

2017 Vaccines in Development

Allergies Drug Name

Organization

Indication

Development Phase

allergy immunotherapeutic vaccine

United Therapeutics
Hauppauge, NY

IgE-mediated allergy response

Phase I
www.unitedbiomedical.com

AR101
(oral immunotherapy)

Aimmune Therapeutics
Brisbane, CA

peanut allergy (treatment)
(Fast Track)

Phase III
www.aimmune.com

ASP-0892
(immunotherapeutic plasmid based DNA vaccine)

Astellas Pharma US
Northbrook, IL
Immunomic Therapeutics
Rockville, MD

peanut allergy (treatment)
(Fast Track)

Phase I
www.immunomix.com

HAL-MPE1
(subcutaneous immunotherapy)

HAL Allergy
Leiden, Netherlands

peanut allergy (treatment)

Phase I
www.hal-allergy.com

injectable MPL allergy vaccine

Allergy Therapeutics
West Sussex, United Kingdom

seasonal allergic rhinitis due to either ragweed, grass or tree pollen (prevention)

Phase III
www.allergytherapeutics.com

ragweed mix vaccine

Woodmont Pharmaceuticals
Atlanta, GA

seasonal allergic rhinitis and allergic conjunctivitis due to ragweed

Phase I

SAR439794
(peanut allergy vaccine)

Immune Design
Seattle, WA
Sanofi
Bridgewater, NJ

peanut allergy (treatment)

Phase I
www.immunedesign.com

Allergies
Drug Name

Organization

Indication

Development Phase

STAGR320 (sublingual desensitization immunotherapy)	Stallergenes Greer London, United Kingdom	house dust mite allergic rhinitis	Phase III www.stallergenesgreer.com
Viaskin® Milk epicutaneous immunotherapy	DBV Technologies Summit, NJ	milk allergy (treatment) (pediatric) (Fast Track)	Phase II www.dbv-technologies.com
Viaskin® Peanut epicutaneous immunotherapy	DBV Technologies Summit, NJ	peanut allergy (treatment) (pediatric) (Fast Track)	Phase III www.dbv-technologies.com

Alzheimer's Disease
Drug Name

Organization

Indication

Development Phase

ACI-24 (liposomal therapeutic anti-Abeta vaccine)	AC Immune Lusanne, Switzerland	Alzheimer's disease-like characteristics in patients with Down syndrome (treatment)	Phase I www.acimmune.com
ACI-35 (anti-pTau vaccine)	AC Immune Lusanne, Switzerland Janssen Research & Development Raritan, NJ	Alzheimer's disease in patients with Down syndrome (treatment)	Phase I www.acimmune.com www.janssen.com
CAD106 (VLP immunotherapy vaccine)	Novartis Pharmaceuticals East Hanover, NJ	Alzheimer's disease (treatment)	Phase II/III www.novartis.com
UB-311 (anti-amyloid endobody vaccine)	United Neuroscience Hauppauge, NY	Alzheimer's disease (treatment)	Phase II www.unitedneuroscience.com

Autoimmune Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
CrohnsVax™ Crohn's disease vaccine	Immune Response BioPharma Atlantic City, NJ	Crohn's disease	Phase I www.immuneresponsebiopharma.com
Diamyd®/GABA autoimmune diabetes vaccine/ gamma-aminobutyric acid (GABA)	Diamyd Medical Stockholm, Sweden University of Alabama Birmingham, AL	type 1 diabetes (treatment) (pediatric)	Phase I www.diamyd.com
DV-100 (autologous dendritic cell immunotherapy vaccine)	DiaVacs La Jolla, CA	type 1 diabetes (treatment)	Phase I completed www.diavac.com
IFN-Kinoid (inactivated immunogenic interferon alpha-based vaccine)	Neovacs Paris, France	systemic lupus erythematosus (Fast Track)	Phase II www.neovacs.fr
NeuroVax™ multiple sclerosis vaccine ORPHAN DRUG	Immune Response BioPharma Atlantic City, NJ	multiple sclerosis (Fast Track)	Phase II www.immuneresponsebiopharma.com
Nexvax2® peptide-based vaccine	ImmusanT Cambridge, MA	celiac disease (treatment)	Phase I www.immusant.com
RAVAX™ rheumatoid arthritis vaccine	Immune Response BioPharma Atlantic City, NJ	rheumatoid arthritis	Phase III www.immuneresponsebiopharma.com
Zorcell™ psoriasis vaccine	Immune Response BioPharma Atlantic City, NJ	psoriasis	Phase II www.immuneresponsebiopharma.com

