tumors	Phase I aveooncology.com
<b>Avastin®</b> bevacizumab (Orphan Drug)	Genentech <i>South San Francisco, CA</i> Roche <i>Nutley, NJ</i>	mAb	ovarian cancer  ----- HER-2 negative-breast cancer, HER-2 positive breast cancer, high- risk carcinoid tumors, glioblastoma multiforme, metastatic ovarian cancer, NSCLC	application submitted gene.com  Phase III gene.com
AVX701	AlphaVax <i>Rsch. Triangle Park, NC</i>	virus replicon particle vaccine	CEA-expressing colorectal cancer	Phase I/II alphavax.com
AVX901	AlphaVax <i>Rsch. Triangle Park, NC</i>	virus replicon particle vaccine	HER2-expressing breast cancer	Phase I alphavax.com
B7-2/GM-CSF cancer gene therapy (combination immunogene therapy)	NuVax Therapeutics (Radiant Pharmaceuticals) <i>Tustin, CA</i>	gene therapy	cancer	Phase I radiant-pharma.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
bavituximab	Peregrine Pharmaceuticals <i>Tustin, CA</i>	mAb	NSCLC, pancreatic cancer	Phase II peregrineinc.com
			breast cancer, liver cancer, prostate cancer, rectal adenocarcinoma	Phase I/II peregrineinc.com
BAX-69	Baxter International <i>Deerfield, IL</i>	mAb	solid tumors (see also other)	Phase I baxter.com
BAY 79-4620	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	mAb	solid tumors	Phase I bayerpharma.com
BAY 94-9343	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	mAb	solid tumors	Phase I bayerpharma.com
BAY 20-10112	Amgen <i>Thousand Oaks, CA</i> Bayer HealthCare Pharmaceuticals <i>Wayne, PA</i>	mAb	solid tumors	Phase I amgen.com bayerpharma.com
BC-819 (Orphan Drug)	BioCancell Therapeutics <i>Jerusalem, Israel</i>	gene therapy	bladder cancer, pancreatic cancer (Fast Track)	Phase II biocancell.com
			ovarian cancer	Phase I/II biocancell.com
BHQ880	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	multiple myeloma	Phase II novartis.com
BI-505 (Orphan Drug)	BioInvent International <i>Lund, Sweden</i>	mAb	multiple myeloma	Phase I bioinvent.com
BI-836845	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	mAb	solid tumors	Phase I boehringer-ingelheim.com
<b>BiovaxID</b> <sup>®</sup> B-cell lymphoma vaccine	Biovest International <i>Tampa, FL</i>	autologous idiotype vaccine	follicular lymphoma (Fast Track)	Phase III biovest.com
			mantle-cell lymphoma	Phase II biovest.com
blinatumomab (Orphan Drug)	Amgen <i>Thousand Oaks, CA</i>	mAb	leukemia and lymphoma	Phase II amgen.com
BP-100-1.01 (liposomal Grb-2)	Bio-Path Holdings <i>Houston, TX</i>	antisense	acute lymphocytic leukemia (ALL), AML, CML, myelodysplastic syndromes	Phase I biopathholdings.com



## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
BPX-101	Bellicum Pharmaceuticals <i>Houston, TX</i>	dendritic cell vaccine	prostate cancer	Phase I/II bellicum.com
breast cancer vaccine	MabVax Therapeutics <i>San Diego, CA</i>	mAb vaccine	breast cancer	Phase I mabvax.com
BT-062 (indatuximab ravtansine) (Orphan Drug)	Biotest <i>Dreieich, Germany</i>	mAb	multiple myeloma	Phase I/II biotest.de
BYM338	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	cancer-related cachexia (see also musculoskeletal)	Phase II novartis.com
CALAA-01	Calando Pharmaceuticals <i>Pasadena, CA</i>	RNA interference	solid tumors	Phase I arrowheadresearch.com
calaspargase pegol	Sigma-Tau Pharmaceuticals <i>Gaithersburg, MD</i>	pegylated enzyme	ALL in adolescents and children	Phase III sigmatau.com
cancer medicine	Eli Lilly <i>Indianapolis, IN</i>	biologic	cancer	Phase I lilly.com
cancer medicine	Eli Lilly <i>Indianapolis, IN</i>	biologic	cancer	Phase I lilly.com
cancer vaccine	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> Stellar Biotechnologies <i>Port Hueneme, CA</i>	autologous idiotype vaccine	follicular lymphoma	Phase I bayerpharma.com
cancer vaccine	EMD Millipore <i>Billerica, MA</i>	dendritic cell vaccine	malignant melanoma	Phase I completed millipore.com
cancer vaccine	Gradalis <i>Carrollton, TX</i> Mary Crowley Cancer Research Center <i>Dallas, TX</i>	genetically-modified vaccine	solid tumors	Phase I gradalisinc.com marycrowley.org
cancer vaccine	Immunitor <i>Vancouver, Canada</i>	vaccine	cancer	Phase I/II immunitor.com
cancer vaccine (AdhTAP)	TapImmune <i>Seattle, WA</i>	therapeutic vaccine	breast cancer	Phase I tapimmune.com
catumaxomab	Fresenius Biotech North America <i>Waltham, MA</i>	mAb	malignant ascites, ovarian cancer	Phase II completed fresenius-biotech.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
CDX-011 (glembatumumab vedotin)	Celldex Therapeutics <i>Needham, MA</i>	mAb	breast cancer (Fast Track), malignant melanoma	Phase II celldextherapeutics.com
CDX-1127	Celldex Therapeutics <i>Needham, MA</i>	mAb	hematological malignancies, solid tumors	Phase I celldextherapeutics.com
CDX-1401	Celldex Therapeutics <i>Needham, MA</i>	mAb vaccine	solid tumors	Phase I/II celldextherapeutics.com
cell therapy	Cell Medica <i>London, United Kingdom</i> Center for Cell and Gene Therapy <i>Houston, TX</i>	cell therapy	cancer (see also infectious)	Phase II cellmedica.co.uk
CEP-37250/KNK-2804	Teva North America <i>North Wales, PA</i> Kyowa Hakko Kirin Pharma <i>Princeton, NJ</i>	mAb	adenocarcinoma	Phase I tevapharm.com kyowa-kirin-pharma.com
CG201 (anti-hCG vaccine)	CG Therapeutics <i>Seattle, WA</i>	antibody vaccine	solid tumors	Phase II cgtherapeutics.com
ch14.18 mAb (Orphan Drug)	United Therapeutics <i>Silver Spring, MD</i>	mAb	neuroblastoma	Phase III unither.com
cixutumumab (LY3012217)	Eli Lilly <i>Indianapolis, IN</i> Imclone Systems <i>Princeton, NJ</i>	mAb	NSCLC	Phase II lilly.com
CLT-008	Cellerant Therapeutics <i>San Carlos, CA</i>	cell therapy	chemotherapy-induced neutropenia (see also transplantation)	Phase I/II cellerant.com
CNTO-328 (siltuximab)	Janssen Biotech <i>Horsham, PA</i>	mAb	giant lymph node hyperplasia, multiple myeloma, myelodysplastic syndromes ----- prostate cancer	Phase II janssenbiotech.com  Phase I janssenbiotech.com
<b>Cotara™</b> mAb TNT (Orphan Drug)	Peregrine Pharmaceuticals <i>Tustin, CA</i>	mAb	recurrent glioblastoma (Fast Track)	Phase II peregrineinc.com
CRS-207	Aduro Biotech <i>Berkeley, CA</i>	genetically- modified vaccine	pancreatic cancer ----- mesothelioma	Phase II adurobiotech.com  Phase I adurobiotech.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
CSF-1R mAb (IMC-CS4)	Eli Lilly <i>Indianapolis, IN</i> ImClone Systems <i>Bridgewater, NJ</i>	mAb	solid tumors	Phase I lilly.com
CT-011 (pidilizumab)	CureTech <i>Yavne, Israel</i>	mAb	AML, colorectal cancer, diffuse large B-cell lymphoma, follicular lymphoma, malignant melanoma	Phase II curetechbio.com
CTL019	Novartis <i>East Hanover, NJ</i> University of Pennsylvania <i>Philadelphia, PA</i>	cell therapy	CLL	Phase II novartis.com
custirsen (OGX-011)	OncoGenex Technologies <i>Vancouver, Canada</i> Teva Pharmaceuticals <i>Tikva, Israel</i>	antisense	NSCLC, prostate cancer (Fast Track)  ----- first-time NSCLC	Phase III oncogenex.com tevapharm.com  ----- Phase II oncogenex.com tevapharm.com
CV-301	BN ImmunoTherapeutics <i>Mountain View, CA</i>	cancer vaccine	metastatic breast cancer	Phase II bavarian-nordic.com
<b>CVac™</b> cancer vaccine MUC-1	Prima BioMed <i>Melbourne, Australia</i>	personalized dendritic cell vaccine	ovarian cancer	Phase II/III primabiomed.com.au
CYT107 (interleukin-7)	Cytheris <i>Rockville, MD</i>	recombinant interleukin	malignant melanoma, renal cancer (see also blood, infectious, transplantation)	Phase I cytheris.com
CYT-6091 (Aurimmune™)	Cytimmune Sciences <i>Rockville, MD</i>	tumor necrosis factor	solid tumors	Phase I cytimmune.com
dalotuzumab (MK-0646)	Merck <i>Whitehouse Station, NJ</i>	mAb	breast cancer, neuroendocrine tumors, NSCLC	Phase II merck.com
daratumumab	Janssen Biotech <i>Horsham, PA</i>	mAb	multiple myeloma	Phase I/II janssenbiotech.com
DC-IL-12	ZIOPHARM Oncology <i>New York, NY</i>	cell therapy	malignant melanoma	Phase I ziopharm.com
<b>DCVax®-L</b> brain cancer vaccine (Orphan Drug)	Northwest Biotherapeutics <i>Bethesda, MD</i>	dendritic cell vaccine	glioblastoma	Phase III nwbio.com

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Product Name	Sponsor	Product Category	Indication	Development Phase
DEDN6526A (antibody drug conjugate)	Genentech South San Francisco, CA	mAb	malignant melanoma	Phase I gene.com
demcizumab (OMP-21M18)	GlaxoSmithKline Rsch. Triangle Park, NC OncoMed Pharmaceuticals Redwood City, CA	mAb	solid tumors	Phase I gsk.com oncomed.com
DFRF4539A	Genentech South San Francisco, CA	mAb	multiple myeloma	Phase I gene.com
DI17E6 (anti-integrin mAb)	EMD Serono Rockland, MA	mAb	colorectal cancer, prostate cancer	Phase II emdserono.com
DKN-01	Dekun Cambridge, MA	mAb	solid tumors	Phase I
DN24-02	Dendreon Seattle, WA	personalized dendritic cell vaccine	HER2-positive urogenital cancer	Phase II dendreon.com
DPX-0907	Immunovaccine Halifax, Canada	vaccine	breast cancer, ovarian cancer, prostate cancer	Phase I imvaccine.com
DPX-Survivac	Immunovaccine Halifax, Canada	peptide vaccine	ovarian cancer	Phase I/II imvaccine.com
EC17	Endocyte West Lafayette, IN	vaccine	renal cancer (combination therapy)	Phase I endocyte.com
ecromeximab (KW-2871)	Life Science Pharmaceuticals Darien, CT	mAb	metastatic melanoma	Phase II investinlife.com
EGEN-001 (Orphan Drug)	EGEN Huntsville, AL	gene therapy	ovarian cancer	Phase II egeninc.com
			colorectal cancer	Phase I/II egeninc.com
elotuzumab	Bristol-Myers Squibb Princeton, NJ AbbVie North Chicago, IL	mAb	multiple myeloma	Phase III bms.com abbvie.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
enavatuzumab	AbbVie North Chicago, IL	mAb	solid tumors	Phase I completed abbvie.com
encapsulated cell therapy	Metromedia Bio-Science New York, NY Rogovin Institute New York, NY	cell therapy	colorectal cancer, pancreatic cancer, prostate cancer	Phase II rogovin.org
encapsulated cell therapy	Nuvilex Silver Spring, MD	cell therapy	pancreatic cancer	Phase II nuvilex.com
ensituximab (NPC-1C)	Neogenix Oncology Great Neck, NY	mAb	colorectal cancer, pancreatic cancer	Phase I neogenix.com
entolimod (CBLB502)	Cleveland BioLabs Buffalo, NY	engineered peptide	radiation damage in cancer patients (see also other)	Phase I cbiolabs.com
epratuzumab Y-90/ veltuzumab combination	Immunomedics Morris Plains, NJ	mAb	non-Hodgkin lymphoma	Phase I/II immunomedics.com
<b>Erbix<sup>®</sup></b> cetuximab	Bristol-Myers Squibb Princeton, NJ Eli Lilly Indianapolis, IN ImClone Systems Princeton, NJ	mAb	esophageal cancer	Phase III bms.com lilly.com
ETBX-011	Etubics Seattle, WA	vector vaccine	colon cancer	Phase II etubics.com
EZN-2968	Enzon Pharmaceuticals Piscataway, NJ	antisense	lymphoma, solid tumors	Phase I enzon.com
EZN-4176	Enzon Pharmaceuticals Piscataway, NJ	antisense	prostate cancer	Phase I enzon.com
F-627	Generon Shanghai, China	recombinant fusion protein	chemotherapy-induced neutropenia	Phase II generonbiomed.com
<b>Fang<sup>™</sup> Vaccine</b> autologous tumor cell vaccine	Gradalis Carrollton, TX	autologous cell vaccine	solid tumors	Phase II gradalisinc.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
farletuzumab (MORAb-003) (Orphan Drug)	Eisai <i>Woodcliff Lake, NJ</i>	mAb	platinum-sensitive ovarian cancer	Phase III eisai.com
			NSCLC	Phase II eisai.com
FG-3019	FibroGen <i>San Francisco, CA</i>	mAb	pancreatic cancer (see also respiratory, other)	Phase II fibrogen.com
ficlatuzumab	AVEO Oncology <i>Cambridge, MA</i>	mAb	glioblastoma, lymphoma, multiple myeloma, solid tumors	Phase I aveooncology.com
flanvotumab (TYRP1 protein)	Eli Lilly <i>Indianapolis, IN</i>	mAb	malignant melanoma	Phase I lilly.com
folate binding protein-E39 (FBP)	Galena Biopharma <i>Lake Oswego, OR</i>	peptide vaccine	endometrial cancer, ovarian cancer	Phase I/II galenabiopharma.com
FP-1039	Five Prime Therapeutics <i>San Francisco, CA</i>	recombinant fusion protein	solid tumors	Phase I fiveprime.com
Fzd7 (vantictumab)	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> OncoMed Pharmaceuticals <i>Redwood City, CA</i>	mAb	solid tumors	Phase I bayerpharma.com oncomed.com
ganitumab	Amgen <i>Thousand Oaks, CA</i>	mAb	pancreatic cancer	Phase III amgen.com
			breast cancer, colorectal cancer, sarcoma	Phase II amgen.com
GC-33/RG7686	Chugai Pharma USA <i>Berkeley Heights, NJ</i> Roche <i>Nutley, NJ</i>	mAb	liver cancer	Phase II chugai-pharm.com roche.com
GI-4000	GlobeImmune <i>Louisville, CO</i>	genetically- modified vaccine	colorectal cancer, NSCLC, pancreatic cancer	Phase II globeimmune.com
GI-6207	GlobeImmune <i>Louisville, CO</i>	genetically- modified vaccine	medullary thyroid cancer	Phase II globeimmune.com
GI-6301 (brachyury peptide vaccine)	GlobeImmune <i>Louisville, CO</i>	genetically- modified vaccine	solid tumors	Phase I globeimmune.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
GL-0817 (MAGE-A3 immunomodulator) (Orphan Drug)	Gliknik <i>Baltimore, MD</i>	peptide vaccine	head and neck cancer, multiple myeloma	Phase II gliknik.com
<b>GliAtak™</b> cancer gene therapy (Orphan Drug)	Advantagene <i>Auburndale, MA</i>	gene therapy	malignant glioma	Phase II advantagene.com
<b>Glionix™</b> brain vaccine	NovaRx <i>San Diego, CA</i>	antisense gene-modified cell vaccine	glioma	Phase I completed novarx.com
GS-6624 (simtuzumab)	Gilead Sciences <i>Foster City, CA</i>	mAb	colorectal cancer, pancreatic cancer (see also respiratory, other)	Phase II gilead.com
<b>GVAX® Breast</b> cancer immunotherapy	BioSante Pharmaceuticals <i>Lincolnshire, IL</i>	genetically-modified vaccine	breast cancer	Phase I biosantepharma.com
<b>GVAX® Colorectal</b> cancer immunotherapy	BioSante Pharmaceuticals <i>Lincolnshire, IL</i>	genetically-modified vaccine	colorectal cancer	Phase I biosantepharma.com
<b>GVAX® Leukemia</b> cancer immunotherapy (Orphan Drug)	BioSante Pharmaceuticals <i>Lincolnshire, IL</i>	genetically-modified vaccine	AML, CML	Phase II biosantepharma.com
<b>GVAX® Multiple Myeloma</b> cancer immunotherapeutic	BioSante Pharmaceuticals <i>Lincolnshire, IL</i>	genetically-modified vaccine	multiple myeloma	Phase II biosantepharma.com
<b>GVAX® Pancreas</b> cancer immunotherapy (Orphan Drug)	AduroBiotech <i>Berkeley, CA</i> BioSante Pharmaceuticals <i>Lincolnshire, IL</i>	genetically-modified vaccine	pancreatic cancer	Phase II adurobiotech.com biosantepharma.com
<b>GVAX® Prostate</b> cancer immunotherapy	AduroBiotech <i>Berkeley, CA</i> BioSante Pharmaceuticals <i>Lincolnshire, IL</i>	genetically-modified vaccine	prostate cancer (Fast Track)	Phase III adurobiotech.com biosantepharma.com
HCD122 (anti-CD40 mAb)	Novartis Pharmaceuticals <i>East Hanover, NJ</i> XOMA <i>Berkeley, CA</i>	mAb	lymphoma	Phase I/II novartis.com xoma.com
HGS-ETR1 (mapatumumab)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	mAb	liver cancer, multiple myeloma, NSCLC	Phase II gsk.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
HS-110	Heat Biologics <i>Chapel Hill, NC</i>	genetically-modified vaccine	NSCLC	Phase II heatbio.com
hTERT cancer vaccine	Merck <i>Whitehouse Station, NJ</i> Vical <i>San Diego, CA</i>	DNA vaccine	cancer	Phase I merck.com vical.com
HuL2G7	Galaxy Biotech <i>Sunnyvale, CA</i>	mAb	solid tumors	Phase I galaxybiotech.com
HuM195/rGel	Targa Therapeutics <i>San Diego, CA</i>	mAb	AML, CML, myelodysplastic syndromes	Phase I targatherapeutics.com
huN901-DM1 (lorvotuzumab mertansine) (Orphan Drug)	ImmunoGen <i>Cambridge, MA</i>	mAb	SCLC	Phase II immunogen.com
			multiple myeloma, solid tumors	Phase I immunogen.com
<b>HyperAcute® Lung</b> turgempumatucel-L	NewLink Genetics <i>Ames, IA</i>	DNA vaccine	NSCLC	Phase II/III linkp.com
<b>HyperAcute® Melanoma</b> melanoma cancer vaccine	NewLink Genetics <i>Ames, IA</i>	DNA vaccine	malignant melanoma	Phase II linkp.com
<b>HyperAcute® Pancreas</b> algenpantucel-L (Orphan Drug)	NewLink Genetics <i>Ames, IA</i>	DNA vaccine	pancreatic cancer (Fast Track)	Phase III linkp.com
icrucumab (LY3012212)	Eli Lilly <i>Indianapolis, IN</i> ImClone Systems <i>Bridgewater, NJ</i>	mAb	bladder cancer, breast cancer, colorectal cancer	Phase II lilly.com
ICT-107 (Orphan Drug)	ImmunoCellular Therapeutics <i>Woodland Hills, CA</i>	personalized dendritic cell vaccine	glioblastoma	Phase II imuc.com
IL-21 (BMS-982470) (Orphan Drug)	Bristol-Myers Squibb <i>Princeton, NJ</i>	interleukin	solid tumors	Phase I bms.com
IMA901 (intradermal vaccine) (Orphan Drug)	immatics biotechnologies <i>Tübingen, Germany</i>	peptide vaccine	renal cancer treatment	Phase III immatics.com



## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
IMA950 (intradermal vaccine)	immatics biotechnologies <i>Tübingen, Germany</i>	peptide vaccine	glioblastoma	Phase I immatics.com
IMC-gp100	Immunocore <i>Oxon, United Kingdom</i>	recombinant vaccine	malignant melanoma treatment	Phase 0 immunocore.com
IMC-TR1 (LY3022859)	Eli Lilly <i>Indianapolis, IN</i> ImClone Systems <i>Bridgewater, NJ</i>	mAb	solid tumors	Phase I lilly.com
IMF-001	ImmunoFrontier <i>Tokyo, Japan</i>	recombinant vaccine	solid tumors	Phase I immunofrontier.com
IMGN529	ImmunoGen <i>Waltham, MA</i>	mAb	non-Hodgkin lymphoma	Phase I immunogen.com
IMGN853	ImmunoGen <i>Waltham, MA</i>	mAb	solid tumors	Phase I immunogen.com
IMMU-102 (epratuzumab Y-90)	Immunomedics <i>Morris Plains, NJ</i>	mAb	non-Hodgkin lymphoma	Phase I/II immunomedics.com
IMT-1012	Immunotope <i>Doylestown, PA</i>	peptide immunotherapeutic vaccine	breast cancer, ovarian cancer	Phase I immunotope.com
inotuzumab ozogamicin (CMC-544)	Pfizer <i>New York, NY</i> UCB <i>Smyrna, GA</i>	mAb	aggressive non-Hodgkin lymphoma, ALL	Phase III pfizer.com ucb.com
interleukin-12 gene therapy	OncoSec Medical <i>San Diego, CA</i>	gene therapy	cutaneous T-cell lymphoma, malignant melanoma, merkel cell carcinoma	Phase II oncosec.com
lomab-B (anti-CD45 mAb)	Actinium Pharmaceuticals <i>New York, NY</i>	mAb	AML	Phase II actiniumpharmaceuticals.com
IRX-2	IRX Therapeutics <i>New York, NY</i>	cytokine	head and neck cancer (Fast Track)	Phase II irxtherapeutics.com
ISF35	Memgen <i>San Diego, CA</i>	gene vaccine	CLL, non-Hodgkin lymphoma	Phase II memgenbio.com
ISIS-EIF4E <sub>Rx</sub> (EIF-4E ASO)	Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	NSCLC, pancreatic cancer	Phase II isispharm.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
ISIS-STAT3 <sub>Rx</sub>	AstraZeneca Wilmington, DE Isis Pharmaceuticals Carlsbad, CA	antisense	cancer	Phase II astrazeneca.com isispharm.com
J 591 Lu-177	BZL Biologics New York, NY	mAb	prostate cancer	Phase II
JVRS-100 immunotherapeutic	Colby Pharmaceuticals San Jose, CA	DNA vaccine	leukemia	Phase I colbypharma.com
JX-594	Jennerex Biotherapeutics San Francisco, CA	genetically- engineered virus	liver cancer ----- colorectal cancer	Phase II jennerex.com ----- Phase I jennerex.com
JX-929	Jennerex Biotherapeutics San Francisco, CA	genetically- engineered virus	breast cancer, pancreatic cancer	Phase I jennerex.com
KB004	KaloBios Pharmaceuticals South San Francisco, CA	mAb	hematological malignancies	Phase I kalobios.com
LA-EP2006 (pegfilgrastim biosimilar)	Sandoz Princeton, NJ	growth factor	chemotherapy-related febrile neutropenia	Phase III us.sandoz.com
leukemia DNA vaccine (WT1)	Inovio Pharmaceuticals Blue Bell, PA University of Southampton Hampshire, United Kingdom	DNA vaccine	AML, CML	Phase II inovio.com
<b>Leukine</b> <sup>®</sup> sargramostim	Bayer HealthCare Pharmaceuticals Wayne, NJ	granulocyte macrophage colony- stimulating factor	CLL	Phase II bayerpharma.com
LFA102	Novartis Pharmaceuticals East Hanover, NJ XOMA Berkeley, CA	mAb	breast cancer, prostate cancer	Phase I novartis.com
LG631	Lentigen Gaithersburg, MD	stem cell therapy	chemoprotection in patients with glioblastoma	Phase I lentigen.com
lirilumab (anti-KIR)	Bristol-Myers Squibb Princeton, NJ	mAb	cancer	Phase I bms.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
LOR-2040 (Orphan Drug)	Lorus Therapeutics <i>Toronto, Canada</i>	antisense	AML	Phase II lorusthera.com
<b>Lucanix®</b> belagen pumatucel-L	NovaRx <i>San Diego, CA</i>	antisense gene-modified cell vaccine	NSCLC (Fast Track)	Phase III novarx.com
LY2495655 (anti-myostatin mAb)	Eli Lilly <i>Indianapolis, IN</i>	mAb	cancer cachexia (see also musculoskeletal)	Phase II lilly.com
LY2875358 (c-met mAb)	Eli Lilly <i>Indianapolis, IN</i>	mAb	cancer	Phase II lilly.com
MABp1	XBiotech <i>Austin, TX</i>	mAb	cancer-related cachexia (see also cardiovascular, diabetes, skin)	Phase III xbiotech.com
			advanced cancer	Phase I/II xbiotech.com
			leukemia	Phase I xbiotech.com
MAGE-A3 (antigen-specific cancer immunotherapeutic)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	recombinant immuno- therapeutic vaccine	bladder cancer, melanoma, NSCLC	Phase III gsk.com
MEDI-551 (anti-CD19 mAb)	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	mAb	hematological malignancies (see also autoimmune)	Phase II astrazeneca.com medimmune.com
MEDI-565 (anti-CEA BiTE)	Amgen <i>Thousand Oaks, CA</i> AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	bispecific antibody	solid tumors	Phase I amgen.com astrazeneca.com medimmune.com
MEDI-573 (anti-IGF mAb)	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	mAb	solid tumors	Phase II astrazeneca.com medimmune.com
MEDI-575 (anti-PDGFRα mAb)	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	mAb	glioblastoma, NSCLC	Phase II astrazeneca.com medimmune.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
MEDI-0639 (anti-DLL-4 mAb)	AstraZeneca Wilmington, DE MedImmune Gaithersburg, MD	mAb	solid tumors	Phase I astrazeneca.com medimmune.com
MEDI-3617 (anti-ANG-2 mAb)	AstraZeneca Wilmington, DE MedImmune Gaithersburg, MD	mAb	solid tumors	Phase I astrazeneca.com medimmune.com
MEDI-4736 (anti-CD274 mAb)	AstraZeneca Wilmington, DE MedImmune Gaithersburg, MD	mAb	cancer	Phase I astrazeneca.com medimmune.com
MEDI-6469 (anti-OX40 mAb)	AgonOx Portland, OR AstraZeneca Wilmington, DE MedImmune Gaithersburg, MD	mAb	solid tumors	Phase I agonox.com astrazeneca.com medimmune.com
melanoma vaccine	MabVax Therapeutics San Diego, CA	mAb vaccine	malignant melanoma	Phase I mabvax.com
melanoma vaccine (POL-103A)	Polynoma San Diego, CA	vaccine	malignant melanoma	Phase III polynoma.com
MGA271 (anti-B7-H3)	MacroGenics Rockville, MD	mAb	solid tumors	Phase I macrogenics.com
MGAH22 (anti-HER2)	MacroGenics Rockville, MD	mAb	solid tumors	Phase I macrogenics.com
milatuzumab (Orphan Drug)	Immunomedics Morris Plains, NJ	mAb	CLL	Phase I immunomedics.com
milatuzumab-DOX	Immunomedics Morris Plains, NJ	mAb	multiple myeloma	Phase I immunomedics.com
MINT1526A	Genentech South San Francisco, CA	mAb	solid tumors	Phase I gene.com
MK-3475	Merck Whitehouse Station, NJ	mAb	malignant melanoma	Phase II merck.com
			NSCLC	Phase I merck.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
MKC1106-MT	Colby Pharmaceuticals <i>San Jose, CA</i>	vaccine	malignant melanoma	Phase II colbypharma.com
MLN0264 (GCC antibody drug conjugate)	Millennium Pharmaceuticals <i>Cambridge, MA</i>	mAb	gastrointestinal cancer	Phase I mlnm.com
MM-111	Merrimack Pharmaceuticals <i>Cambridge, MA</i>	recombinant fusion protein	breast cancer, solid tumors	Phase I merrimackpharma.com
mogamulizimab (Orphan Drug)	Kyowa Hakko Kirin Pharma <i>Princeton, NJ</i>	mAb	cutaneous T-cell lymphoma ----- adult T-cell lymphoma, T-cell leukemia	Phase III kyowa-kirin-pharma.com ----- Phase II kyowa-kirin-pharma.com
MORAb-004	Eisai <i>Woodcliff Lake, NJ</i>	mAb	colorectal cancer, melanoma, sarcoma	Phase II eisai.com
MORAb-009 (amatuximab) (Orphan Drug)	Eisai <i>Woodcliff Lake, NJ</i>	mAb	mesothelioma	Phase II eisai.com
moxetumomab pasudotox	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	mAb	hematological malignancies	Phase I astrazeneca.com medimmune.com
<b>Multikine®</b> leukocyte interleukin cancer (Orphan Drug)	CEL-SCI <i>Vienna, VA</i>	growth factor, interferon, interleukin	head and neck cancer	Phase III cel-sci.com
<b>MVA-BN® HER2</b>	BN ImmunoTherapeutics <i>Mountain View, CA</i>	cell vaccine	breast cancer	Phase I bavarian-nordic.com
<b>MVA-BN®-PRO</b>	BN ImmunoTherapeutics <i>Mountain View, CA</i>	vaccine	prostate cancer	Phase I/II bavarian-nordic.com
mycobacterium cell wall-DNA complex (MCC)	Bioniche Therapeutics <i>Pointe-Claire, Canada</i>	myco-bacterial DNA	bladder cancer (Fast Track)	Phase III bioniche.com
necitumumab	Bristol-Myers Squibb <i>Princeton, NJ</i> Eli Lilly <i>Indianapolis, IN</i> ImClone Systems <i>Princeton, NJ</i>	mAb	NSCLC	Phase III bms.com lilly.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
neuroblastoma vaccine	MabVax Therapeutics <i>San Diego, CA</i>	mAb vaccine	neuroblastoma	Phase I mabvax.com
<b>NeuVax™</b> nelipepmut-S	Galena Biopharma <i>Lake Oswego, OR</i>	peptide vaccine	breast cancer	Phase III galenabiopharma.com
			prostate cancer	Phase I/II galenabiopharma.com
NGR-TNF (Orphan Drug)	Molmed <i>Milan, Italy</i>	recombinant fusion protein	mesothelioma	Phase III molmed.com
NHS-IL 12	EMD Serono <i>Rockland, MA</i> National Cancer Institute <i>Bethesda, MD</i>	interleukin	solid tumors	Phase I emdserono.com
<b>NiCord®</b> umbilical cord blood stem cell therapy	Gamida Cell <i>Jerusalem, Israel</i>	stem cell therapy	hematological malignancies (see also blood)	Phase I/II gamida-cell.com
nimotuzumab (Orphan Drug)	InnoMab PTE <i>Singapore</i>	mAb	glioma	Phase II innomab.net
nivolumab (anti-PD1)	Bristol-Myers Squibb <i>Princeton, NJ</i>	mAb	melanoma, NSCLC, renal cell carcinoma	Phase III bms.com
			solid tumors	Phase I/II bms.com
<b>Nplate™</b> romiplostim	Amgen <i>Thousand Oaks, CA</i>	recombinant fusion protein	chemotherapy-induced thrombocytopenia (see also autoimmune)	Phase II amgen.com
NTDDS (intradermal gene therapy)	Periphagen Holdings <i>Pittsburgh, PA</i>	gene therapy	cancer pain	Phase II completed
NY-ESO-1 antigen-specific cancer immunotherapeutic	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	malignant melanoma	Phase I gsk.com
obinutuzumab (GA101)	Biogen Idec <i>Weston, MA</i> Genentech <i>South San Francisco, CA</i>	mAb	CLL, diffuse large B-cell lymphoma, non-Hodgkin lymphoma	Phase III biogenidec.com gene.com
OHR/AVR118	Ohr Pharmaceutical <i>New York, NY</i>	immune-based therapy	cachexia associated with cancer	Phase II ohrpharmaceutical.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
olaratumab (LY3012207)	Eli Lilly Indianapolis, IN ImClone Systems Princeton, NJ	mAb	glioblastoma	Phase II lilly.com
OMP-52M51 (anti-Notch 1)	GlaxoSmithKline Rsch. Triangle Park, NC OncoMed Pharmaceuticals Redwood City, CA	mAb	hematological malignancies	Phase I gsk.com oncomed.com
OMP-59R5 (anti-Notch 2/3)	GlaxoSmithKline Rsch. Triangle Park, NC OncoMed Pharmaceuticals Redwood City, CA	mAb	pancreatic cancer	Phase I/II gsk.com oncomed.com
onartuzumab (anti-c-met- mAb)	Genentech South San Francisco, CA	mAb	metastatic NSCLC	Phase III gene.com
<b>Onconase</b> <sup>®</sup> ranpirinase	Tamir Biotechnology Monmouth Junction, NJ	ribonuclease	NSCLC	Phase II tamirbio.com
<b>Oncoprex</b> <sup>™</sup> TUSC2 nanoparticles	Genprex Austin, TX	gene therapy	NSCLC	Phase I genprex.com
<b>OncoVAX</b> <sup>®</sup> colorectal cancer vaccine	Vaccinogen Frederick, MD	cell vaccine	colorectal cancer (Fast Track)	Phase I/II vaccinogeninc.com
ONT-10	Oncothyreon Seattle, WA	vaccine	solid tumors	Phase I oncothyreon.com
<b>Ontak</b> <sup>®</sup> denileukin diftitox	Eisai Woodcliff Lake, NJ	recombinant fusion protein	malignant melanoma	Phase II eisai.com
OPT-822/OPT-821	Optimer Biotechnology Taipei, Taiwan	vaccine	breast cancer	Phase III optimerbiotech.com
oregovomab (Orphan Drug)	Quest Pharmatech Edmonton, Canada	mAb	ovarian cancer	Phase II questpharmatech.com
ovarian cancer vaccine	MabVax Therapeutics San Diego, CA	mAb vaccine	ovarian cancer	Phase II mabvax.com
<b>PancAtak</b> <sup>™</sup> cancer gene therapy	Advantagene Auburndale, MA	gene therapy	pancreatic cancer	Phase I/II advantagene.com
pbi-shRNA <sup>™</sup> STMN1 LP	Gradalis Carrollton, TX	gene therapy	solid tumors	Phase I gradalisinc.com

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Product Name	Sponsor	Product Category	Indication	Development Phase
PEGPH20	Halozyme Therapeutics San Diego, CA	recombinant enzyme	solid tumors	Phase II halozyme.com
<b>Perjeta™</b> pertuzumab	Genentech South San Francisco, CA	mAb	early HER2-positive breast cancer ----- HER2-positive metastatic breast cancer (second-line treatment), HER2-positive gastric cancer	Phase III gene.com ----- Phase II gene.com
PF-03446962	Pfizer New York, NY	mAb	solid tumors	Phase I pfizer.com
PF-04605412	Pfizer New York, NY	mAb	solid tumors	Phase I pfizer.com
PF-04856884 (CVX060)	Pfizer New York, NY	fusion peptide	renal cancer ----- solid tumors	Phase II pfizer.com ----- Phase I pfizer.com
PF-05082566	Pfizer New York, NY	mAb	cancer, lymphoma	Phase I pfizer.com
PF-05280014 (trastuzumab biosimilar)	Pfizer New York, NY	mAb	metastatic breast cancer	Phase I pfizer.com
polyclonal antibody stimulator (Orphan Drug)	Cancer Advances Durham, NC	polyclonal antibody vaccine	gastric cancer, pancreatic cancer (see also digestive) ----- colorectal cancer	Phase III canceradvances.com ----- Phase II canceradvances.com
PRAME antigen-specific cancer immunotherapeutic	GlaxoSmithKline Rsch. Triangle Park, NC	recombinant vaccine	malignant melanoma, NSCLC	Phase I gsk.com
prophage cancer vaccine (G-series)	Agenus Lexington, MA	vaccine	glioma	Phase II agenusbio.com
prophage cancer vaccine (M-series) (Orphan Drug)	Agenus Lexington, MA	vaccine	malignant melanoma (Fast Track)	Phase III agenusbio.com
prophage cancer vaccine (R-series)	Agenus Lexington, MA	vaccine	renal cancer (Fast Track)	Phase III agenusbio.com



## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
<b>ProstAtak™</b> cancer gene therapy	Advantagene <i>Auburndale, MA</i>	gene therapy	prostate cancer (Fast Track)	Phase III advantagene.com
<b>PROSTVAC®</b> recombinant vaccinia virus-expressing PSA	BN ImmunoTherapeutics <i>Mountain View, CA</i>	recombinant vaccine	prostate cancer	Phase III bavarian-nordic.com
<b>Provenge®</b> sipuleucel-T	Dendreon <i>Seattle, WA</i>	dendritic cell vaccine	prostate cancer (early-stage disease, recurrent)	Phase III dendreon.com
			prostate cancer (early-stage disease, neoadjuvant therapy), prostate cancer (metastatic, first-line therapy)	Phase II dendreon.com
PSMA-ADC	Progenics Pharmaceuticals <i>Tarrytown, NY</i>	mAb	prostate cancer	Phase II progenics.com
PT107	Pique Therapeutics <i>Durham, NC</i>	vaccine	NSCLC	Phase II piquetherapeutics.com
purine nucleoside phosphorylase gene therapy	PNP Therapeutics <i>Birmingham, AL</i>	gene therapy	solid tumors	Phase I pnptherapeutics.com
PVX-410 immunotherapeutic	OncoPep <i>Methuen, MA</i>	peptide vaccine	multiple myeloma	Phase I/II oncopep.com
QBI-139	Quintessence Biosciences <i>Madison, WI</i>	ribonuclease	solid tumors	Phase I quintbio.com
ramucirumab (LY3009806)	Eli Lilly <i>Indianapolis, IN</i> ImClone Systems <i>Princeton, NJ</i>	mAb	breast cancer, colorectal cancer, gastric cancer	Phase III lilly.com
<b>Redectane®</b> girentuximab I-124	Wilex <i>Munich, Germany</i>	mAb	diagnosis of kidney cancer	Phase III wilex.com
REGN1400	Regeneron Pharmaceuticals <i>Tarrytown, NY</i>	mAb	cancer	Phase I regeneron.com
REIC gene therapy	Momotaro-Gene <i>Okayama, Japan</i>	gene therapy	prostate cancer	Phase I mt-gene.com
RG7116	Roche <i>Nutley, NJ</i>	mAb	solid tumors	Phase I roche.com
RG7155	Roche <i>Nutley, NJ</i>	mAb	solid tumors	Phase I roche.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
RG7160 (humAb EGFR)	Roche <i>Nutley, NJ</i>	mAb	colorectal cancer	Phase II roche.com
RG7212	Roche <i>Nutley, NJ</i>	mAb	solid tumors	Phase I roche.com
RG7356 (anti-CD44 mAb)	Roche <i>Nutley, NJ</i>	mAb	AML, solid tumors	Phase I roche.com
RG7458 (antibody-drug conjugate)	Genentech <i>South San Francisco, CA</i> Seattle Genetics <i>Bothell, WA</i>	mAb	ovarian cancer	Phase I gene.com
<b>RIGScan™</b> radiodiagnostic agent	Navidea Biopharmaceuticals <i>Dublin, OH</i>	mAb	diagnosis of colorectal cancer	in clinical trials navidea.com
rilotumumab	Amgen <i>Thousand Oaks, CA</i>	mAb	colorectal cancer, gastric cancer, prostate cancer, SCLC	Phase II amgen.com
rindopepimut (Orphan Drug)	Celldex Therapeutics <i>Needham, MA</i>	vaccine	first-line glioblastoma (Fast Track) ----- second-line glioblastoma (Fast Track)	Phase III celldextherapeutics.com ----- Phase II celldextherapeutics.com
<b>Rituxan®</b> rituximab	Genentech <i>South San Francisco, CA</i>	mAb	diffuse large B-cell lymphoma	Phase III gene.com
RON8 mAb	Eli Lilly <i>Indianapolis, IN</i> ImClone Systems <i>Princeton, NJ</i>	mAb	cancer	Phase I lilly.com
SAR3419 (maytansin-loaded anti-CD19 mAb)	Sanofi US <i>Bridgewater, NJ</i>	mAb	ALL, non-Hodgkin lymphoma	Phase II sanofi.com
SAR153192 (REGN 421) (anti-DLL4 mAb)	Regeneron Pharmaceuticals <i>Tarrytown, NY</i> Sanofi US <i>Bridgewater, NJ</i>	mAb	cancer	Phase I regeneron.com sanofi.com
SAR256212 (MM-121) (anti-ErbB3 mAb)	Merrimack Pharmaceuticals <i>Cambridge, MA</i> Sanofi US <i>Bridgewater, NJ</i>	mAb	breast cancer ----- solid tumors (combination therapy)	Phase II merrimackpharma.com sanofi.com ----- Phase I merrimackpharma.com sanofi.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
SAR307746 (REGN910) (anti-angiopoietin-2 mAb)	Regeneron Pharmaceuticals <i>Tarrytown, NY</i> Sanofi US <i>Bridgewater, NJ</i>	mAb	solid tumors	Phase I regeneron.com sanofi.com
SAR566658 (maytansin-loaded anti-DS6)	Sanofi US <i>Bridgewater, NJ</i>	mAb	DS6-positive solid tumors	Phase I sanofi.com
SAR650984 (anti-CD38 naked mAb)	Sanofi US <i>Bridgewater, NJ</i>	mAb	hematological malignancies	Phase I sanofi.com
sarcoma cancer vaccine	MabVax Therapeutics <i>San Diego, CA</i>	mAb vaccine	sarcoma	Phase II mabvax.com
SB-313	Sangamo BioSciences <i>Richmond, CA</i>	cell therapy	glioblastoma	Phase I sangamo.com
SCH-721015	FKD Therapies <i>Kuopio, Finland</i>	gene therapy	bladder cancer	Phase II
SGN-75 (vorsetuzumab mafodotin)	Seattle Genetics <i>Bothell, WA</i>	mAb	non-Hodgkin lymphoma, renal cancer	Phase I seattlegenetics.com
SL-401 (Orphan Drug)	Stemline Therapeutics <i>New York, NY</i>	recombinant fusion protein	AML, myelodysplastic syndromes	Phase I/II stemline.com
SL-701	Stemline Therapeutics <i>New York, NY</i>	dendritic cell vaccine	glioma	Phase I/II stemline.com
small-cell lung cancer vaccine	MabVax Therapeutics <i>San Diego, CA</i>	mAb vaccine	SCLC	Phase I mabvax.com
SNS01-T	Senesco Technologies <i>Bridgewater, NJ</i>	gene therapy; RNA interference	diffuse large B-cell lymphoma, mantle cell lymphoma, multiple myeloma	Phase I/II senesco.com
sotatercept (ACE-011)	Acceleron Pharma <i>Cambridge, MA</i> Celgene <i>Summit, NJ</i>	recombinant fusion protein	chemotherapy-induced anemia (see also blood)	Phase III/III acceleronpharma.com celgene.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
SPI-2012 (granulocyte colony-stimulating factor, long-acting)	Hanmi Pharmaceutical <i>Seoul, South Korea</i> Spectrum Pharmaceuticals <i>Henderson, NV</i>	growth factor	neutropenia in cancer patients	Phase II sppirx.com
<b>StemEx</b> <sup>®</sup> carlecortemcel-L (Orphan Drug)	Gamida Cell <i>Jerusalem, Israel</i> Teva Pharmaceutical <i>Tikva, Israel</i>	stem cell therapy	hematological malignancies (Fast Track)	Phase III gamida-cell.com tevapharm.com
<b>Stimuvax</b> <sup>®</sup> liposomal cancer vaccine	EMD Serono <i>Rockland, MA</i> Oncothyreon <i>Seattle, WA</i>	peptide vaccine	NSCLC (Fast Track)	Phase III emdserono.com oncothyreon.com
Sym004	EMD Serono <i>Rockland, MA</i> Symphogen <i>Lyngby, Denmark</i>	mAb	head and neck cancer  ----- solid tumors	Phase II emdserono.com symphogen.com  ----- Phase I emdserono.com symphogen.com
tabalumab (BAFF inhibitor)	Eli Lilly <i>Indianapolis, IN</i>	mAb	multiple myeloma (see also autoimmune)	Phase III lilly.com
talactoferrin alfa (Orphan Drug)	Agennix <i>Princeton, NJ</i>	recombinant protein	NSCLC (Fast Track)	Phase III completed agennix.com
talminogene laherparepvec	Amgen <i>Thousand Oaks, CA</i>	gene therapy	malignant melanoma	Phase III amgen.com
<b>TeloB-Vax</b> telomerase cancer vaccine	Adamis Pharmaceuticals <i>San Diego, CA</i>	DNA vaccine	prostate cancer	Phase I adamispharmaceuticals.com
TF2	Immunomedics <i>Morris Plains, NJ</i>	mAb	diagnosis of colorectal cancer	Phase I immunomedics.com
TG-1101 (ublituximab) (Orphan Drug)	TG Therapeutics <i>New York, NY</i>	mAb	CLL, non-Hodgkin lymphoma	Phase I/II tgtherapeutics.com
tigatuzumab	Daiichi Sankyo <i>Parsippany, NJ</i>	mAb	breast cancer, liver cancer, ovarian cancer, pancreatic cancer	Phase II dsi.com
TKM-PLK1	Tekmira Pharmaceuticals <i>Burnaby, Canada</i>	RNA interference	lymphoma, solid tumors	Phase I tekmirapharm.com

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Product Name	Sponsor	Product Category	Indication	Development Phase
Toca-511 (cytosine deaminase gene therapy)	Tocagen <i>San Diego, CA</i>	gene therapy	glioblastoma	Phase I/II tocagen.com
trastuzumab emtansine (T-DM1)	Genentech <i>South San Francisco, CA</i> Roche <i>Nutley, NJ</i>	mAb	first-line HER2-positive metastatic breast cancer, third-line HER2-positive metastatic breast cancer	Phase III gene.com roche.com
			early HER2-positive breast cancer, advanced HER2-positive gastric cancer	Phase II gene.com roche.com
TRC105	TRACON Pharmaceuticals <i>San Diego, CA</i>	mAb	bladder cancer, liver cancer, ovarian cancer, prostate cancer	Phase II traconpharma.com
			solid tumors	Phase I traconpharma.com
tremelimumab (anti-CTLA4 mAb)	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	mAb	solid tumors	Phase II astrazeneca.com medimmune.com
<b>Trivax</b> cancer vaccine	Activartis Biotech <i>Vienna, Austria</i>	personalized dendritic cell vaccine	glioblastoma	Phase II activartis.com
tumor immunotherapy mAb	Genentech <i>South San Francisco, CA</i>	mAb	solid tumors	Phase I gene.com
TV1-Brain-1	TVAX Biomedical <i>Lenexa, KS</i>	cell vaccine	glioblastoma	Phase II tvaxbiomedical.com
TV1-Kidney-1	TVAX Biomedical <i>Lenexa, KS</i>	cell vaccine	renal cancer	Phase II tvaxbiomedical.com
U3-1565	Daiichi Sankyo <i>Parsippany, NJ</i>	mAb	solid tumors	Phase I dsi.com
urelumab (anti-CD137)	Bristol-Myers Squibb <i>Princeton, NJ</i>	mAb	cancer	Phase I bms.com

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Product Name	Sponsor	Product Category	Indication	Development Phase
V503	Merck <i>Whitehouse Station, NJ</i>	vaccine	prevention of cervical cancer, prevention of vulvovaginal cancer (see also infectious)	Phase III merck.com
VAY736	MorphoSys <i>Munich, Germany</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	CLL (see also other)	Phase I morphosys.com novartis.com
VB-111	VBL Therapeutics <i>Or Yehuda, Israel</i>	gene therapy	thyroid cancer	Phase II vblrx.com
			glioblastoma	Phase I/II vblrx.com
VB4-845 (Orphan Drug)	Viventia Biotechnologies <i>Mississauga, Canada</i>	mAb	bladder cancer	Phase II viventia.com
<b>Vectibix®</b> panitumumab	Amgen <i>Thousand Oaks, CA</i>	mAb	colorectal cancer (first-line therapy, second-line therapy)	application submitted amgen.com
VEGFR3 mAb (IMC-3C5)	Eli Lilly <i>Indianapolis, IN</i> ImClone Systems <i>Bridgewater, NJ</i>	mAb	cancer	Phase I lilly.com
veltuzumab (IMMU-106) (Orphan Drug)	Immunomedics <i>Morris Plains, NJ</i>	mAb	CLL, non-Hodgkin lymphoma (see also autoimmune)	Phase I/II immunomedics.com
VGX-100	Circadian Technologies <i>Victoria, Australia</i>	mAb	solid tumors	Phase I circadian.com.au
VGX-3100	Inovio Pharmaceuticals <i>Blue Bell, PA</i>	DNA vaccine	cervical dysplasia	Phase II inovio.com
volociximab	AbbVie <i>North Chicago, IL</i>	mAb	NSCLC	Phase I completed abbvie.com
VX15	Vaccinex <i>Rochester, NY</i>	mAb	solid tumors (see also autoimmune)	Phase I vaccinex.com
WT1 antigen- specific cancer immunotherapeutic	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	AML	Phase II gsk.com
			breast cancer	Phase I gsk.com

## CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
WT2725	Sunovion Pharmaceuticals <i>Marlborough, MA</i>	peptide vaccine	solid tumors	Phase I sunovion.com
<b>Xgeva</b> <sup>®</sup> denosumab	Amgen <i>Thousand Oaks, CA</i>	mAb	delay or prevention of bone metastases in prostate cancer	application submitted amgen.com
			delay or prevention of bone metastases in breast cancer	Phase III amgen.com
			giant cell tumor of the bone	Phase II amgen.com
<b>Xiaflex</b> <sup>®</sup> collagenase clostridium histolyticum	BioSpecifics Technologies <i>Lynbrook, NY</i>	peptide	lipoma (see also musculoskeletal, other)	Phase II biospecifics.com
<b>XmAb</b> <sup>®</sup> high ADCC mAb	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> Xencor <i>Monrovia, CA</i>	mAb	cancer	Phase I boehringer-ingelheim.com xencor.com
<b>XmAb</b> <sup>®</sup> 2513 anti-CD30 mAb	Xencor <i>Monrovia, CA</i>	mAb	Hodgkin disease, T-cell lymphoma	Phase I xencor.com
<b>XmAb</b> <sup>®</sup> 5574 anti-CD19 mAb	MorphoSys <i>Munich, Germany</i> Xencor <i>Monrovia, CA</i>	mAb	CLL	Phase I morphosys.com xencor.com
Y-90 hPAM 4 (IMMU-107) (Orphan Drug)	Immunomedics <i>Morris Plains, NJ</i>	mAb	pancreatic cancer (Fast Track)	Phase I/II immunomedics.com
<b>Yervoy</b> <sup>™</sup> ipilimumab (Orphan Drug)	Bristol-Myers Squibb <i>Princeton, NJ</i>	mAb	adjuvant melanoma, NSCLC, prostate cancer, SCLC	Phase III bms.com
			gastric cancer, ovarian cancer	Phase II bms.com
zanolimumab	Emergent BioSolutions <i>Rockville, MD</i>	mAb	peripheral T-cell lymphoma	Phase II emergentbiosolutions.com
<b>Zevalin</b> <sup>®</sup> ibrutumomab tiuxetan	Spectrum Pharmaceuticals <i>Henderson, NV</i>	mAb	diffuse large B-cell lymphoma	Phase III sppirx.com
			non-Hodgkin lymphoma	Phase II sppirx.com

## CARDIOVASCULAR DISEASE

Product Name	Sponsor	Product Category	Indication	Development Phase
3K3A-APC	ZZ Biotech <i>Houston, TX</i>	recombinant protein	stroke	Phase I zzbiotech.com
ACP-501 (rhLCAT)	AlphaCore Pharma <i>Ann Arbor, MI</i>	recombinant protein	atherosclerosis, coronary artery disease	Phase I alphacorepharma.com
ACY001	Artericyte <i>Cleveland, OH</i>	stem cell therapy	chronic coronary ischemia	Phase I completed artericyte.com
adipose stem cell therapy	Cytori Therapeutics <i>San Diego, CA</i>	stem cell therapy	myocardial ischemia	Phase I/II cytori.com
adult autologous stem cell therapy	Baxter International <i>Deerfield, IL</i>	stem cell therapy	myocardial ischemia	Phase III baxter.com
			critical limb ischemia	Phase I/II completed baxter.com
adult mesenchymal stem cell therapy	BioCardia <i>San Carlos, CA</i>	stem cell therapy	ischemic heart disorders	Phase I/II biocardia.com
ALD-201	Cytomedix <i>Gaithersburg, MD</i>	stem cell therapy	ischemic heart failure	Phase I completed cytomedix.com
ALD-301	Cytomedix <i>Gaithersburg, MD</i>	stem cell therapy	critical limb ischemia	Phase I/II cytomedix.com
ALD-401	Cytomedix <i>Gaithersburg, MD</i>	stem cell therapy	ischemic stroke	Phase II cytomedix.com
allogeneic stem cell therapy	Stemedica Cell Technologies <i>San Diego, CA</i>	stem cell therapy	ischemic stroke	Phase I/II stemedica.com
ALN-PCS	Alnylam Pharmaceuticals <i>Cambridge, MA</i>	RNA interference	hypercholesterolemia	Phase I alnylam.com
ALO-212	Artericyte <i>Cleveland, OH</i>	stem cell therapy	critical limb ischemia	Phase I artericyte.com
AMG 145	Amgen <i>Thousand Oaks, CA</i>	mAb	hypercholesterolemia	Phase III amgen.com
			hyperlipoproteinemia type IIa	Phase II/III amgen.com
AMR-001	Amorcyte <i>Allendale, NJ</i> NeoStem <i>New York, NY</i>	stem cell therapy	myocardial infarction	Phase II amorcyte.com neostem.com



## CARDIOVASCULAR DISEASE

Product Name	Sponsor	Product Category	Indication	Development Phase
<b>Anginera™</b> epicardial angiogenesis patch	Theregen <i>San Francisco, CA</i>	fibroblast cell therapy	heart failure, ischemic heart disorders	Phase I theragen.com
anti-fibrin mAb 3B6/22 Tc-99m	Agenix <i>Sydney, Australia</i>	mAb	diagnosis of deep vein thrombosis, diagnosis of pulmonary embolism	Phase II agenix.com
anti-oxLDL (BI-204/RG7418)	BioInvent International <i>Lund, Sweden</i> Genentech <i>South San Francisco, CA</i>	mAb	atherosclerosis	Phase II gene.com
anti-PCSK9 mAb (RG7652)	Genentech <i>South San Francisco, CA</i>	mAb	cardiovascular disease	Phase II gene.com
cardiovascular medicine	Eli Lilly <i>Indianapolis, IN</i>	biologic	cardiovascular disease	Phase I lilly.com
<b>Collategene®</b> beperninogene perplasmid	AnGes MG <i>Gaithersburg, MD</i> Mitsubishi Tanabe Pharma <i>Osaka, Japan</i>	gene therapy	peripheral arterial disease (Fast Track)	Phase II anges-mg.com
			ischemic heart disease	Phase I anges-mg.com
combination autologous stem cell therapy	TCA Cellular Therapy <i>Covington, LA</i>	stem cell therapy	coronary ischemia, ischemic heart disorders	Phase II tcacellulartherapy.com
CPI-003 (intracoronary cardio-sphere-derived stem cell therapy)	Capricor <i>Beverly Hills, CA</i>	stem cell therapy	myocardial infarction	Phase I capricor.com
desmoteplase	Lundbeck <i>Deerfield, IL</i>	recombinant protein	ischemic stroke (Fast Track)	Phase III lundbeck.com
endometrial blood stem cell therapy	Medistem <i>San Diego, CA</i>	stem cell therapy	heart failure	Phase II medisteminc.com
fibroblast growth factor-1	CardioVascular BioTherapeutics <i>Las Vegas, NV</i>	fibroblast growth factor	severe coronary heart disease (see also skin)	Phase II cvbt.com
<b>Generx™</b> alferminogene tadenovec	Cardium Therapeutics <i>San Diego, CA</i>	gene therapy	myocardial ischemia (Fast Track)	Phase III cardiumthx.com
GGF2 (glial growth factor 2)	Acorda Therapeutics <i>Hawthorne, NY</i>	growth factor	congestive heart failure	Phase I acorda.com
GSK249320	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	mAb	stroke	Phase II gsk.com

## CARDIOVASCULAR DISEASE

Product Name	Sponsor	Product Category	Indication	Development Phase
IL-1 $\beta$ antibody	Eli Lilly <i>Indianapolis, IN</i>	mAb	cardiovascular disease	Phase I lilly.com
<b>Ilaris</b> <sup>®</sup> canakinumab	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	secondary prevention of cardiovascular events (see also autoimmune, diabetes, musculoskeletal)	Phase III novartis.com
inclacumab (RG1512)	Roche <i>Nutley, NJ</i>	mAb	peripheral vascular disease	Phase II roche.com
<b>Iprivask</b> <sup>®</sup> desirudin	Canyon Pharmaceuticals <i>Columbia, MD</i>	recombinant protein	prevention of thrombosis	in clinical trials canyonpharma.com
ischemic tolerant allogeneic mesenchymal stem cell therapy	Stemmedica Cell Technologies <i>San Diego, CA</i>	stem cell therapy	acute myocardial infarction	Phase II stemmedica.com
ISIS-APOCIII <sub>Rx</sub>	Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	coronary artery disease	Phase II isispharm.com
ISIS-CRP <sub>Rx</sub>	Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	atrial fibrillation, coronary artery disease (see also autoimmune)	Phase II isispharm.com
ixmyelocel-T (Orphan Drug)	Aastrom Biosciences <i>Ann Arbor, MI</i>	stem cell therapy	critical limb ischemia (Fast Track) ----- dilated cardiomyopathy	Phase III aastrom.com  Phase II aastrom.com
MABp1	XBiotech <i>Austin, TX</i>	mAb	vascular restinosis (see also cancer, diabetes, skin)	Phase II xbiotech.com
mesenchymal precursor cell (MPC) product	Mesoblast <i>New York, NY</i>	stem cell therapy	congestive heart failure, myocardial infarction (see also diabetes, musculoskeletal, transplantation)	Phase II mesoblast.com
<b>MultiGeneAngio</b>	MultiGene Vascular Systems <i>Nesher, Israel</i>	cell therapy	peripheral arterial disorders	Phase I/II mgvs.co.il
<b>MultiStem</b> <sup>®</sup> stem cell therapy	Athersys <i>Cleveland, OH</i>	stem cell therapy	myocardial infarction, stroke (see also digestive, transplantation)	Phase II athersys.com
<b>Mydicar</b> <sup>™</sup> SERCA 2a gene therapy	Celladon <i>La Jolla, CA</i>	gene therapy	advanced heart failure class III/IV	Phase II celladon.net
<b>MyoCell</b> <sup>®</sup> muscle stem cell therapy	Bioheart <i>Sunrise, FL</i>	stem cell therapy	congestive heart failure	Phase II/III bioheartinc.com