Cancer Drug Name	Organization	Indication	Development Phase
adagloxad simolenin (cancer immunotherapy)	OBI Pharma Taipei, Taiwan	metastatic breast	Phase II/III www.obipharma.com
ADXS-DUAL (cancer immunotherapy)	Advaxis Princeton, NJ Bristol Myers-Squibb Princeton, NJ	cervical (with nivolumab)	Phase II www.advaxis.com
ADXS-HER2 (cancer immunotherapy)	Advaxis Princeton, NJ	HER2-expressing metastatic solid tumors	Phase II www.advaxis.com
ADXS-PSA (cancer immunotherapy)	Advaxis Princeton, NJ	metastatic castration-resistant prostate (monotherapy)	Phase I/II www.advaxis.com
		metastatic prostate (with pembrolizumab)	Phase I/II www.advaxis.com
AE37 (HER-2/neu li-key hybrid cancer vaccine)	Antigen Express Wellesley, MA	newly-diagnosed breast, metastatic triple negative breast (with pembrolizumab)	Phase II www.antigenexpress.com
		metastatic prostate (monotherapy)	Phase I www.antigenexpress.com
AlloStim® T-cell therapy-device combination	Immunovative Therapies Jerusalem, Israel	metastatic colorectal	Phase II www.immunovative.com

Cancer Drug Name	Organization	Indication	Development Phase
AST-VAC1 (dendritic cell vaccine)	Asterias Biotherapeutics Fremont, CA Immunomic Therapeutics Rockville, MD	acute myeloid leukemia (AML)	Phase II www.asteriasbiotherapeutics.com www.immunomix.com
AutoSynVax™ autologous synthetic vaccine	Agenus Lexington, MA	cancer (prevention)	Phase I www.agenusbio.com
AVX701 (alphavirus VRP cancer vaccine)	AlphaVax Durham, NC	CEA-expressing colon	Phase I/II www.alphavax.com
AVX901 (alphavirus VRP cancer vaccine)	AlphaVax Durham, NC	HER2-expressing breast	Phase I www.alphavax.com
axalimogene filolisbac (AXAL) (cancer immunotherapy) ORPHAN DRUG	Advaxis Princeton, NJ	high-risk locally advanced cervical (Fast Track)	Phase III www.advaxis.com
		metastatic cervical, metastatic head and neck (with durvalumab)	Phase II www.advaxis.com
		metastatic anal (monotherapy)	Phase II www.advaxis.com
BB-MPI-03 (RNA-derived cancer vaccine)	Benovus Bio Atlanta, GA	AML, multiple myeloma, myelodysplastic syndromes	Phase I www.benovusbio.com

Cancer Drug Name	Organization	Indication	Development Phase
BI 1361849 (mRNA cancer vaccine)	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	non-small cell lung cancer (NSCLC)	Phase II www.boehringer-ingelheim.com
BriaVax™ SV-BR-1 GM cancer vaccine	BriaCell Therapeutics Berkeley, CA	breast	Phase I/II www.briacell.com
CMB305 (prime-boost immunotherapy) ORPHAN DRUG	Immune Design Seattle, WA	soft tissue sarcoma, NY-ESO-1 solid tumors (adult and elderly)	Phase II www.immunedesign.com
CMP-001 (virus-like particle cancer vaccine)	Checkmate Pharmaceuticals Cambridge, MA	malignant melanoma (with pembrolizumab)	Phase I www.checkmatepharma.com
colorectal cancer vaccine (therapeutic cancer vaccine)	Targeted Diagnostics & Therapeutics Exton, PA Viral Gene Philadelphia, PA	colorectal	Phase I www.viralgeneinc.com
CRS-207 (<i>Listeria monocytogenes</i> cancer vaccine) ORPHAN DRUG	Aduro Biotech Berkeley, CA	gastric (combination therapy), mesothelioma (combination therapy)	Phase II www.aduro.com
		ovarian (combination therapy)	Phase I/I www.aduro.com
CV301 (CEA/MUC-1 targeted immunotherapy)	Bavarian Nordic Morrisville, NC	NSCLC (with nivolumab)	Phase II www.bavarian-nordic.com

Cancer Drug Name	Organization	Indication	Development Phase
DCVax®-Direct personalized immune therapy	Northwest Biotherapeutics Bethesda, MD	solid tumors	Phase I/II www.nwbio.com
DCVax®-L personalized immune therapy ORPHAN DRUG	Northwest Biotherapeutics Bethesda, MD	newly-diagnosed glioblastoma	Phase III www.nwbio.com
DCVax®-Prostate personalized immune therapy	Northwest Biotherapeutics Bethesda, MD	prostate	Phase II completed www.nwbio.com
DPV-001 (tumor-derived, autophagosome-enriched cancer vaccine)	UbiVac Portland, OR	definitely-treated stage III NSCLC	Phase II www.ubivac.com
		advanced prostate	Phase I www.ubivac.com
DPX E7 (peptide cancer vaccine)	Immunovaccine Halifax, Canada	human papillomavirus (HPV)-related anal, cervical, head and neck	Phase I/II www.imvaccine.com
DPX Survivac (peptide cancer vaccine) ORPHAN DRUG	Immunovaccine Halifax, Canada	ovarian (combination therapy) (Fast Track)	Phase I www.imvaccine.com

Cancer Drug Name	Organization	Indication	Development Phase
DSP-7888 (peptide cancer vaccine) ORPHAN DRUG	Boston Biomedical Cambridge, MA	glioblastoma (combination therapy)	Phase II www.bostonbiomedical.com
		hematologic malignancies, solid tumors	Phase I www.bostonbiomedical.com
Elenagen™ p62 anti-cancer DNA Vaccine	CureLab Oncology Canton, MA	solid tumors	Phase I/II www.curelaboncology.com
EP-101 (multi-antigen vaccine)	EpiThany Seattle, WA	breast	Phase I www.epithany.com
EP-201 (single-antigen vaccine - IGFBP-2)	EpiThany Seattle, WA	ovarian	Phase II www.epithany.com
EP-301 (single-antigen vaccine - HER2-ICD)	EpiThany Seattle, WA	breast	Phase I www.epithany.com
EP-302 (multi-antigen vaccine)	EpiThany Seattle, WA	breast	Phase II www.epithany.com
ERC1671 (allogeneic/autologous cell vaccine) ORPHAN DRUG	Eritopoietic Research Pasadena, CA	glioblastoma	Phase II www.erc-immunotherapy.com