## CARDIOVASCULAR DISEASE

Product Name	Sponsor	Product Category	Indication	Development Phase
<b>MyoCell® SDF-1</b> muscle stem cell therapy (second-generation)	Bioheart <i>Sunrise, FL</i>	stem cell therapy	congestive heart failure	Phase I bioheartinc.com
<b>NTx®-265</b>	Stem Cell Therapeutics <i>Toronto, Canada</i>	stem cell therapy	stroke	Phase II stemcellthera.com
PB-1046	PhaseBio Pharmaceuticals <i>Malvern, PA</i>	recombinant fusion protein	essential hypertension	Phase I phasebio.com
PCSK9 adnectin	Bristol-Myers Squibb <i>Princeton, NJ</i>	adnectin	cardiovascular disease	Phase I bms.com
PF-04950615 (RN316)	Pfizer <i>New York, NY</i>	mAb	hypercholesterolemia	Phase II pfizer.com
PF-05335810	Pfizer <i>New York, NY</i>	biologic	hypercholesterolemia	Phase I pfizer.com
PLX-PAD	Pluristem Therapeutics <i>Haifa, Israel</i>	stem cell therapy	intermittent claudication	Phase II pluristem.com
<b>Prochymal®</b> remestemcel-L	Osiris Therapeutics <i>Columbia, MD</i>	stem cell therapy	acute myocardial infarction (see also diabetes, digestive, respiratory, transplantation)	Phase II osiris.com
PRT-201 (Orphan Drug)	Proteon Therapeutics <i>Waltham, MA</i>	recombinant protein	vascular access for hemodialysis (Fast Track) ----- peripheral vascular disease	Phase II proteontherapeutics.com ----- Phase I proteontherapeutics.com
SAR236553/REGN727 (anti-PCSK-9 mAb)	Regeneron Pharmaceuticals <i>Tarrytown, NY</i> Sanofi US <i>Bridgewater, NJ</i>	mAb	hypercholesterolemia	Phase III regeneron.com sanofi.com
SB623	SanBio <i>Mountain View, CA</i>	stem cell therapy	stroke	Phase I/II san-bio.com
SDF-1 (stromal cell-derived factor-1)	Juventas Therapeutics <i>Cleveland, OH</i>	gene therapy	critical limb ischemia, heart failure	Phase II juventasinc.com
<b>Syncrion®</b> albiglutide	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	recombinant fusion protein	heart failure (see also diabetes)	Phase II gsk.com
TS01	Thrombolytic Science International <i>Cambridge, MA</i>	recombinant protein	acute ischemic stroke	Phase I tsillc.net

## CARDIOVASCULAR DISEASE

Product Name	Sponsor	Product Category	Indication	Development Phase
<b>Vascugel®</b> cell therapy (Orphan Drug)	Shire Regenerative Medicine <i>Wayne, PA</i>	cell therapy	peripheral vascular disorder in patients undergoing arteriovenous access procedures for hemodialysis (Fast Track)	Phase II shire.com
VM-202 (modified hepatocyte growth factor gene therapy)	VW BioPharma <i>Atlanta, GA</i>	gene therapy	peripheral arterial disease (see also neurologic) ----- myocardial ischemia	Phase II viromed.co.kr  Phase I viromed.co.kr

## DIABETES

Product Name	Sponsor	Product Category	Indication	Development Phase
BHT-3201	Bayhill Therapeutics <i>Palo Alto, CA</i>	DNA vaccine	type 1 diabetes	Phase I completed bayhilltx.com
CVX-096 (PF-04856883)	Pfizer <i>New York, NY</i>	recombinant fusion protein	type 2 diabetes	Phase I pfizer.com
diabetes medicine	Eli Lilly <i>Indianapolis, IN</i>	biologic	diabetes	Phase I lilly.com
diabetes medicine	Eli Lilly <i>Indianapolis, IN</i>	biologic	diabetes	Phase I lilly.com
diabetes medicine	Eli Lilly <i>Indianapolis, IN</i>	biologic	diabetes	Phase I lilly.com
<b>Diamyd®</b> autoimmune diabetes vaccine (Orphan Drug)	Diamyd <i>Pittsburgh, PA</i>	vaccine	type 1 diabetes	Phase III diamyd.com
dulaglutide (GLP-1)	Eli Lilly <i>Indianapolis, IN</i>	recombinant fusion protein	type 2 diabetes	Phase III lilly.com
gevokizumab (IL-1B inhibitor mAb)	XOMA <i>Berkeley, CA</i>	mAb	type 1 diabetes, type 2 diabetes (see also eye, musculoskeletal, skin)	Phase II xoma.com
GSK1070806 (IL-18 mAb)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	mAb	type 2 diabetes (see also digestive)	Phase II gsk.com
IBC-VS01 (insulin B-chain vaccine)	Orban Biotech <i>Brookline, MA</i>	vaccine	type I diabetes	Phase I completed orbanbiotech.com

## DIABETES

Product Name	Sponsor	Product Category	Indication	Development Phase
<b>Ilaris®</b> canakinumab	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	type 2 diabetes (see also autoimmune, cardiovascular, musculoskeletal)	Phase II/III novartis.com
			type 1 diabetes	Phase II novartis.com
INGAP peptide	Exsulin <i>Minneapolis, MN</i>	peptide fragment	type 1 diabetes, type 2 diabetes	Phase II exsulin.com
insulin glargine (rDNA origin) (new formulation)	Sanofi US <i>Bridgewater, NJ</i>	recombinant insulin	type 1 diabetes, type 2 diabetes	Phase III sanofi.com
insulin lispro/BC106 (LY275585)	Adocia <i>Lyon, France</i> Eli Lilly <i>Indianapolis, IN</i>	recombinant protein	type 1 diabetes, type 2 diabetes	Phase I lilly.com
ISIS-GCCR <sub>Rx</sub>	Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	type 2 diabetes (see also other)	Phase I isispharm.com
ISIS-GCGR <sub>Rx</sub>	Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	type 2 diabetes	Phase I isispharm.com
ISIS-PTP1B <sub>Rx</sub> (PTP-1B gene inhibitor)	Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	type 2 diabetes	Phase I isispharm.com
<b>Lantus®</b> insulin glargine (rDNA origin) injection and lixisenatide combination	Sanofi US <i>Bridgewater, NJ</i>	recombinant insulin	type 2 diabetes (see also cardiovascular)	Phase I sanofi.com
LY2605541 (novel basal insulin/ insulin peglispro)	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> Eli Lilly <i>Indianapolis, IN</i>	insulin hormone	type 1 diabetes, type 2 diabetes	Phase III boehringer-ingelheim. com lilly.com
LY2963016 (new insulin glargine product)	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> Eli Lilly <i>Indianapolis, IN</i>	insulin hormone	type 1 diabetes, type 2 diabetes	Phase III boehringer-ingelheim. com lilly.com
MABp1	XBiotech <i>Austin, TX</i>	mAb	type 2 diabetes (see also cancer, cardiovascular, skin)	Phase II xbiotech.com
mesenchymal precursor cell (MPC) product	Mesoblast <i>New York, NY</i>	stem cell therapy	type 2 diabetes (see also cardiovascular, musculoskeletal, transplantation)	Phase II mesoblast.com

## DIABETES

Product Name	Sponsor	Product Category	Indication	Development Phase
PB-1023 (GLP-1 receptor agonist)	PhaseBio Pharmaceuticals <i>Malvern, PA</i>	recombinant fusion protein	type 2 diabetes	Phase II phasebio.com
PF-05231023	Pfizer <i>New York, NY</i>	biologic	type 2 diabetes	Phase I pfizer.com
<b>Prochymal</b> <sup>®</sup> remestemcel-L (Orphan Drug)	Osiris Therapeutics <i>Columbia, MD</i>	stem cell therapy	type 1 diabetes (see also cardiovascular, digestive, respiratory, transplantation)	Phase II osiris.com
rHuPH20/insulin	Halozyme Therapeutics <i>San Diego, CA</i>	recombinant fusion protein	type 1 diabetes, type 2 diabetes	Phase II halozyme.com
<b>SyncrIA</b> <sup>®</sup> albiglutide	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	recombinant fusion protein	type 2 diabetes (see also cardiovascular)	application submitted gsk.com
teplizumab (Orphan Drug)	MacroGenics <i>Rockville, MD</i>	mAb	type 1 diabetes	Phase III macrogenics.com

## DIGESTIVE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
alicaforsen	Atlantic Healthcare <i>Essex, United Kingdom</i>	antisense	pouchitis (Fast Track), distal ulcerative colitis, proximal ulcerative colitis	Phase III atlantichc.com
ALV003	Alvine Pharmaceuticals <i>San Carlos, CA</i>	recombinant protein	celiac disease	Phase I alvinepharma.com
AMG 139/MEDI-2070	Amgen <i>Thousand Oaks, CA</i> AstraZeneca <i>Wilmington, DE</i>	mAb	Crohn's disease	Phase I amgen.com astrazeneca.com
AMG 181/MEDI-7183	Amgen <i>Thousand Oaks, CA</i> AstraZeneca <i>Wilmington, DE</i>	mAb	Crohn's disease, ulcerative colitis	Phase II amgen.com astrazeneca.com
anrukizumab (IMA-638)	Pfizer <i>New York, NY</i>	mAb	ulcerative colitis	Phase II pfizer.com
anti-IP10	Bristol-Myers Squibb <i>Princeton, NJ</i>	mAb	Crohn's disease, ulcerative colitis	Phase II bms.com

## DIGESTIVE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
clazakizumab (anti-IL6)	Bristol-Myers Squibb <i>Princeton, NJ</i> Alder Biopharmaceuticals <i>Bothell, WA</i>	mAb	Crohn's disease (see also autoimmune, musculoskeletal)	Phase II bms.com alderbio.com
etrolizumab (rhuMAB-β7)	Genentech <i>South San Francisco, CA</i>	mAb	ulcerative colitis	Phase II gene.com
GSK1070806 (IL-18 mAb)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	mAb	inflammatory bowel disease (see also diabetes)	Phase I gsk.com
HLA-DQ2 peptide vaccine	ImmusanT <i>Cambridge, MA</i>	peptide vaccine	celiac disease	Phase I immusant.com
<b>Humira®</b> adalimumab	AbbVie <i>North Chicago, IL</i>	mAb	Crohn's disease in children and adolescents (see also autoimmune, eye, musculoskeletal, skin, other)	Phase III abbvie.com
<b>MultiStem®</b> stem cell therapy (PF-05285401)	Athersys <i>Cleveland, OH</i> Pfizer <i>New York, NY</i>	stem cell therapy	ulcerative colitis (see also cardiovascular, transplantation)	Phase II athersys.com pfizer.com
NN8717 (rFXIII)	Novo Nordisk <i>Princeton, NJ</i>	recombinant protein	ulcerative colitis	Phase II novonordisk.com
PDA-001 (cenplacel-L)	Celgene Cellular Therapeutics <i>Summit, NJ</i>	stem cell therapy	Crohn's disease (see also autoimmune)	Phase II celgene.com
PF-00547659	Pfizer <i>New York, NY</i>	mAb	Crohn's disease	Phase II pfizer.com
PF-04236921	Pfizer <i>New York, NY</i>	mAb	Crohn's disease (see also autoimmune)	Phase II pfizer.com
polyclonal antibody stimulator	Cancer Advances <i>Durham, NC</i>	polyclonal antibody vaccine	gastrointestinal reflux disease (GERD) (see also cancer)	Phase II canceradvancesinc.com
<b>Prochymal®</b> remestemcel-L	Osiris Therapeutics <i>Columbia, MD</i>	stem cell therapy	Crohn's disease (Fast Track), gastrointestinal injury from radiation exposure (see also cardiovascular, diabetes, respiratory, transplantation)	Phase III osiris.com

## DIGESTIVE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
QAX576	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	rectal fistula in patients with Crohn's disease (see also respiratory)	Phase II novartis.com
<b>Remicade®</b> infliximab	Janssen Biotech <i>Horsham, PA</i>	mAb	Crohn's disease (prevention of relapse after surgery resection)	Phase III janssenbiotech.com
SAR252067 (anti-LIGHT mAb)	Sanofi US <i>Bridgewater, NJ</i>	mAb	Crohn's disease, ulcerative colitis	Phase I sanofi.com
SAR339658 (VLA2 antagonist)	Sanofi US <i>Bridgewater, NJ</i>	mAb	inflammatory bowel disease	Phase II sanofi.com
<b>Simponi®</b> golimumab (subcutaneous)	Janssen Biotech <i>Horsham, PA</i>	mAb	ulcerative colitis (see also autoimmune)	application submitted janssenbiotech.com
<b>Stelara®</b> ustekinumab	Janssen Biotech <i>Horsham, PA</i>	mAb	Crohn's disease (see also autoimmune, musculoskeletal, other)	Phase II/III janssenbiotech.com
tralokinumab	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	mAb	ulcerative colitis (see also respiratory)	Phase II astrazeneca.com medimmune.com
vedolizumab (MLN0002)	Takeda Pharmaceuticals <i>Deerfield, IL</i>	mAb	Crohn's disease, ulcerative colitis	Phase III takeda.com

## EYE CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
anti-factor D (RG7417)	Genentech <i>South San Francisco, CA</i>	mAb	geographic atrophy associated with age-related macular degeneration	Phase II gene.com
anti-LINGO (BIIB033)	Biogen Idec <i>Weston, MA</i>	mAb	optic neuritis (see also autoimmune)	Phase I biogenidec.com
AVA-101	Avalanche Biotechnologies <i>San Francisco, CA</i>	gene therapy	age-related macular degeneration	Phase I/II avalanchebiotech.com
eye disorder therapeutic	MorphoSys <i>Martinsried, Germany</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	eye disorders	Phase I novartis.com



## EYE CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
<b>Eylea®</b> afibercept	Bayer HealthCare Pharmaceuticals Wayne, NJ Regeneron Pharmaceuticals Tarrytown, NY	recombinant fusion protein	diabetic macular edema, macular edema following branch retinal vein occlusion	Phase III bayerpharma.com regeneron.com
gevokizumab (IL-1B inhibitor mAb) (Orphan Drug)	XOMA Berkeley, CA	mAb	intermediate or posterior uveitis (see also diabetes, musculoskeletal, skin)	Phase III xoma.com
GSK933776A (anti-B amyloid mAb)	GlaxoSmithKline Rsch. Triangle Park, NC	mAb	age-related macular degeneration (see also neurologic)	Phase II gsk.com
GZ402663 (FLT-01) anti-vascular endothelial growth-factor gene therapy	Applied Genetic Technologies Alachua, FL Genzyme Cambridge, MA	gene therapy	wet (neovascular) age-related macular degeneration	Phase I agtc.com genzyme.com
hl-con1	Iconic Therapeutics Atlanta, GA	recombinant protein	age-related macular degeneration	Phase I iconictherapeutics.com
<b>HuCNS-SC®</b> adult neural stem cell therapy (intraocular)	StemCells Newark, CA	stem cell therapy	age-related macular degeneration (see also genetic, neurologic)	Phase I/II stemcellsinc.com
human retinal pigment epithelial cell therapy (Orphan Drug)	Advanced Cell Technology Santa Monica, CA	stem cell therapy	dry age-related macular degeneration, Stargardt's macular degeneration	Phase I/II advancedcell.com
<b>Humira®</b> adalimumab	AbbVie North Chicago, IL	mAb	uveitis (see also autoimmune, digestive, musculoskeletal, skin, other)	Phase III abbvie.com
<b>iSONEP™</b> sonepcizumab (intravitreal)	Lpath San Diego, CA	mAb	wet age-related macular degeneration	Phase II lpath.com
iCo-007	iCo Therapeutics Vancouver, Canada	antisense	diabetic macular edema	Phase II icotherapeutics.com

## EYE CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
<b>Lucentis®</b> ranibizumab	Genentech <i>South San Francisco, CA</i> Roche <i>Nutley, NJ</i>	mAb	age-related macular degeneration (0.5 mg PRN)	application submitted gene.com roche.com
			age-related macular degeneration (sustained-delivery), diabetic macular edema (sustained-delivery), retinal vein occlusion	Phase I gene.com roche.com
<b>Mitosol®</b> mitomycin ophthalmic	Mobius Therapeutics <i>St. Louis, MO</i>	recombinant protein	prevention of pterygium recurrence after excision surgery	application submitted mobiustherapeutics.com
NT 501 (ciliary neurotrophic factor) (Orphan Drug)	Neurotech Pharmaceuticals <i>Cumberland, RI</i>	cell therapy	retinitis pigmentosa (Fast Track)	Phase II/III neurotechusa.com
			age-related macular degeneration (Fast Track)	Phase II neurotechusa.com
PF-655 (RTP801i14)	Quark Pharmaceuticals <i>Fremont, CA</i>	RNA interference	wet age-related macular degeneration, diabetic macular edema	Phase II quarkpharma.com
PF-04382923 (RN6G)	Pfizer <i>New York, NY</i>	antibody	age-related macular degeneration	Phase II pfizer.com
QPI-1007	Quark Pharmaceuticals <i>Fremont, CA</i>	RNA interference	optic neuropathy	Phase I quarkpharma.com
<b>RetinoStat®</b> angiostatin endostatin gene therapy	Oxford BioMedica <i>Oxford, United Kingdom</i> Sanofi US <i>Bridgewater, NJ</i>	gene therapy	wet age-related macular degeneration	Phase I sanofi.com
RU-101 (recombinant human serum albumin)	R-Tech Ueno <i>Tokyo, Japan</i>	recombinant protein	dry eyes	Phase I rtechueno.com
secukinumab (AIN457)	Alcon Labs <i>Fort Worth, TX</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	uveitis (see also autoimmune, musculoskeletal, skin)	Phase III alcon.com novartis.com
<b>Soliris®</b> eculizumab	Alexion Pharmaceuticals <i>Cheshire, CT</i>	mAb	severe or refractory neuromyelitis optica (see also autoimmune, infectious, transplantation)	Phase II alxn.com

## EYE CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Phase
<b>StarGen®</b> Stargardt's disease gene therapy (Orphan Drug)	Sanofi US <i>Bridgewater, NJ</i>	gene therapy	Stargardt's disease (juvenile-onset macular dystrophy)	Phase I/II sanofi.com

## GENETIC DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
adrenoleucodystrophy gene therapy	bluebird bio <i>Cambridge, MA</i> INSERM <i>Paris, France</i>	gene therapy	adrenoleucodystrophy	Phase I/II bluebirdbio.com
AGTC-0106 adeno-associated virus vector-medictoten (Orphan Drug)	Applied Genetic Technologies <i>Alachua, FL</i>	gene therapy	alpha-1-antitrypsin deficiency	Phase II agtc.com
ALD-601	Cytomedix <i>Gaithersburg, MD</i>	stem cell therapy	infantile-onset lysosomal storage disease	Phase I cytomedix.com
ALN-TTR02	Alnylam Pharmaceuticals <i>Cambridge, MA</i>	RNA interference	TTR-mediated amyloidosis	Phase II alnylam.com
asfotase alfa (Orphan Drug)	Alexion Pharmaceuticals <i>Cheshire, CT</i>	recombinant fusion protein	hypophosphatasia in infants and children (Fast Track) <hr/> hypophosphatasia in adults and adolescents	Phase II/III alxn.com <hr/> Phase II alxn.com
AVI-4658 (eteplirsen)	Sarepta Therapeutics <i>Cambridge, MA</i>	antisense	Duchenne muscular dystrophy	Phase II sareptatherapeutics.com
<b>Biothropin™</b> muscular dystrophy gene therapy	Asklêpios BioPharmaceuticals <i>Chapel Hill, NC</i>	gene therapy	Duchenne muscular dystrophy	Phase I askbio.com
BMN-110 (Orphan Drug)	BioMarin Pharmaceutical <i>Novato, CA</i>	recombinant enzyme	mucopolysaccharidosis IV (Morquio A syndrome)	Phase III bmrn.com

## GENETIC DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
BMN-701 (Orphan Drug)	BioMarin Pharmaceutical <i>Novato, CA</i>	recombinant fusion protein	glycogen storage disease type II (Pompe disease)	Phase II bmrn.com
CEQ508 (Orphan Drug)	Marina Biotech <i>Bothell, WA</i>	RNA interference	familial adenomatous polyposis	Phase I/II marinabio.com
GNE lipoplex (muscular dystrophy gene therapy)	Gradalis <i>Carrollton, TX</i>	gene therapy	muscular dystrophy	Phase I gradalisinc.com
GSK2402968 (PRO-051) (Orphan Drug)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Prosensa <i>Leiden, The Netherlands</i>	antisense	Duchenne muscular dystrophy	Phase II gsk.com prosensa.eu
GSK2696273	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	stem cell therapy	adenosine deaminase severe combined immune deficiency	Phase III gsk.com
GZ402665 (rhASM) (Orphan Drug)	Genzyme <i>Cambridge, MA</i>	recombinant enzyme	Niemann-Pick type B	Phase I genzyme.com
HGT2310 (Orphan Drug)	Shire <i>Dublin, Ireland</i>	enzyme replacement therapy	Hunter syndrome (mucopolysaccharidosis II)	Phase I/II shire.com
HuCNS-SC® adult neural stem cell therapy (intracerebral)	StemCells <i>Newark, CA</i>	stem cell therapy	Pelizaeus-Merzbacher disease (see also eye, neurologic)	Phase I stemcellsinc.com
ISIS-SMN <sub>Rx</sub> (Orphan Drug)	Biogen Idec <i>Weston, MA</i> Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	spinal muscular atrophy	Phase II biogenidec.com isispharm.com
ISIS-TTR <sub>Rx</sub> (Orphan Drug)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	familial amyloid polyneuropathy	Phase III gsk.com isispharm.com
Kineret® anakinra (Orphan Drug)	Sobi <i>Ardmore, PA</i>	recombinant protein	cryopyrin-associated periodic syndrome	application submitted sobi.com
KRN-23	Kyowa Hakko Kirin Pharma <i>Princeton, NJ</i>	mAb	X-linked dominant hypophosphatemic rickets	Phase I/II kyowa-kirin-pharma.com