Cancer Drug Name	Organization	Indication	Development Phase
ETBX-011 (Ad5 CEA cancer vaccine)	Etubics Seattle, WA NantCell Culver City, CA	colorectal, pancreatic	Phase I/II www.etubics.com
ETBX-021 (Ad5 HER2/neu cancer vaccine)	Etubics Seattle, WA NantCell Culver City, CA	breast	Phase I www.etubics.com
GALE-301 (folate binding protein E39-targeted peptide vaccine) ORPHAN DRUG	Galena Biopharma San Ramon, CA	endometrial, ovarian (prevention of recurrence)	Phase II completed www.galenabiopharma.com
GALE-301 + GALE-302 (immunogenic peptide vaccine combination) ORPHAN DRUG	Galena Biopharma San Ramon, CA	breast, ovarian	Phase I completed www.galenabiopharma.com
galinpepimut-S (WT1 cancer vaccine) ORPHAN DRUG	Sellas Life Sciences New York, NY	AML (Fast Track), chronic myeloid leukemia (CML), mesothelioma (Fast Track), multiple myeloma, ovarian (with nivolumab)	Phase II www.sellaslifesciences.com
GBM-LAMP-Vax (DNA immunotherapeutic vaccine)	Immunomic Therapeutics Rockville, MD	newly-diagnosed glioblastoma	Phase II www.immunomix.com

Cancer Drug Name	Organization	Indication	Development Phase
GI-4000 (mutated Ras cancer vaccine)	GlobeImmune Louisville, CO NantCell Culver City, CA	pancreatic (combination therapy)	Phase II www.globeimmune.com
GI-6207 (CEA inhibitor cancer vaccine)	GlobeImmune Louisville, CO NantCell Culver City, CA	medullary thyroid cancer	Phase II www.globeimmune.com
GI-6301 (brachyury peptide cancer vaccine)	GlobeImmune Louisville, CO NantCell Culver City, CA	chordoma	Phase II www.globeimmune.com
		advanced cancer	Phase I www.globeimmune.com
GL 0817 (MAGE-A3 vaccine) ORPHAN DRUG	Gliknik Baltimore, MD	head and neck, squamous cell	Phase II www.gliknik.com
GRN 1201 (peptide cancer vaccine)	BrightPath Biotherapeutics Kurume, Japan	NSCLC (combination therapy), melanoma	Phase II www.brightpathbio.com
ICT-107 (dendritic cell vaccine) ORPHAN DRUG	ImmunoCellular Therapeutics Calabasas, CA	newly-diagnosed glioblastoma	Phase III www.imuc.com

Cancer Drug Name	Organization	Indication	Development Phase
ICT-121 (dendritic cell vaccine)	ImmunoCellular Therapeutics Calabasas, CA	recurrent glioblastoma	Phase I www.imuc.com
IMT1012 (multi-peptide antigen cancer vaccine)	Immunotope Doylestown, PA	breast, ovarian	Phase I www.immunotope.com
INO-1400 (hTERT DNA cancer vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	breast, lung, pancreatic	Phase I www.inovio.com
INO-3106 (E6, E7 DNA cancer vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	precancerous lesions and malignancies	Phase I www.inovio.com
INO-5150 (PSA, PSMA DNA cancer vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	prostate	Phase I www.inovio.com
INT230-6 (cisplatin based cancer vaccine)	Intensity Therapeutics Westport, CT	cancer	Phase I/II www.intensitytherapeutics.com
JNJ-64041757 (ADU-214) (<i>Listeria monocytogenes</i> immunotherapy)	Aduro Biotech Berkeley, CA Janssen Research & Development Raritan, NJ	NSCLC	Phase I www.aduro.com www.janssen.com
JNJ-64041809 (ADU-741) (<i>Listeria monocytogenes</i> immunotherapy)	Aduro Biotech Berkeley, CA Janssen Research & Development Raritan, NJ	prostate	Phase I www.aduro.com www.janssen.com