## GENETIC DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
<b>Kynamro™</b> mipomersen (Orphan Drug)	Genzyme <i>Cambridge, MA</i> Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	severe heterozygous familial hypercholesterolemia	Phase III genzyme.com isispharm.com
leber congenital amaurosis gene therapy (Orphan Drug)	Applied Genetic Technologies <i>Alachua, FL</i>	gene therapy	leber congenital amaurosis	Phase I/II agtc.com
NAV™ therapeutic	ReGenX Biosciences <i>Washington, DC</i>	gene therapy	Batten disease (see also blood)	Phase II regenxbio.com
PEG-PAL (Orphan Drug)	BioMarin Pharmaceutical <i>Novato, CA</i>	recombinant enzyme	phenylketonuria	Phase II bmrn.com
PF-06252616	Pfizer <i>New York, NY</i>	biologic	muscular dystrophy	Phase I pfizer.com
PRX-102 (alpha-galactosidase)	Protalix Biotherapeutics <i>Carmiel, Israel</i>	recombinant protein	Fabry's disease	Phase I/II protalix.com
recombinant human C1 esterase inhibitor (Orphan Drug)	Pharming Group <i>Leiden, The Netherlands</i> Santarus <i>San Diego, CA</i>	recombinant protein	hereditary angioedema (Fast Track)	Phase III santarus.com
sebelipase alfa (Orphan Drug)	Synageva BioPharma <i>Lexington, MA</i>	recombinant protein	Wolman disease (lysosomal acid lipase deficiency) (Fast Track)	Phase II/III synageva.com
<b>UshStat®</b> usher syndrome gene therapy (Orphan Drug)	Sanofi US <i>Bridgewater, NJ</i>	gene therapy	usher syndrome 1B	Phase I/II sanofi.com
WAS gene therapy	Children's Hospital Boston <i>Boston, MA</i> Genethon <i>Évry, France</i>	gene therapy	Wiskott-Aldrich syndrome	Phase I/II genethon.fr

## INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Phase
ACAM-Cdiff ( <i>Clostridium difficile</i> toxoid vaccine)	Sanofi Pasteur Swiftwater, PA	vaccine	prevention and treatment of <i>Clostridium difficile</i> infections (Fast Track)	Phase II sanofipasteur.us
ACE527	TD Vaccines Skorping, Denmark	vaccine	prevention of enterotoxigenic <i>Escherichia coli</i> (ETEC) infections	Phase II tdvaccines.com
acellular pertussis combo vaccine	Novartis Vaccines Cambridge, MA	vaccine	diphtheria, pertussis, tetanus	Phase I novartisvaccines.com
ADVAX (DNA vaccine)	Aaron Diamond AIDS Research Center New York, NY International AIDS Vaccine Initiative New York, NY Ichor Medical Systems San Diego, CA	DNA vaccine	HIV infection prevention  ----- HIV infection prevention (new delivery system)	Phase I completed adarc.org iavi.org  Phase I completed adarc.org iavi.org
AERAS-402/Ad35	Aeras Rockville, MD Crucell Leiden, The Netherlands	recombinant vaccine	tuberculosis prevention	Phase I aeras.org crucell.com
<b>Agriflu</b> <sup>®</sup> influenza virus vaccine	Novartis Vaccines Cambridge, MA	vaccine	influenza virus infections (pediatric ention)	Phase III novartisvaccines.com
AGS-004	Argos Therapeutics Durham, NC	personalized dendritic cell vaccine	HIV infection	Phase II argostherapeutics.com
<b>Alferon LDO</b> <sup>®</sup> interferon-alpha-n3 oral	Hemispherx Bioscience Philadelphia, PA	interferon	human papillomavirus infections  ----- influenza	Phase I/II hemispherx.net  Phase I hemispherx.net
ALN-RSV01	Alnylam Pharmaceuticals Cambridge, MA	RNA interference	respiratory syncytial virus (RSV) treatment	Phase II alnylam.com
<b>Anthim</b> <sup>™</sup> (ETI-204) (Orphan Drug)	Elusys Therapeutics Pine Brook, NJ	mAb	anthrax (Fast Track)	Phase I elusys.com
anthrax immune globulin	Cangene Berwyn, PA	mAb	anthrax	Phase III cangene.com
anti-PD-L1	Bristol-Myers Squibb Princeton, NJ	mAb	hepatitis B (see also cancer)	Phase I bms.com

## INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Phase
ASP-0113 (cytomegalovirus DNA vaccine) (Orphan Drug)	AbbVie <i>North Chicago, IL</i> Astellas Pharma US <i>Northbrook, IL</i> Vical <i>San Diego, CA</i>	DNA vaccine	prevention of cytomegalovirus (CMV) infections in stem cell transplantation	Phase III us.astellas.com
			prevention of CMV infections in solid organ transplantation	Phase II us.astellas.com
AVI-7100 radavirsen	Sarepta Therapeutics <i>Cambridge, MA</i>	antisense	influenza A virus infections	Phase I sareptatherapeutics.com
AVI-7288 (Orphan Drug)	Sarepta Therapeutics <i>Cambridge, MA</i>	antisense	Marburg virus disease	Phase I sareptatherapeutics.com
AVI-7537	Sarepta Therapeutics <i>Cambridge, MA</i>	antisense	post-exposure treatment of Ebola virus infections	Phase I sareptatherapeutics.com
AVX101 (single gene HIV vaccine)	AlphaVax <i>Rsch. Triangle Park, NC</i>	gene vaccine	HIV-1 infection prevention	Phase I alphavax.com
AVX601	AlphaVax <i>Rsch. Triangle Park, NC</i> Novartis Vaccines <i>Cambridge, MA</i>	genetically-modified vaccine	prevention of CMV infections	Phase I alphavax.com novartisvaccines.com
AZD9773 (anti-TNF-alpha polyclonal antibody)	AstraZeneca <i>Wilmington, DE</i>	polyclonal antibody	severe sepsis	Phase II astrazeneca.com
<b>Bexsero</b> <sup>®</sup> meningococcal vaccine group B	Novartis Vaccines <i>Cambridge, MA</i>	recombinant vaccine	meningococcal group B infections	Phase II novartisvaccines.com
<b>BioThrax</b> <sup>®</sup> anthrax vaccine	Emergent BioSolutions <i>Rockville, MD</i>	vaccine	prevention of post-exposure anthrax infection in combination with other antibacterials (Fast Track)	Phase II emergentbiosolutions.com
botulinum toxin vaccine	DynPort Vaccine <i>Frederick, MD</i>	recombinant vaccine	botulism	Phase II completed csc.com/dvc
cell therapy	Cell Medica <i>London, United Kingdom</i> Center for Cell and Gene Therapy <i>Houston, TX</i>	cell therapy	viral infections (see also cancer)	Phase I/II cellmedica.co.uk
chikungunya virus vaccine	Inviragen <i>Fort Collins, Co</i>	vaccine	chikungunya virus infections	Phase II inviragen.com

## INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Phase
cholera vaccine	PaxVax <i>Menlo Park, CA</i>	live, attenuated vaccine	prevention of cholera infection	Phase I paxvax.com
<b>Chronvac-C®</b> hepatitis C DNA vaccine	Inovio Pharmaceuticals <i>Blue Bell, PA</i> ChronTech Pharma <i>Huddinge, Sweden</i>	gene therapy vaccine	treatment of hepatitis C	Phase II inovio.com
CYT107 (interleukin-7)	Cytheris <i>Rockville, MD</i>	recombinant interleukin	HIV infection treatment (see also blood, cancer, transplantation)	Phase II cytheris.com
<b>Cytolin®</b> anti-CD8 mAb	CytoDyn <i>Lake Oswego, OR</i>	mAb	HIV infection treatment	Phase I cytodyn.com
DCVax-001	Celldex <i>Needham, MA</i> Rockefeller University <i>New York, NY</i>	recombinant vaccine	HIV infection prevention and treatment	Phase I celldexterapeutics.com
dengue vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	vaccine	dengue	Phase I gsk.com
dengue vaccine	Sanofi Pasteur <i>Swiftwater, PA</i>	vaccine	mild to severe dengue fever	Phase III sanofipasteur.us
<b>DENVax™</b> tetraivalent hybrid dengue virus vaccine	Inviragen <i>Fort Collins, CO</i>	vaccine	dengue	Phase I inviragen.com
<b>DermaVir™ Patch</b> DNA topical patch vaccine	Genetic Immunity <i>McLean, VA</i>	DNA vaccine	HIV-1 infection treatment	Phase II geneticimmunity.com
DNA vaccine (dengue)	Naval Medical Research Center <i>Silver Spring, MD</i> Vical <i>San Diego, CA</i>	DNA vaccine	prevention of dengue fever	Phase I vical.com
DTP-HepB-polio-Hib (pediatric hexavalent vaccine) (V419)	Merck <i>Whitehouse Station, NJ</i> Sanofi Pasteur <i>Swiftwater, PA</i>	vaccine	diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis, <i>Haemophilus influenzae</i> type b	Phase III merck.com sanofipasteur.us
Ebola vaccine	Crucell <i>Leiden, The Netherlands</i>	DNA vaccine	prevention of Ebola virus infections	Phase I crucell.com



## INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Phase
Ebola virus vaccine	GenPhar <i>Mt. Pleasant, SC</i>	vaccine	Ebola virus infections	in clinical trials genphar.com
enterovirus 71 vaccine (INV21)	Inviragen <i>Fort Collins, CO</i>	vaccine	prevention of head, foot and mouth disease	Phase I inviragen.com
EP1300 (malaria DNA vaccine)	VaxOnco <i>Seoul, South Korea</i> National Institute of Allergy and Infectious Diseases <i>Bethesda, MD</i>	DNA vaccine	prevention of malaria infection	Phase I
FGI-101-1A6	Functional Genetics <i>Gaithersburg, MD</i>	mAb	influenza	Phase I completed functional-genetics.com
<b>Fluad</b> <sup>®</sup> influenza virus vaccine	Novartis Vaccines <i>Cambridge, MA</i>	vaccine	influenza virus infections in the elderly and children	Phase III novartisvaccines.com
<b>FluBlok</b> <sup>®</sup> derived from recombinant hemagglutinin (rHA)	Protein Sciences <i>Meriden, CT</i>	recombinant vaccine	prevention of influenza virus infections in infants and children	Phase I/II proteinsciences.com
<b>Fludase</b> <sup>®</sup> DAS-181 inhalation	NexBio <i>San Diego, CA</i>	recombinant fusion protein	influenza A virus H1N1 infections, prevention of influenza virus infections	Phase II completed nexbio.com
<b>FluLaval</b> <sup>®</sup> QIV influenza virus vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	vaccine	prevention of influenza infections	application submitted gsk.com
<b>FluNhance</b> <sup>®</sup> influenza virus vaccine (rNA)	Protein Sciences <i>Meriden, CT</i>	recombinant vaccine	influenza virus infections	Phase III proteinsciences.com
<b>Fluzone</b> <sup>®</sup> QIV IM quadrivalent influenza virus vaccine	Sanofi Pasteur <i>Swiftwater, PA</i>	vaccine	seasonal influenza virus infections	application submitted sanofipasteur.us
foravirumab	Crucell <i>Leiden, The Netherlands</i>	mAb	post-exposure prevention of rabies	Phase II crucell.com
GI-5005	GlobeImmune <i>Louisville, CO</i>	genetically-modified vaccine	hepatitis C	Phase II globeimmune.com

## INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Phase
GSK692342 (Mtb72F/AS02A)	Aeras Rockville, MD GlaxoSmithKline Rsch. Triangle Park, NC	recombinant vaccine	prevention of tuberculosis	Phase II gsk.com
GSK1437173A (varicella zoster vaccine)	GlaxoSmithKline Rsch. Triangle Park, NC	recombinant vaccine	prevention of varicella zoster virus infections	Phase III gsk.com
GSK1492903A (cytomegalovirus glycoprotein vaccine)	GlaxoSmithKline Rsch. Triangle Park, NC	recombinant vaccine	prevention of CMV infections	Phase I gsk.com
GSK2189242A ( <i>Streptococcus pneumoniae</i> recombinant-conjugated vaccine)	GlaxoSmithKline Rsch. Triangle Park, NC	recombinant vaccine	prevention of pneumococcal infections	Phase II gsk.com
GSK2654909A	GlaxoSmithKline Rsch. Triangle Park, NC	vaccine	prevention of influenza A virus H9N2 subtype (avian flu)	Phase I gsk.com
GSK2654911A	GlaxoSmithKline Rsch. Triangle Park, NC	vaccine	prevention of influenza A virus H9N2 subtype (avian flu)	Phase I gsk.com
GSK2830930A	GlaxoSmithKline Rsch. Triangle Park, NC	vaccine	prevention of pneumococcal infections	Phase I gsk.com
GSK2838497A	GlaxoSmithKline Rsch. Triangle Park, NC	vaccine	prevention of <i>Haemophilus</i> infections	Phase I gsk.com
HBV-002	Hawaii Biotech Aiea, Hawaii	recombinant vaccine	prevention of West Nile virus infections	Phase I completed hibiotech.com
hepatitis C immune globulin (Orphan Drug)	Biotest Pharmaceuticals Boca Raton, FL	polyclonal antibody	hepatitis C prevention	Phase II biotestpharma.com
hepatitis C vaccine therapy	Okairos Basel, Switzerland	gene vaccine	prevention of hepatitis C	Phase I/II okairos.com
<b>Heplisav™</b> hepatitis B vaccine	Dynavax Technologies Berkeley, CA	DNA vaccine	prevention of hepatitis B	application submitted dynavax.com
HerpV (herpes vaccine)	Agenus Lexington, MA	recombinant protein vaccine	treatment of herpes simplex virus infections	Phase II agenusbio.com
<b>Hexaxim™</b> DTP-HepB-polio-Hib vaccine	Sanofi Pasteur Swiftwater, PA	vaccine	diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis, <i>Haemophilus influenzae</i> type b	application submitted sanofipasteur.us

## INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Phase
HIV gene therapy	Adaptimmune Philadelphia, PA Cardiff University Cardiff, Wales University of Pennsylvania Philadelphia, PA	gene therapy	HIV infection	Phase I adaptimmune.com
HIV recombinant vaccine	GlaxoSmithKline Rsch. Triangle Park, NC	recombinant vaccine	HIV infection prevention	Phase I gsk.com
HIV recombinant vaccine	GlaxoSmithKline Rsch. Triangle Park, NC	recombinant vaccine	HIV infection treatment	Phase II gsk.com
HIV vaccine	Crucell Leiden, The Netherlands Beth Israel Deaconess Medical Center Boston, MA International AIDS Vaccine Initiative New York, NY	recombinant vaccine	HIV infection prevention	Phase I crucell.com
HIV vaccine	GeoVax Smyrna, GA	vaccine	HIV infection prevention	Phase II geovax.com
HIV vaccine	GeoVax Smyrna, GA	vaccine	HIV infection treatment	Phase I/II geovax.com
HIV vaccine	Massachusetts General Hospital Boston, MA Opal Therapeutics Parkvill, Australia	vaccine	HIV infection	Phase I
HIV vaccine	Novartis Vaccines Cambridge, MA	vaccine	HIV infection	Phase I novartisvaccines.com
HIV vaccine	PaxVax San Diego, CA	oral vaccine	HIV infection prevention	in clinical trials paxvax.com
HIV vaccine (MAG pDNA)	Profectus Biosciences Baltimore, MD	DNA vaccine	HIV infection prevention	Phase I profectusbiosciences.com
HIV vaccine (rVSV)	Profectus Biosciences Baltimore, MD	recombinant vaccine	HIV-1 infection prevention	Phase I profectusbiosciences.com
HIV-1 gene therapy (MazF)	Takara Bio Shiga, Japan	gene therapy	HIV-1 infection	Phase I takara-bio.com

## INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Phase
HIV-1 vaccine (SAV001)	Sumagen <i>Seoul, South Korea</i>	vaccine	HIV-1 infection	Phase I sumagen.co.kr
<b>HIVAX™</b> replication-defective HIV-1 vaccine	GeneCure Biotechnologies <i>Norcross, GA</i>	vaccine	HIV-1 infection	Phase I genecure.com
HSV-2 Tx	Genocea Biosciences <i>Cambridge, MA</i>	T-cell vaccine	treatment of herpes simplex virus 2 infections	Phase I/II genocea.com
human interferon alpha oral (Orphan Drug)	Amarillo Biosciences <i>Amarillo, TX</i>	interferon	hepatitis C, influenza	Phase II amarbio.com
ibalizumab (TMB-355)	TaiMed Biologics USA <i>Irvine, CA</i>	mAb	HIV-1 infection (intravenous) (Fast Track)	Phase II taimedbiologics.com
			HIV-1 infection (subcutaneous)	Phase I taimedbiologics.com
ID-93/GLA-SE	Aeras Global TB Vaccine Foundation <i>Rockville, MD</i> Infectious Disease Research Institute <i>Seattle, WA</i>	recombinant fusion protein vaccine	tuberculosis	Phase I aeras.org idri.org
<b>Imvamune®</b> smallpox vaccine	Bavarian Nordic <i>Kvistgaard, Denmark</i>	vaccine	smallpox	Phase II bavarian-nordic.com
influenza A virus H1N1 vaccine	CEL-SCI <i>Vienna, VA</i>	peptide vaccine	prevention of influenza A virus H1N1 subtype	Phase I cel-sci.com
influenza A virus H1N1 vaccine	iBio <i>Newark, DE</i>	vaccine	prevention of influenza A virus H1N1 subtype	Phase I ibioinc.com
influenza A virus H1N1 vaccine	Medicago <i>Quebec, Canada</i>	VLP vaccine	influenza A virus H1N1 subtype	Phase I medicago.com
influenza A virus H1N1 vaccine (FVH-1)	Inovio Pharmaceuticals <i>Blue Bell, PA</i>	DNA vaccine	influenza A virus H1N1 subtype prevention	Phase I inovio.com
influenza A virus H1N1 vaccine (li-key hybrid peptide vaccine)	Antigen Express <i>Worcester, MA</i>	peptide vaccine	influenza A virus H1N1 infections	Phase I antigenexpress.com

## INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Phase
influenza A virus H5N1 cell-cultured based vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	cell-cultured vaccine	prevention of pandemic influenza A virus H5N1 subtype infections	Phase I gsk.com
influenza A virus H5N1 intranasal vaccine	Nanotherapeutics <i>Alachua, FL</i>	vaccine	prevention of influenza A virus H5N1 subtype	Phase I nanotherapeutics.com
influenza A virus H5N1 vaccine	iBio <i>Newark, DE</i>	vaccine	influenza A virus H5N1 subtype	Phase I ibioinc.com
influenza A virus H5N1 vaccine	Inovio Pharmaceuticals <i>Blue Bell, PA</i>	vaccine	prevention of influenza A virus H5N1 subtype	Phase I inovio.com
influenza A virus H5N1 vaccine	Medicago <i>Quebec, Canada</i>	VLP vaccine	influenza A virus H5N1 subtype	Phase I medicago.com
influenza A virus H5N1 vaccine	Novartis Vaccines <i>Cambridge, MA</i>	vaccine	prevention of influenza A virus H5N1 subtype	Phase II novartisvaccines.com
influenza A virus H5N1 vaccine	Novavax <i>Rockville, MD</i>	vaccine	prevention of influenza A virus H5N1 subtype	Phase II novavax.com
influenza A virus H5N1 vaccine	PaxVax <i>San Diego, CA</i>	vaccine	prevention of influenza A virus H5N1 subtype	Phase I paxvax.com
influenza A virus H5N1 vaccine	Vaxart <i>San Francisco, CA</i>	vaccine	prevention of influenza A virus H5N1 subtype	Phase I vaxart.com
influenza A virus H5N1 vaccine (li-key hybrid peptide vaccine)	Antigen Express <i>Worcester, MA</i>	peptide vaccine	influenza A virus H5N1 subtype	Phase I antigenexpress.com
influenza A virus H9N2 vaccine	Baxter International <i>Deerfield, IL</i>	vaccine	influenza A virus H9N2 subtype	Phase I/II baxter.com
influenza virus-like particle vaccine	Novavax <i>Rockville, MD</i>	vaccine	prevention of influenza virus infections	Phase II novavax.com
influenza virus vaccine (intradermal)	Crucell <i>Leiden, The Netherlands</i>	vaccine	prevention of influenza virus infections	Phase II crucell.com
<b>Influvac® TC</b> cell culture-derived influenza vaccine	AbbVie <i>North Chicago, IL</i>	cell-cultured vaccine	influenza virus infections (prevention)	Phase I abbvie.com

## INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Phase
interferon-alpha-2b	HanAll Biopharma <i>Seoul, South Korea</i>	interferon	hepatitis C	Phase II hanallbiopharma.com
interferon alpha-2b infusion	Medtronic <i>Minneapolis, MN</i>	interferon	hepatitis C	Phase II completed medtronic.com
<b>Ixiaro</b> <sup>®</sup> Japanese encephalitis vaccine	Intercell <i>Vienna, Austria</i> Novartis Vaccines <i>Cambridge, MA</i>	vaccine	prevention of Japanese encephalitis in children	application submitted intercell.com novartisvaccines.com
KB001-A (antibody-fragment product)	KaloBios Pharmaceuticals <i>South San Francisco, CA</i> Sanofi Pasteur <i>Swiftwater, PA</i>	mAb	<i>Pseudomonas</i> infections in cystic fibrosis patients (KalBios only)	Phase I/II kalobios.com
			prevention of ventilator-associated pneumonia	Phase I kalobios.com sanofipasteur.us
KD-247	Kaketsuken <i>Kumamoto, Japan</i>	mAb	HIV-1 infection	Phase I kaketsuken.or.jp
LIQ-001	Liquidia Technologies <i>Rsch. Triangle Park, NC</i>	vaccine	influenza virus infections	Phase I liquidia.com
Lyme disease vaccine	Baxter Healthcare <i>Deerfield, IL</i>	recombinant vaccine	prevention of Lyme disease	Phase I/II baxter.com
malaria vaccine	Crucell <i>Leiden, The Netherlands</i> GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	malaria	Phase I/II crucell.com gsk.com
malaria vaccine	GenVec <i>Gaithersburg, MD</i> U.S. Naval Medical Research Center <i>Silver Spring, MD</i>	recombinant vaccine	malaria	Phase I/II genvec.com
malaria vaccine	Sanaria <i>Rockville, MD</i>	vaccine	prevention of malaria	Phase I/II sanaria.com
Marburg virus DNA vaccine	GenPhar <i>Mt. Pleasant, SC</i>	vaccine	Marburg virus disease	Phase I genphar.com
MBL-HCV1	MassBiologics <i>Boston, MA</i>	mAb	hepatitis C	Phase II umassmed.edu/ massbiologics

## INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Phase
MEDI-550 (pandemic influenza virus vaccine)	AstraZeneca Wilmington, DE MedImmune Gaithersburg, MD	vaccine	pandemic influenza prevention	Phase I astrazeneca.com medimmune.com
MEDI-557 (RSV mAb-extended half-life)	AstraZeneca Wilmington, DE MedImmune Gaithersburg, MD	mAb	prevention of RSV infections in high risk adults	Phase I astrazeneca.com medimmune.com
MEDI-559 (RSV vaccine)	AstraZeneca Wilmington, DE MedImmune Gaithersburg, MD	vaccine	prevention of RSV infections (pediatric)	Phase I/II astrazeneca.com medimmune.com
MenABCWY (meningococcal vaccine groups A,C,Y,W-135 conjugate)	Novartis Vaccines Cambridge, MA	vaccine	meningococcal infections	Phase II novartisvaccines.com
meninge ACYW conjugate vaccine (2nd-generation meningococcal conjugate infant vaccine)	Sanofi Pasteur Swiftwater, PA	vaccine	meningococcal infections	Phase II sanofipasteur.us
meningococcal vaccine groups A,C,Y,W-135 conjugate	GlaxoSmithKline Rsch. Triangle Park, NC	vaccine	meningococcal infections	Phase III gsk.com
meningococcal vaccine groups A,C,Y,W-135 conjugate	JN-International Medical Omaha, NE	vaccine	meningococcal group A,C,Y,W-135 infections	Phase I jn-vaccines.org
<b>Menveo</b> <sup>®</sup> meningococcal vaccine groups A,C,Y, W-135 conjugate vaccine	Novartis Vaccines Cambridge, MA	vaccine	meningococcal groups A,C,Y,W-35 infection in infants (ages 2–12 months)	application submitted novartisvaccines.com
miravirsin (SPC3649)	Santaris Pharma A/S USA San Diego, CA	antisense	hepatitis C	Phase II santaris.com
MK-3415A (actoxumab/bezlotoxumab)	Merck Whitehouse Station, NJ	mAb	<i>Clostridium difficile</i> infections	Phase III merck.com
MMR vaccine live (GSK209762)	GlaxoSmithKline Rsch. Triangle Park, NC	vaccine	prevention of measles, mumps, rubella	Phase III gsk.com
MnB rLP2086 (PF-05212366)	Pfizer New York, NY	recombinant vaccine	adolescent and young adult meningitis B	Phase III pfizer.com

## INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Phase
<b>MVA-BN<sup>®</sup></b> HIV multiantigen vaccine	Bavarian Nordic <i>Washington, DC</i>	vaccine	HIV-1 infection prevention and treatment	Phase I/II bavarian-nordic.com
NB-001	NanoBio <i>Ann Arbor, MI</i>	nano-emulsion	recurrent herpes simplex virus infections	Phase III nanobio.com
NB-002	NanoBio <i>Ann Arbor, MI</i>	nano-emulsion	distal subungual onychomycosis of the toe	Phase II nanobio.com
NB-1008 (intranasal)	NanoBio <i>Ann Arbor, MI</i>	nano-emulsion vaccine	prevention of influenza virus infections	Phase I completed nanobio.com
NDV-3	NovaDigm Therapeutics <i>Grand Forks, ND</i>	recombinant vaccine	prevention of candidiasis, prevention of methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) infections	Phase I novadigm.net
norovirus virus-like particle vaccine intranasal	LigoCyte Pharmaceuticals <i>Bozeman, MT</i>	vaccine	norovirus infections	Phase I/II ligocyte.com
<b>Nuthrax<sup>™</sup></b> anthrax vaccine adsorbed with CPG 7909 adjuvant	Emergent BioSolutions <i>Rockville, MD</i>	vaccine	anthrax (Fast Track)	Phase I emergentbiosolutions.com
<b>PanBlok<sup>™</sup></b> influenza A virus H5N1 vaccine	Protein Sciences <i>Meriden, CT</i>	vaccine	prevention of influenza A virus H5N1 subtype infections	Phase I/II proteinsciences.com
peginterferon lambda-1a	Bristol-Myers Squibb <i>Princeton, NJ</i>	interferon	hepatitis C	Phase III bms.com
			hepatitis B	Phase II bms.com
<b>Pennvax<sup>®</sup>-B</b> DNA vaccine (clade B)	Inovio Pharmaceuticals <i>Blue Bell, PA</i>	DNA vaccine	HIV infection prevention and treatment	Phase I inovio.com
<b>Pennvax<sup>®</sup>-G</b> DNA vaccine (clades A, C, D)	Inovio Pharmaceuticals <i>Blue Bell, PA</i>	DNA vaccine	HIV infection prevention	Phase I inovio.com
PF-06290510 (SA4Ag)	Pfizer <i>New York, NY</i>	vaccine	<i>Staphylococcus aureus</i> infections	Phase II pfizer.com



## INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Phase
PF-06425090 ( <i>Clostridium difficile</i> vaccine)	Pfizer New York, NY	vaccine	<i>Clostridium difficile</i> colitis	Phase I pfizer.com
plague injectable vaccine	DynPort Vaccine Frederick, MD	vaccine	<i>Yersinia</i> infections	Phase II csc.com/dvc
<b>Preflucel™</b> seasonal influenza virus vaccine	Baxter International Deerfield, IL DynPort Vaccine Frederick, MD	vaccine	prevention of influenza virus infections	Phase III baxter.com csc.com/dvc
<b>Prepandrix™</b> H5N1 (pre-)pandemic influenza virus vaccine	GlaxoSmithKline Rsch. Triangle Park, NC	vaccine	prevention of influenza A virus H5N1 subtype for pandemic use	application submitted gsk.com
			prevention of influenza A virus H5N1 subtype for pandemic use in children and adolescents	Phase III gsk.com
<b>PreviThrax™</b> recombinant protective antigen anthrax vaccine	Emergent Biosolutions Rockville, MD	recombinant vaccine	anthrax (Fast Track)	Phase II emergentbiosolutions.com
PRO 140	CytoDyn Lake Oswego, OR	mAb	HIV infection	Phase II completed cytodyn.com
<b>Quadracel®</b> DTP, polio vaccine	Sanofi Pasteur Swiftwater, PA	vaccine	diphtheria, tetanus, pertussis, poliomyelitis (4-6 years of age)	Phase III sanofipasteur.us
rabies VRVg vaccine (purified vero rabies vaccine)	Sanofi Pasteur Swiftwater, PA	vaccine	prevention of rabies	Phase II sanofipasteur.us
respiratory syncytial virus VLP vaccine	Novavax Rockville, MD	recombinant vaccine	prevention of RSV infections	Phase II novavax.com
<b>Rivax™</b> ricin vaccine (Orphan Drug)	Soligenix Princeton, NJ	vaccine	ricin poisoning (pre-exposure)	Phase I soligenix.com
rotavirus vaccine (live attenuated tetravalent oral vaccine)	Sanofi Pasteur Swiftwater, PA	vaccine	rotavirus	Phase I sanofipasteur.us
SAR279356 (anti-PNAG mAb)	Sanofi US Bridgewater, NJ	mAb	prevention of bacterial infections	Phase II sanofi.com

## INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Phase
SB-728-T	Sangamo BioSciences <i>Richmond, CA</i>	gene therapy	HIV infection	Phase II sangamo.com
<b>Soliris</b> <sup>®</sup> eculizumab (Orphan Drug)	Alexion Pharmaceuticals <i>Cheshire, CT</i>	mAb	Shiga toxin <i>E. coli</i> -related hemolytic uremic syndrome (STEC-HUS) (see also autoimmune, eye, transplantation)	Phase II alxn.com
<b>Stealth Vector</b> <sup>®</sup> HGTV-43 <sup>™</sup> antisense gene medicine	Enzo Therapeutics <i>New York, NY</i>	antisense	HIV-1 infection treatment	Phase I/II enzo.com
streptococcal B vaccine conjugate	Novartis Vaccines <i>Cambridge, MA</i>	mAb	prevention of streptococcal B infections	Phase I novartisvaccines.com
<i>Streptococcus pneumoniae</i> vaccine (meningitis and pneumonia vaccine)	Sanofi Pasteur <i>Swiftwater, PA</i>	vaccine	treatment of meningitis and pneumonia	Phase I sanofipasteur.us
TCN-032 (IgG mAb)	Theraclone Sciences <i>Seattle, WA</i>	mAb	influenza A virus infections	Phase I theraclone-sciences.com
TCN-202	Theraclone Sciences <i>Seattle, WA</i>	mAb	CMV infections	Phase I theraclone-sciences.com
TDENV-PIV (tetravalent vaccine)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	vaccine	dengue	Phase I gsk.com
TG-4040	Transgene <i>Cedex, France</i>	recombinant vaccine	hepatitis C	Phase II transgene.fr
<b>Thraxia</b> <sup>™</sup> fully human anthrax mAb (Orphan Drug)	Emergent BioSolutions <i>Rockville, MD</i>	mAb	post-exposure treatment of anthrax (Fast Track)	Phase I completed emergentbiosolutions.com
TKM-Ebola	Tekmira Pharmaceuticals <i>Burnaby, Canada</i>	RNA interference	Ebola virus infections	Phase I tekmirapharm.com
tuberculosis vaccine (recombinant subunit vaccine)	Sanofi Pasteur <i>Swiftwater, PA</i>	recombinant vaccine	tuberculosis	Phase I sanofipasteur.us
tularemia vaccine	DynaPort Vaccine <i>Frederick, MD</i>	vaccine	tularemia	Phase I completed csc.com/dvc
TUTI-16 (lipoprotein vaccine)	Thymon <i>Short Hills, NJ</i>	vaccine	HIV-1 infection treatment	Phase I/II

## INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Phase
UB-421	United Biomedical <i>Hauppauge, NY</i>	mAb	HIV-1 infection treatment	Phase II unitedbiomedical.com
V114 (pneumococcal 15-valent vaccine conjugate)	Merck <i>Whitehouse Station, NJ</i>	vaccine	prevention of pneumococcal infections	Phase II merck.com
V212	Merck <i>Whitehouse Station, NJ</i>	vaccine	prevention of herpes zoster	Phase III merck.com
V503	Merck <i>Whitehouse Station, NJ</i>	vaccine	prevention of human papillomavirus infections (see also cancer)	Phase III merck.com
Vacc-4x	Bionor Pharma <i>Oslo, Norway</i>	vaccine	HIV-1 infection treatment	Phase II bionorpharma.com
VAX102 (flagellin.HuM2e)	VaxInnate <i>Cranbury, NJ</i>	recombinant fusion protein vaccine	prevention of influenza A virus	Phase I/II completed vaxinnate.com
VAX125 (flagellin.HuHa)	VaxInnate <i>Cranbury, NJ</i>	recombinant fusion protein vaccine	prevention of influenza A virus	Phase II completed vaxinnate.com
VAX128	Emergent BioSolutions <i>Rockville, MD</i> VaxInnate <i>Cranbury, NJ</i>	recombinant vaccine	prevention of influenza A virus H1N1 subtype	Phase I emergentbiosolutions.com vaxinnate.com
VAX161	Emergent BioSolutions <i>Rockville, MD</i> VaxInnate <i>Cranbury, NJ</i>	recombinant vaccine	prevention of influenza A virus H5N1 subtype	Phase I emergentbiosolutions.com vaxinnate.com
<b>VaxiGrip</b> <sup>®</sup> quadrivalent inactivated influenza vaccine	Sanofi Pasteur <i>Swiftwater, PA</i>	vaccine	seasonal influenza virus infections	Phase III sanofipasteur.us
VGX-3400	Inovio Pharmaceuticals <i>Blue Bell, PA</i>	DNA vaccine	prevention of influenza A virus H5N1 subtype	Phase I inovio.com
visceral leishmaniasis vaccine	Infectious Disease Research Institute <i>Seattle, WA</i>	vaccine	visceral leishmaniasis	Phase I idri.org

## INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Phase
XOMA 3AB	XOMA Berkeley, CA National Institute of Allergy and Infectious Diseases Bethesda, MD	mAb	botulism	Phase I xoma.com
<b>Zostavax</b> <sup>®</sup> varicella zoster virus vaccine live	Merck Whitehouse Station, NJ	vaccine	prevention of herpes zoster	Phase I merck.com

## MUSCULOSKELETAL DISORDERS / ARTHRITIS

Product Name	Sponsor	Product Category	Indication	Development Phase
ABT-981	AbbVie North Chicago, IL	mAb	osteoarthritis	Phase I abbvie.com
AMG 167	Amgen Thousand Oaks, CA	antibody	metabolic bone diseases	Phase I amgen.com
AMG 745	Amgen Thousand Oaks, CA	mAb	muscular atrophy	Phase I amgen.com
AMG 827 (brodalumab)	AstraZeneca Wilmington, DE Amgen Thousand Oaks, CA	mAb	psoriatic arthritis (see also respiratory, skin)	Phase II astrazeneca.com amgen.com
blosozumab (LY2541546)	Eli Lilly Indianapolis, IN	mAb	osteoporosis	Phase II lilly.com
BYM338	Novartis Pharmaceuticals East Hanover, NJ	mAb	sporadic inclusion body myositis, muscular atrophy (see also cancer)	Phase II novartis.com
<b>Chondrogen</b> <sup>®</sup> mesenchymal stem cell therapy for meniscal repair	Osiris Therapeutics Columbia, MD	stem cell therapy	knee injuries, prevention of osteoarthritis	Phase II osiris.com
<b>Cimzia</b> <sup>®</sup> certolizumab pegol	UCB Smyrna, GA	mAb	psoriatic arthritis (see also autoimmune)	Phase III ucb.com

## MUSCULOSKELETAL DISORDERS / ARTHRITIS

Product Name	Sponsor	Product Category	Indication	Development Phase
clazakizumab (anti-IL6)	Bristol-Myers Squibb <i>Princeton, NJ</i> Alder Biopharmaceuticals <i>Bothell, WA</i>	mAb	psoriatic arthritis (see also autoimmune, digestive)	Phase II bms.com alderbio.com
<b>Dysport®</b> abobotulinumtoxinA	Ipsen <i>Paris, France</i>	bacterial protein	focal spasticity of upper and lower limb	Phase III ipsen.com
FGF-18 (sprifermin)	EMD Serono <i>Rockland, MA</i>	growth factor	acute cartilage injury of the knee	Phase II emdserono.com
gevokizumab (IL-1B inhibitor mAb)	XOMA <i>Berkeley, CA</i>	mAb	osteoarthritis of the hand (see also diabetes, eye, skin)	Phase II xoma.com
<b>Humira®</b> adalimumab	AbbVie <i>North Chicago, IL</i>	mAb	spondylarthritis (see also autoimmune, digestive, eye, skin, other)	Phase III abbvie.com
<b>Ilaris®</b> canakinumab	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	gouty arthritis (see also autoimmune, cardiovascular, diabetes)	application submitted novartis.com
			osteoarthritis, polymyalgia rheumatica	Phase II novartis.com
ixekizumab (IL-17 antibody)	Eli Lilly <i>Indianapolis, IN</i>	mAb	psoriatic arthritis (see also skin)	Phase III lilly.com
juvenile chondrocyte grafts	ISTO Technologies <i>St. Louis, MO</i>	cell therapy	cartilage disorders	Phase III isotech.com
KTP-001 (recombinant human matrix metalloproteinase)	Kaketsuken <i>Kumamoto, Japan</i> Teijin Pharma <i>Tokyo, Japan</i>	recombinant protein	intervertebral disc displacement	Phase I/II kaketsuken.or.jp teijin-pharma.co.jp
LY2495655 (anti-myostatin mAb)	Eli Lilly <i>Indianapolis, IN</i>	mAb	disuse muscular atrophy (see also cancer)	Phase II lilly.com
<b>MACI®</b> matrix-induced autologous chondrocyte implantation	Genzyme <i>Cambridge, MA</i>	cell therapy	articular cartilage defects	Phase III genzyme.com
MCS110	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	synovitis	Phase II novartis.com

## MUSCULOSKELETAL DISORDERS / ARTHRITIS

Product Name	Sponsor	Product Category	Indication	Development Phase
mesenchymal precursor cell (MPC) product	Mesoblast <i>New York, NY</i>	stem cell therapy	spinal fusion, spondylosis (see also cardiovascular, diabetes, transplantation)	Phase II mesoblast.com
mesenchymal stem cell therapy	Medipost <i>Seoul, South Korea</i>	stem cell therapy	osteoarthritis	Phase I/II medi-post.com
<b>NeoCart®</b> autologous chondrocyte implantation	Histogenics <i>Waltham, MA</i>	cell therapy	cartilage disorders	Phase III histogenics.com
<b>Orencia®</b> abatacept	Bristol-Myers Squibb <i>Princeton, NJ</i>	recombinant fusion protein	psoriatic arthritis (see also autoimmune, other)	Phase II bms.com
<b>Prolia®</b> denosumab	Amgen <i>Thousand Oaks, CA</i>	mAb	male osteoporosis (see also autoimmune)	Phase III amgen.com
romosozumab (AMG 785)	Amgen <i>Thousand Oaks, CA</i>	mAb	postmenopausal osteoporosis	Phase III amgen.com
SAR391786 (REGN1033)	Regeneron Pharmaceuticals <i>Tarrytown, NY</i> Sanofi US <i>Bridgewater, NJ</i>	mAb	treatment of muscle atrophy post-orthopedic surgery	Phase I regeneron.com sanofi.com
secukinumab (AIN 457)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	psoriatic arthritis (see also autoimmune, eye, skin) ----- polymyalgia rheumatica	Phase III novartis.com  Phase II novartis.com
SI-6603	Seikagaku <i>Tokyo, Japan</i>	enzyme	intervertebral disc displacement	Phase II seikagaku.co.jp
<b>Stelara®</b> ustekinumab	Janssen Biotech <i>Horsham, PA</i>	mAb	psoriatic arthritis (see also autoimmune, digestive, other)	application submitted janssenbiotech.com
tanezumab	Pfizer <i>New York, NY</i>	mAb	osteoarthritis (see also neurologic)	Phase III pfizer.com
teriparatide (recombinant PTH 1-34)	Eli Lilly <i>Indianapolis, IN</i>	recombinant hormone	healing of fractures in patients with osteoporosis	Phase III lilly.com
TG-C	TissueGene <i>Rockville, MD</i>	cell therapy	osteoarthritis	Phase II tissuegene.com
<b>Xiaflex®</b> collagenase clostridium histolyticum	Auxilium Pharmaceuticals <i>Chesterbrook, PA</i> BioSpecifics Technologies	peptide	frozen shoulder (see also cancer, other)	Phase II auxilium.com biospecifics.com

## NEUROLOGIC DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
AAB-002	Janssen Alzheimer Immunotherapy South San Francisco, CA Pfizer New York, NY	mAb	Alzheimer's disease	Phase 0 janimm.com pfizer.com
AAB-003/PF-05236812	Janssen Alzheimer Immunotherapy South San Francisco, CA Pfizer New York, NY	mAb	Alzheimer's disease	Phase I janimm.com pfizer.com
AAV1-FS344 (gene therapy-delivered myostatin inhibitor) (Orphan Drug)	Milo Biotechnology Cleveland, OH	gene therapy	Becker muscular dystrophy	Phase I/II milobiotechnology.com
ABT-110	AbbVie North Chicago, IL	mAb	chronic pain	Phase II abbvie.com
ACC-001 (PF-05236806)	Janssen Alzheimer Immunotherapy South San Francisco, CA Pfizer New York, NY	peptide vaccine	Alzheimer's disease	Phase II janimm.com pfizer.com
AD02 vaccine	AFFiRis Vienna, Austria GlaxoSmithKline Rsch. Triangle Park, NC	vaccine	Alzheimer's disease	Phase II affiris.com gsk.com
AD03 vaccine	AFFiRis Vienna, Austria GlaxoSmithKline Rsch. Triangle Park, NC	vaccine	Alzheimer's disease	Phase I affiris.com gsk.com
AGN-214868 (senrobotase)	Allergan Irvine, CA	recombinant protein	postherpetic neuralgia (see also other)	Phase II allergan.com
ALD403	Alder Biopharmaceuticals Bothell, WA	mAb	prevention of migraine	Phase I alderbio.com
ATI355 (anti-Nogo-A mAb) (Orphan Drug)	Novartis Pharmaceuticals East Hanover, NJ	mAb	spinal cord injury	Phase I novartis.com

## NEUROLOGIC DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
AYX-1	Adynxx San Francisco, CA	oglionucleotide	postoperative pain	Phase I adynxx.com
BA-210 (Orphan Drug)	BioAxone Biosciences Cambridge, MA	recombinant fusion protein	spinal cord injury	Phase II bioaxonebio.com
BAN2401 (amyloid beta-protein inhibitor)	BioArctic Neuroscience Stockholm, Sweden Eisai Woodcliff Lake, NJ	mAb	Alzheimer's disease	Phase I bioarctic.se eisai.com
bapineuzumab (subcutaneous) (AAB-001)	Janssen Alzheimer Immunotherapy South San Francisco, CA Pfizer New York, NY	mAb	Alzheimer's disease	Phase II janimm.com pfizer.com
<b>Botox®</b> onabotulinumtoxinA	Allergan Irvine, CA	bacterial protein	motor neuron disease (see also other)	Phase III allergan.com
CAD106	Cytos Biotechnology Zurich, Switzerland Novartis Pharmaceuticals East Hanover, NJ	therapeutic vaccine	Alzheimer's disease	Phase II cytos.com novartis.com
CERE-110 (AAV-NGF)	Ceregene San Diego, CA	gene therapy	Alzheimer's disease	Phase II ceregene.com
CERE-120 (AAV-NTN)	Ceregene San Diego, CA	gene therapy	Parkinson's disease	Phase II ceregene.com
chondrocyte tissue grafts	ISTO Technologies St. Louis, MO	cell therapy	back pain	Phase I isotech.com
crenezumab (anti-Abeta)	Genentech South San Francisco, CA	mAb	Alzheimer's disease	Phase II gene.com
fulranumab	Janssen Research & Development Raritan, NJ	mAb	cancer pain	Phase II janssenrnd.com
GDNF-producing adult stem cell therapy (Orphan Drug)	BrainStorm Cell Therapeutics New York, NY	stem cell therapy	amyotrophic lateral sclerosis (ALS)	Phase I/II brainstorm-cell.com
GSK1223249 (NOGO-A mAb)	GlaxoSmithKline Rsch. Triangle Park, NC	mAb	ALS (see also autoimmune)	Phase I gsk.com
GSK933776A (anti-B amyloid mAb)	GlaxoSmithKline Rsch. Triangle Park, NC	mAb	Alzheimer's disease (see also eye)	Phase I completed gsk.com



## NEUROLOGIC DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
GZ404477 (AAV-hAADC gene therapy)	Genzyme Cambridge, MA	gene therapy	Parkinson's disease	Phase I genzyme.com
<b>HuCNS-SC®</b> adult neural stem cell therapy (intraosseous)	StemCells Newark, CA	stem cell therapy	thoracic spinal cord injury (see also eye, genetic)	Phase I/II stemcellsinc.com
LY2951742 (CGRP peptide)	Arteus Therapeutics Cambridge, MA Eli Lilly Indianapolis, IN	mAb	migraine prevention	Phase II lilly.com
MEDI-5117 (anti-IL-6 mAb)	AstraZeneca Wilmington, DE MedImmune Gaithersburg, MD	mAb	osteoarthritis pain	Phase I astrazeneca.com medimmune.com
neurological disorders stem cell therapy	TCA Cellular Therapy Covington, LA	stem cell therapy	ALS, spinal cord injuries	Phase I tcacellularterapy.com
NSI-566 (Orphan Drug)	Neuralstem Rockville, MD	stem cell therapy	ALS	Phase I neuralstem.com
RG1450 (gantenerumab)	Roche Nutley, NJ	mAb	prodromal Alzheimer's disease	Phase II/III roche.com
RN-307 (anti-CGRP mAb)	Labrys Biologics San Francisco, CA	mAb	migraine	Phase II
SAR228810 (anti-protofibrillar AB mAb)	Sanofi US Bridgewater, NJ	mAb	Alzheimer's disease	Phase I sanofi.com
solanezumab (LY2062430)	Eli Lilly Indianapolis, IN	mAb	Alzheimer's disease	Phase III lilly.com
tanezumab	Pfizer New York, NY	mAb	chronic pain (see also musculoskeletal)	Phase II pfizer.com
UB-311 immunotherapeutic	United Biomedical Hauppauge, NY	vaccine	Alzheimer's disease	Phase II unitedbiomedical.com
V950	Merck Whitehouse Station, NJ	vaccine	Alzheimer's disease	Phase I completed merck.com
VM-202 (modified hepatocyte growth factor gene therapy)	VM BioPharma Atlanta, GA	gene therapy	diabetic neuropathy (see also cardiovascular)	Phase II viromed.co.kr

## NEUROLOGIC DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
<b>Xeomin®</b> incobotulinumtoxinA	Merz Pharmaceuticals Greensboro, NC	bacterial protein	post-stroke spasticity	Phase III merzusa.com
			sialorrhea in patients with Parkinson's disease and ALS	Phase II merzusa.com

## RESPIRATORY DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
ALT-836	Altor BioScience Miramar, FL Genentech South San Francisco, CA	mAb	acute lung injury, adult respiratory distress syndrome (see also cancer)	Phase II altorbioscience.com gene.com
AMG 157/MEDI-9929	Amgen Thousand Oaks, CA AstraZeneca Wilmington, DE	mAb	asthma	Phase I amgen.com astrazeneca.com
AMG 761	Amgen Thousand Oaks, CA	mAb	asthma	Phase I amgen.com
AMG 827 (brodalumab)	Amgen Thousand Oaks, CA AstraZeneca Wilmington, DE	mAb	asthma (see also musculoskeletal, skin)	Phase II amgen.com astrazeneca.com
ASM8	Pharmaxis Exton, PA	antisense	asthma	Phase II pharmaxis.com.au
benralizumab	AstraZeneca Wilmington, DE MedImmune Gaithersburg, MD	mAb	asthma, chronic obstructive pulmonary disease (COPD)	Phase II astrazeneca.com medimmune.com
<b>Bosatria™</b> mepolizumab	GlaxoSmithKline Rsch. Triangle Park, NC	mAb	asthma	Phase III gsk.com
carlumab	Janssen Biotech Horsham, PA	mAb	pulmonary fibrosis	Phase II janssenbiotech.com

## RESPIRATORY DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
CNTO-3157	Janssen Biotech <i>Horsham, PA</i>	mAb	asthma	Phase I janssenbiotech.com
CNTO-5825	Janssen Biotech <i>Horsham, PA</i>	mAb	allergic asthma	Phase I janssenbiotech.com
CYT003	Cytos Biotechnology <i>Zurich, Switzerland</i>	vaccine	allergic asthma	Phase II cytos.com
<b>Excellair™</b> syk kinase silencer	ZaBeCor Pharmaceuticals <i>Bala Cynwyd, PA</i>	RNA interference	asthma	Phase II zabecor.com
FG-3019	FibroGen <i>San Francisco, CA</i>	mAb	idiopathic pulmonary fibrosis (see also cancer, other)	Phase II fibrogen.com
grass pollen extract	Stallergenes <i>Cedex, France</i>	immuno-therapy	seasonal allergic rhinitis	Phase III stallergenes.com
GS-6624 (simtuzumab)	Gilead Sciences <i>Foster City, CA</i>	mAb	idiopathic pulmonary fibrosis (see also cancer, other)	Phase I gilead.com
GSK2586881 (APN01)	Apeiron Biologics <i>Vienna, Austria</i> GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	recombinant protein	acute lung injury	Phase I gsk.com
KB003	KaloBios Pharmaceuticals <i>South San Francisco, CA</i>	mAb	severe asthma	Phase II kalobios.com
MEDI-4212 (anti-IgE mAb)	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	mAb	asthma	Phase I astrazeneca.com medimmune.com
MEDI-7814 (anti-C5/C5a mAb)	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	mAb	COPD	Phase I astrazeneca.com medimmune.com
MEDI-8968 (anti-IL-1R mAb)	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	mAb	COPD	Phase II astrazeneca.com medimmune.com

## RESPIRATORY DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
MK-3641 ragweed allergy vaccine (sublingual)	Merck <i>Whitehouse Station, NJ</i>	immuno- therapy vaccine	ragweed pollen-induced rhinoconjunctivitis	Phase III merck.com
MK-7243 grass pollen allergy tablet vaccine	Merck <i>Whitehouse Station, NJ</i>	immuno- therapy	grass pollen-induced allergic rhinoconjunctivitis	Phase III merck.com
MK-8237 house dust mite allergy vaccine tablet	Merck <i>Whitehouse Station, NJ</i>	vaccine	allergic asthma, allergic rhinitis, allergic rhinoconjunctivitis	Phase II merck.com
<b>Pollinex® Quattro</b> injectable MPL allergy vaccine	Allergy Therapeutics <i>West Sussex, United Kingdom</i>	vaccine	grass pollen hypersensitivity, ragweed pollen hypersensitivity	Phase III allergytherapeutics.com
			tree pollen hypersensitivity	Phase II allergytherapeutics.com
PRM-151 (rhPTX-2 for injection) (Orphan Drug)	Promedior <i>Lexington, MA</i>	recombinant protein	idiopathic pulmonary fibrosis (see also other)	Phase I promedior.com
<b>Prochymal®</b> remestemcel-L	Osiris Therapeutics <i>Columbia, MD</i>	stem cell therapy	COPD (see also cardiovascular, diabetes, digestive, transplantation)	Phase II osiris.com
QAX576	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	asthma, idiopathic pulmonary fibrosis (see also digestive)	Phase II novartis.com
QBX258	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	asthma	Phase II novartis.com
QGE031	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	allergic asthma (see also skin)	Phase II novartis.com
quilizumab (anti-M1 prime mAb)	Genentech <i>South San Francisco, CA</i>	mAb	allergic asthma, allergic rhinitis	Phase II gene.com
ragweed allergy immunotherapy (sublingual)	Stallergenes <i>Cedex, France</i>	vaccine	seasonal allergic rhinitis	Phase I stallergenes.com
ragweed allergy vaccine (sublingual)	Greer Laboratories <i>Lenoir, NC</i>	vaccine	seasonal allergic rhinitis	Phase III greerlabs.com

## RESPIRATORY DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Phase
reslizumab (Orphan Drug)	Cephalon <i>Frazer, PA</i>	mAb	asthma, eosinophilic esophagitis in adolescents and children	Phase III cephalon.com
RG3637 (lebrikizumab)	Genentech <i>South San Francisco, CA</i> Roche <i>Nutley, NJ</i>	mAb	severe asthma	Phase III gene.com roche.com
SAR156597 (bispecific interleukin-4/ interleukin-13 mAb)	Sanofi US <i>Bridgewater, NJ</i>	mAb	idiopathic pulmonary fibrosis	Phase II sanofi.com
SAR231893 (anti-IL4 mAb)	Regeneron Pharmaceuticals <i>Tarrytown, NY</i> Sanofi US <i>Bridgewater, NJ</i>	mAb	asthma (see also skin)	Phase II regeneron.com sanofi.com
STX-100	Biogen Idec <i>Weston, MA</i>	mAb	idiopathic pulmonary fibrosis	Phase II biogenidec.com
tralokinumab	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	mAb	asthma (see also digestive)	Phase II astrazeneca.com medimmune.com

## SKIN DISEASES

*medicines for skin cancer are listed under Cancer*

Product Name	Sponsor	Product Category	Indication	Development Phase
AbGn-168H	AbGenomics International <i>Los Altos, CA</i>	mAb	plaque psoriasis	Phase I completed abgenomics.com
<b>Amevive</b> <sup>®</sup> alefacept	Astellas Pharma US <i>Deerfield, IL</i>	recombinant fusion protein	psoriasis in adolescents	Phase II completed us.astellas.com
AMG 827 (brodalumab)	Amgen <i>Thousand Oaks, CA</i> AstraZeneca <i>Wilmington, DE</i>	mAb	psoriasis (see also musculoskeletal, respiratory)	Phase II amgen.com astrazeneca.com
ANT-1207 (botulinum toxin A)	Anterios <i>New York, NY</i>	bacterial protein, nanotechnol- ogy	acne vulgaris	Phase II

## SKIN DISEASES

*medicines for skin cancer are listed under Cancer*

Product Name	Sponsor	Product Category	Indication	Development Phase
BT-061	AbbVie North Chicago, IL Biotest Dreieich, Germany	mAb	plaque psoriasis (see also autoimmune)	Phase II abbvie.com biotest.de
CNTO-1959	Janssen Biotech Horsham, PA	mAb	plaque psoriasis (see also autoimmune)	Phase II janssenbiotech.com
<b>CureXcell™</b> white blood cell therapy	MacroCure Tikva, Israel	cell therapy	diabetic foot ulcer	Phase I/II macroCure.com
<b>Enbrel®</b> etanercept	Amgen Thousand Oaks, CA	recombinant fusion protein	plaque psoriasis in adolescents and children	application submitted amgen.com
fibroblast growth factor-1	CardioVascular Therapeutics Las Vegas, NV	fibroblast growth factor	wounds in diabetes (see also cardiovascular)	Phase II cvbt.com
GBT 009	Garnet BioTherapeutics Malvern, PA	cell therapy	scar prevention	Phase II garnetbio.com
gevokizumab (IL-1B inhibitor mAb)	XOMA Berkeley, CA	mAb	acne vulgaris (see also diabetes, eye, musculoskeletal)	Phase II xoma.com
HP802-247 (allogeneic human skin replacement)	Healthpoint Biotherapeutics Fort Worth, TX	cell therapy	leg ulcers  ----- Mohs micrographic surgical wounds	Phase III healthpointbio.com  Phase II healthpointbio.com
<b>Humira®</b> adalimumab	AbbVie North Chicago, IL	mAb	hidradenitis suppurativa (see also autoimmune, digestive, eye, musculoskeletal, other)	Phase III abbvie.com
ixekizumab (IL-17 antibody)	Eli Lilly Indianapolis, IN	mAb	psoriasis (see also musculoskeletal)	Phase III lilly.com
JVS-100 (stromal cell-derived factor-1)	SironRX Therapeutics Cleveland, OH	gene therapy	wound healing related to cardiovascular surgery	Phase I sironrx.com
KUR-211 (bioactive wound-healing foam)	Baxter International Deerfield, IL Kuros Biosurgery Zurich, Switzerland	growth factor	diabetic foot ulcers	Phase II baxter.com kuros.ch

## SKIN DISEASES

*medicines for skin cancer are listed under Cancer*

Product Name	Sponsor	Product Category	Indication	Development Phase
<b>laViv™</b> azficel-T	Fibrocell Science <i>Exton, PA</i>	fibroblast cell therapy	scars	Phase II/III fibrocellscience.com
MABp1	XBiotech <i>Austin, TX</i>	mAb	acne, psoriasis (see also cancer, cardiovascular, diabetes)	Phase II xbiotech.com
MK-3222 (tildrakizumab)	Merck <i>Whitehouse Station, NJ</i>	mAb	plaque psoriasis	Phase III merck.com
PF-06473871 (EXC 001)	Pfizer <i>New York, NY</i>	antisense	dermal scarring	Phase II pfizer.com
QGE031	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	atopic dermatitis (see also respiratory)	Phase II novartis.com
REGN846	Regeneron Pharmaceuticals <i>Tarrytown, NY</i>	mAb	atopic dermatitis	Phase I/II regeneron.com
RT001 (botulinum toxin A)	Revance Therapeutics <i>Newark, CA</i>	bacterial protein	lateral canthal lines (see also other)	Phase II revance.com
RXI-109	RXi Pharmaceuticals <i>Westborough, MA</i>	RNA interference	dermal scarring	Phase I rxipharma.com
SAR231893 (anti-IL4 mAb)	Regeneron Pharmaceuticals <i>Tarrytown, NY</i> Sanofi US <i>Bridgewater, NJ</i>	mAb	atopic dermatitis (see also respiratory)	Phase II regeneron.com sanofi.com
SDF-1	SironRX <i>Cleveland, OH</i>	gene therapy	wound healing and reduction of scarring	Phase I sironrx.com
secukinumab (AIN457)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	plaque psoriasis (see also autoimmune, eye, musculoskeletal)	Phase III novartis.com
<b>StrataGraft®</b> tissue repair cell therapy (Orphan Drug)	Stratatech <i>Madison, WI</i>	cell therapy	chronic wounds	Phase I/II stratatechcorp.com
TD101	TransDerm <i>Santa Cruz, CA</i>	RNA interference	pachyonychia congenita	Phase I transderminc.com
<b>Xolair®</b> omalizumab	Genentech <i>South San Francisco, CA</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	chronic idiopathic urticaria	Phase III gene.com novartis.com

## TRANSPLANTATION

Product Name	Sponsor	Product Category	Indication	Development Phase
ASKP-1240	Astellas Pharma US <i>Deerfield, IL</i> Kyowa Hakko Kirin Pharma <i>Princeton, NJ</i>	mAb	prevention of organ transplant rejection	Phase II us.astellas.com kyowa-kirin-pharma.com
<b>Benlysta</b> <sup>®</sup> belimumab (intravenous)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	mAb	immunosuppression (see also autoimmune, blood)	Phase II gsk.com
<b>CaspaCIDE</b> <sup>™</sup> DLI T-cell replacement therapy	Bellicum Pharmaceuticals <i>Houston, TX</i>	cell therapy	graft-versus-host disease in patients with late-stage cancer undergoing bone marrow transplantation	Phase I/II bellicum.com
CDX-301 (Fms-like tyrosine kinase 3 ligand)	Celldex Therapeutics <i>Needham, MA</i>	recombinant protein	hematopoietic stem cell transplantation	Phase I celldextherapeutics.com
CLT-008	Cellerant Therapeutics <i>San Carlos, CA</i>	cell therapy	facilitate engraftment in core blood transplants (see also cancer)	Phase I cellerant.com
CYT107 (interleukin-7)	Cytheris <i>Rockville, MD</i>	recombinant interleukin	prevention of bone marrow transplant rejection (see also blood, cancer, infectious)	Phase I cytheris.com
mesenchymal precursor cell (MPC) product (Orphan Drug)	Mesoblast <i>New York, NY</i>	stem cell therapy	for bone marrow regeneration in patients undergoing bone marrow transplantation (see also cardiovascular, diabetes, musculoskeletal)	Phase III mesoblast.com
<b>MultiStem</b> <sup>®</sup> stem cell therapy (Orphan Drug)	Athersys <i>Cleveland, OH</i>	stem cell therapy	graft-versus-host disease (see also cardiovascular, digestive)	Phase I athersys.com
NX001 (Orphan Drug)	Nephrx <i>Kalamazoo, MI</i>	growth factor	delayed graft function in renal transplant patients	Phase I nephrx.com
<b>Prochymal</b> <sup>®</sup> remestemcel-L (Orphan Drug)	Osiris Therapeutics <i>Columbia, MD</i>	stem cell therapy	graft-versus-host disease (Fast Track) (see also cardiovascular, diabetes, digestive, respiratory)	Phase III osiris.com
QPI 1002 (I5NP) (Orphan Drug)	Quark Pharmaceuticals <i>Fremont, CA</i>	RNA interference	prevention of delayed graft function (see also other)	Phase II quarkpharma.com
<b>Soliris</b> <sup>®</sup> eculizumab	Alexion Pharmaceuticals <i>Cheshire, CT</i>	mAb	presensitized kidney transplant (acute humoral rejection) (see also autoimmune, eye, infectious)	Phase II alxn.com



## TRANSPLANTATION

Product Name	Sponsor	Product Category	Indication	Development Phase
TOL101 (Orphan Drug)	Tolera Therapeutics <i>Kalamazoo, MI</i>	mAb	prevention of transplant rejection	Phase I/II tolera.com

## OTHER

Product Name	Sponsor	Product Category	Indication	Development Phase
AC607 (allogeneic multi-potent stem cell therapy) (Orphan Drug)	AlloCure <i>Burlington, MA</i>	stem cell therapy	acute kidney injury (Fast Track)	Phase II allocure.com
AGN-214868 (senrobotase)	Allergan <i>Irvine, CA</i>	recombinant protein	overactive bladder with urinary incontinence (see also neurologic)	Phase II allergan.com
ALD-451	Cytomedix <i>Gaithersburg, MD</i>	stem cell therapy	cognition disorders following treatment for malignant glioma	Phase I cytomedix.com
<b>Ampligen</b> <sup>®</sup> rintatolimid (Orphan Drug)	Hemispherx Biopharma <i>Philadelphia, PA</i>	RNA product	chronic fatigue syndrome	application submitted hemispherx.net
antibody therapeutic	MorphoSys <i>Munich, Germany</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	undisclosed	Phase I morphosys.com novartis.com
antibody therapeutic	MorphoSys <i>Munich, Germany</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	undisclosed	Phase II morphosys.com novartis.com
antibody therapeutic (BI-1)	MorphoSys <i>Munich, Germany</i> Boehringer-Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	mAb	undisclosed	Phase I morphosys.com boehringer-ingelheim.com
anti-IL31	Bristol-Myers Squibb <i>Princeton, NJ</i>	mAb	immunology	Phase I bms.com

## OTHER

Product Name	Sponsor	Product Category	Indication	Development Phase
anti-TWEAK (BIIB 023)	Biogen Idec Weston, MA	mAb	lupus nephritis	Phase II biogenidec.com
BAX-69	Baxter International Deerfield, IL	mAb	lupus nephritis (see also cancer)	Phase I baxter.com
<b>Botox</b> <sup>®</sup> onabotulinumtoxinA	Allergan Irvine, CA	bacterial protein	idiopathic overactive bladder (see also neurologic)	application submitted allergan.com
			benign prostatic hyperplasia	Phase II allergan.com
cat allergy vaccine	Circassia Oxford, United Kingdom	vaccine	hypersensitivity in patients with rhinoconjunctivitis caused by cat allergy	Phase III circassia.co.uk
CDX-1135	Celldex Therapeutics Needham, MA	recombinant protein	kidney disorders	Phase I celldexterapeutics.com
CM-AT	CureMark Rye, NY	enzyme replacement therapy	autistic disorder (Fast Track)	Phase III curemark.com
CNTO-5	Janssen Biotech Horsham, PA MorphoSys Munich, Germany	mAb	inflammation	Phase I janssenbiotech.com morphosys.com
CNTO-136 (sirukumab)	Janssen Biotech Horsham, PA	mAb	lupus nephritis (see also autoimmune)	Phase II janssenbiotech.com
<b>ELAD</b> <sup>®</sup> human-cell-based bioartificial liver (Orphan Drug)	Vital Therapies San Diego, CA	cell therapy	liver failure	Phase II/III vitaltherapies.com
entolimod (CBLB502) (Orphan Drug)	Cleveland BioLabs Buffalo, NY	engineered peptide	acute radiation syndrome (Fast Track) (see also cancer)	Phase I cbiolabs.com
FB 301	Cytovance Biologics Oklahoma City, OK Fountain Biopharma Taipei, Taiwan	mAb	hypersensitivity (IgE-mediated allergic diseases)	in clinical trials cytovance.com
FG-3019	FibroGen San Francisco, CA	mAb	liver fibrosis due to chronic hepatitis B infection (see also cancer, respiratory)	Phase II fibrogen.com

## OTHER

Product Name	Sponsor	Product Category	Indication	Development Phase
food allergy immunotherapy	DBV Technologies <i>Paris, France</i>	topical vaccine	peanut hypersensitivity	Phase II dbv-technologies.com
fresolimumab (TGFβ antagonist)	Genzyme <i>Cambridge, MA</i>	mAb	fibrosis	Phase II genzyme.com
GS-6624 (simtuzumab)	Gilead Sciences <i>Foster City, CA</i>	mAb	liver fibrosis, myelofibrosis (see also cancer, respiratory)	Phase II gilead.com
GSK1070806 (anti-interleukin 18 mAb)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	mAb	metabolic disorders	Phase II gsk.com
hMaxi-K gene therapy	Ion Channel Innovations <i>New York, NY</i>	gene therapy	overactive bladder	Phase I completed ionchannelinnovations.com
<b>Humira</b> <sup>®</sup> adalimumab	AbbVie <i>North Chicago, IL</i>	mAb	interstitial cystitis (see also autoimmune, digestive, eye, musculoskeletal, skin)	Phase III abbvie.com
ISIS-FGFR <sub>4</sub> <sub>Rx</sub>	Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	obesity	Phase II isispharm.com
ISIS-GCCR <sub>Rx</sub>	Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	Cushing syndrome (see also diabetes)	Phase I isispharm.com
JRC-LAMP-vax	Immunomic Therapeutics <i>Lancaster, PA</i>	DNA vaccine	Japanese red cedar pollen-induced rhinoconjunctivitis	Phase I immunomix.com
kidney disease medicine	Eli Lilly <i>Indianapolis, IN</i>	biologic	chronic kidney disease	Phase I lilly.com
liprotamase (LY3031642) (Orphan Drug)	Eli Lilly <i>Indianapolis, IN</i>	enzyme replacement therapy	treatment of exocrine pancreatic enzyme insufficiency, including in cystic fibrosis patients (Fast Track)	application submitted lilly.com
liraglutide (NN8022)	Novo Nordisk <i>Princeton, NJ</i>	recombinant peptide	obesity	Phase III novonordisk.com
liver cell therapy (Orphan Drug)	Cytonet <i>Weinheim, Germany</i>	cell therapy	urea cycle disorders in children and infants	Phase II cytonet.de
LY2382770 (TGF-β antibody)	Eli Lilly <i>Indianapolis, IN</i>	mAb	diabetic nephropathy	Phase II lilly.com

## OTHER

Product Name	Sponsor	Product Category	Indication	Development Phase
mAb	Genentech <i>South San Francisco, CA</i>	mAb	metabolic disorders	Phase I gene.com
Meth-mAb	InterveXion Therapeutics <i>Little Rock, AR</i>	mAb	methamphetamine abuse	Phase I intervexion.com
metreleptin	Bristol-Myers Squibb <i>Princeton, NJ</i>	recombinant hormone	lipodystrophy	application submitted bms.com
<b>Natpara®</b> recombinant human parathyroid hormone (rhPTH) (Orphan Drug)	NPS Pharmaceuticals <i>Salt Lake City, UT</i>	recombinant hormone	hypoparathyroidism	Phase III npsp.com
<b>Neo-Urinary Conduit™</b> autologous cultured urological tissue cells	Tengion <i>Winston-Salem, NC</i>	cell therapy	cystectomy due to bladder cancer	Phase I tengion.com
NIC002	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	vaccine	smoking withdrawal	Phase II novartis.com
<b>Orencia®</b> abatacept	Bristol-Myers Squibb <i>Princeton, NJ</i>	recombinant fusion protein	lupus nephritis (see also autoimmune, musculoskeletal)	Phase III bms.com
PF-05402536	Pfizer <i>New York, NY</i>	vaccine	smoking cessation	Phase I pfizer.com
PRM-151 (rhPTX-2 for injection)	Promedior <i>Lexington, MA</i>	recombinant protein	myelofibrosis (see also respiratory)	Phase I promedior.com
prohibitin targeting peptide-1	Ablaris Therapeutics <i>Pasadena, CA</i>	homing peptide	obesity	Phase I ablaris.com
PRT-105	Protalix Biotherapeutics <i>Carmiel, Israel</i>	recombinant enzyme	poisoning	Phase I completed protalix.com
QPI-1002 (I5Np)	Quark Pharmaceuticals <i>Fremont, CA</i>	RNA interference	prevention of renal failure in patients undergoing cardiovascular surgery (see also transplantation)	Phase I/II quarkpharma.com
recombinant human hepatocyte growth factor	Kringle Pharma <i>Osaka, Japan</i>	recombinant growth factor	acute renal failure	Phase I kringle-pharma.com
REGN728	Regeneron Pharmaceuticals <i>Tarrytown, NY</i>	mAb	undisclosed	Phase I regeneron.com

## OTHER

Product Name	Sponsor	Product Category	Indication	Development Phase
RT001 (botulinum toxin A)	Revence Therapeutics <i>Newark, CA</i>	bacterial protein	hyperhidrosis (see also skin)	Phase II revance.com
SEL-068	Selecta Biosciences <i>Watertown, MA</i>	nanoparticle vaccine	smoking withdrawal	Phase I selectabio.com
somatropin biosimilar (sustained-release)	LG Life Sciences <i>Seoul, South Korea</i>	recombinant human growth hormone	somatropin deficiency	Phase III lgls.com
<b>Stelara®</b> ustekinumab	Janssen Biotech <i>Horsham, PA</i>	mAb	primary biliary cirrhosis (see also autoimmune, digestive, musculoskeletal)	Phase II janssenbiotech.com
TA-CD	Celtic Pharma <i>Hamilton, Bermuda</i>	immuno-therapeutic vaccine	cocaine abuse	Phase II celtictherapeutic.com
UMK-121	Proteonomix <i>Hawthorne, NJ</i>	stem cell therapy	liver failure	Phase I proteonomix.com
VAY736	MorphoSys <i>Munich, Germany</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	inflammation (see also cancer)	Phase I morphosys.com novartis.com
VEN100 (recombinant human lactoferrin)	Ventria Bioscience <i>Fort Collins, CO</i>	recombinant protein	antibiotic-associated diarrhea	Phase II ventria.com
VRS-317 (human growth hormone)	Versartis <i>Redwood City, CA</i>	recombinant human growth hormone	somatropin deficiency	Phase I/II versartis.com
<b>Xiaflex®</b> collagenase clostridium histolyticum (Orphan Drug)	Auxilium Pharmaceuticals <i>Chesterbrook, PA</i> BioSpecifics Technologies <i>Lynbrook, NY</i>	peptide	Peyronie's disease (see also cancer, musculoskeletal)	application submitted auxilium.com biospecifics.com
			cellulite	Phase I auxilium.com biospecifics.com

**adjuvant**—Substance or drug that aids another substance in its action.

**angioedema**—Swelling of the mucous membranes, tissues beneath the skin, or an internal organ due to an allergic reaction.

**ankylosing spondylitis**—An inflammatory disorder of unknown cause that primarily affects the spine. The vertebrae may fuse together and form a rigid back that is impossible to bend.

**antisense**—An antisense drug is the mirror or complementary image of a small segment of messenger RNA (mRNA), the substance that carries instructions (“sense”) from the genes to the cell’s protein-making machinery. The antisense drug readily binds to the mRNA strand, keeping it from transmitting its instructions to the cell, and thus inhibiting the production of an unwanted protein.

**application submitted**—An application for marketing has been submitted by the company to the Food and Drug Administration (FDA).

**biotechnology**—The collection of processes that involve the use of biological systems. For some of the industries, these processes involve the use of genetically engineered organisms. For the purpose of this report, only those products that involve recombinant DNA, monoclonal antibody/hybridoma, continuous cell lines, cellular therapy, gene therapy and vaccines technology are included.

***Clostridium difficile***—A bacterium that produces an irritating toxin that causes a form of colitis characterized by profuse, watery diarrhea with cramps and low-grade fever.

**colony stimulating factor (CSF)**—Protein responsible for controlling the production of white blood cells.

**Crohn’s disease**—A subacute chronic gastrointestinal disorder, involving the small intestine, characterized by patchy deep ulcers that may cause fistulas and a narrowing and thickening of the bowel.

**cytomegalovirus (CMV)**—A DNA virus related to the herpes virus, affecting mostly neonatal infants and immunocompromised individuals. CMV can occur without symptoms or result in mild flu-like symptoms.

**erythropoietin**—Hormone that stimulates red blood cell production in the bone marrow.

**Fast Track**—A process designed to facilitate the development and expedite the review of drugs to treat serious diseases and fill an unmet medical need. The status is assigned by the U.S. Food and Drug Administration. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious diseases. Generally, determining factors include whether the drug will have an impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially superior to existing therapy. Once a drug receives Fast Track designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.

**gene therapy**—Therapy at the intracellular level to replace or inactivate the effects of disease-causing genes or to augment normal gene functions to overcome illness.

**glioblastoma**—The most common primary brain tumor and one of the most aggressive forms of brain cancer, primarily affecting adults over the age of 50.

**growth factors**—Factors responsible for regulating cell proliferation (rapid and repeated reproduction), function and differentiation.

**growth hormone**—Pituitary hormone that stimulates the growth of long bones in prepubertal children.

**hemophilia A and B**—Hemophilia A, the “classic” hemophilia, is a genetic bleeding disorder due to deficiency of the coagulation factor VIII. Hemophilia B, or “Christmas” disease, is caused by deficiency of coagulation factor IX.

**hepatitis**—Inflammation of the liver with accompanying liver cell damage or death, caused most often by viral infection, e.g., **hepatitis B, and C.**

**herpes simplex virus**—A strain of herpes virus that may lie dormant in nerve tissue and

can be reactivated to produce painful sores of the anus or genitals.

**human papillomavirus**—Viral agent of warts, believed to be contagious and usually harmless, but it can lead to cervical cancer.

**interferon**—A glycoprotein naturally produced by cells that interferes with the ability of a virus to reproduce after it invades the body.

**interleukin**—An endogenous substance that stimulates the production of different types of white blood cells or leukocytes.

**ischemia**—Insufficient supply of blood to an organ or tissue, which can cause organ damage such as an **ischemic stroke.**

**lymphoma**—Cancers in which the cells of lymphoid tissue, found mainly in the lymph nodes and spleen, multiply unchecked. Lymphomas fall into two categories: One is called **Hodgkin disease**, characterized by a particular kind of abnormal cell. All others are called **non-Hodgkin lymphomas**, which vary in their malignancy according to the nature and activity of the abnormal cells.

**mAb (monoclonal antibodies)**—Large protein molecules produced by white blood cells that seek out and destroy harmful foreign substances.

**macular degeneration**—A progressive disorder that affects the central part of the retina, causing gradual loss of vision. It is a painless condition, usually affects both eyes and is common in the elderly.

**metastases/metastatic**—Cancers that have spread from the primary or original cancer site. Cancer cells can break away from a tumor and travel to other areas of the body through the bloodstream or the lymph system. They are often more difficult to treat than primary tumors.

**multiple myeloma**—A malignant condition characterized by uncontrolled proliferation of plasma cells (a class of white blood cells) in bone marrow. Symptoms include pain and destruction of bone tissue, numbness and paralysis, kidney damage, anemia, and frequent infections.

**myelodysplastic syndromes (MDS)**—Blood disorders that ultimately are fatal. Patients usually succumb to infections or bleeding. The term “preleukemia” has been used to describe these disorders.

**myeloid**—Pertaining to, derived from, or manifesting certain features of the bone marrow. In some cases, myeloid also pertains to certain types of non-lymphocyte white blood cells found in the bone marrow.

**myocardial infarction**—Damage to the heart muscle caused by stoppage or impairment of blood flow to the heart, also known as heart attack.

**neuroblastoma**—A tumor of the adrenal glands or sympathetic nervous system (the part of the nervous system responsible for certain automatic body functions, such as the “fight or flight response”).

**neutropenia**—An abnormally low neutrophil count (certain white blood cells).

**Orphan Drug**—A drug to treat a disease that has a patient population of 200,000 or less in the United States, or a disease that has a patient population of more than 200,000 and a development cost that will not be recovered from sales in the United States.

**peripheral vascular disorder**—The obstruction of blood supply to the extremities, particularly the legs, caused by atherosclerosis.

**Phase 0**—First-in-human trials conducted in accordance with FDA’s 2006 guidance on exploratory Investigational New Drug (IND) studies designed to speed up development of promising drugs by establishing very early on whether the agent behaves in human subjects as was anticipated from preclinical studies.

**Phase I**—Researchers test the drug in a small group of people, usually between 20 and 80 healthy adult volunteers, to evaluate its initial safety and tolerability profile, determine a safe dosage range, and identify potential side effects.

**Phase II**—The drug is given to volunteer patients, usually between 100 and 300, to see if it is effective, identify an optimal dose, and to further evaluate its short-term safety.

**Phase III**—The drug is given to a larger, more diverse patient population, often involving between 1,000 and 3,000 patients (but sometime many more thousands), to generate statistically significant evidence to confirm its safety and effectiveness. They are the longest studies, and usually take place in multiple sites around the world.

**pulmonary fibrosis**—Scarring and thickening of lung tissue.

**respiratory syncytial virus (RSV) disease**—One of the most important causes of lower respiratory tract disease in children, accounting for more than 90 percent of cases of bronchiolitis.

**restenosis**—A condition where an artery plugs up again following treatment to open it up.

**sepsis**—A condition associated with a serious bacterial infection of the blood.

**systemic lupus erythematosus (SLE)**—The most serious form of lupus, a chronic autoimmune disorder causing inflammation and damage to multiple organs.

**thrombocytopenia**—A reduction in the number of platelet cells in the blood, which causes a tendency to bleed, especially from the smaller blood vessels.

**ulcerative colitis**—A chronic inflammation and ulceration of the lining of the colon and rectum. It causes bloody diarrhea and mainly involves the left colon.

**uveitis**—Inflammation of the uvea, the middle layer of the eye.

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*The content of this report has been obtained through public, government and industry sources, and the Adis “R&D Insight” database based on the latest information. **Report current as of February 7, 2013.** The information in this report may not be comprehensive. For more specific information about a particular product, contact the individual company directly or go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov). The entire series of Medicines in Development is available on PhRMA’s web site.*

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