Cancer Drug Name	Organization	Indication	Development Phase
KiroVAX-001 (TAPA-pulsed dendritic cell vaccine)	Kiromic Houston, TX	hematological malignancies	Phase I/II www.kiromic.com
KiroVAX-002 (TAPA-pulsed dendritic cell vaccine)	Kiromic Houston, TX	hematological malignancies	Phase I/II www.kiromic.com
KiroVAX-003 (TAPA-pulsed dendritic cell vaccine)	Kiromic Houston, TX	solid tumors	Phase I/II www.kiromic.com
KiroVAX-004 (TAPA-pulsed dendritic cell vaccine)	Kiromic Houston, TX	solid tumors	Phase I/II www.kiromic.com
LV305 (RNA cancer vaccine) ORPHAN DRUG	Immune Design Seattle, WA	breast, malignant melanoma, NSCLC, ovarian, sarcoma	Phase I www.immunedesign.com
MEDI0457 (INO-3112) (DNA cancer vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA MedImmune Gaithersburg, MD	head and neck (HPV type 16/18) (with durvalumab)	Phase I/II www.inovio.com www.medimmune.com
MUC-1 CD40L dendritic cell vaccine	MicroVAX Manassas, VA	solid tumors	Phase I
MVA-BN brachyury vaccine (cancer immunotherapy)	Bavarian Nordic Morrisville, NC	solid tumors	Phase I www.bavarian-nordic.com

Cancer Drug Name	Organization	Indication	Development Phase
MVA p53 vaccine (modified vaccinia virus ankara vaccine expressing p53)	Tara Immuno-Oncology New York, NY	solid tumors	Phase I
MVI-118 (AR plasmid DNA vaccine)	Madison Vaccines Madison, WI	metastatic prostate	Phase I www.madisonvaccinesinc.com
MVI-816 (plasmid DNA vaccine)	Madison Vaccines Madison, WI	biochemically recurrent prostate	Phase II www.madisonvaccinesinc.com
		metastatic castration-resistant prostate (with pembrolizumab)	Phase I www.madisonvaccinesinc.com
NEO-PV-01 (personalized neoantigen vaccine)	Bristol-Myers Squibb Princeton, NJ Neon Therapeutics Cambridge, MA	bladder, melanoma, NSCLC (with nivolumab)	Phase I www.neontherapeutics.com
NeuVax® nelipepimut S (peptide cancer vaccine)	Galena Biopharma San Ramon, CA	triple negative HER2-positive breast (with trastuzumab), HER2-positive breast (with trastuzumab), ductal carcinoma in situ of breast (Fast Track)	Phase II www.galenabiopharma.com
		gastric	Phase I completed www.galenabiopharma.com

Cancer Drug Name	Organization	Indication	Development Phase
Oncoquest™-CLL chronic lymphocytic leukemia vaccine	XEME Biopharma Lombard, IL	chronic lymphocytic leukemia	Phase II www.xemebiopharma.com
Oncoquest-L® personalized cancer vaccine	XEME Biopharma Lombard, IL	non-Hodgkin lymphoma	Phase I completed www.xemebiopharma.com
OncoVAX® personalized colorectal cancer vaccine	Vaccinogen Baltimore, MD	colorectal (Fast Track)	Phase III www.vaccinogeninc.com
OSE-2101 (neo-epitopes cancer vaccine) ORPHAN DRUG	OSE Immunotherapeutics Nantes, France	NSCLC	Phase III www.ose-immuno.com
ovapuldencel-T	AiVita Biomedical Irvine, CA	ovarian	Phase II www.aivitabiomedical.com
PAN-301-1 (nanoparticle-based cancer vaccine)	Panacea Pharmaceuticals Gaithersburg, MD	prostate	Phase I www.panaceapharma.com
PDS0101 (cancer immunotherapy)	PDS Biotechnology North Brunswick, NJ	HPV-related cancer	Phase I www.pdsbiotech.com
PEPIDH1M (dendritic cell cancer vaccine)	Annias Immunotherapeutics Chapel Hill, NC	glioblastoma	Phase I/II www.anniasimmuno.com

Cancer Drug Name	Organization	Indication	Development Phase
PF-06753512 (cancer immunotherapy)	Pfizer New York, NY	prostate	Phase I www.pfizer.com
pLADD (personalized LADD immunotherapy vaccine)	Aduro Biotech Berkeley, CA	microsatellite stable colorectal	Phase I www.aduro.com
polyclonal antibody stimulator (fusion peptide) ORPHAN DRUG	Cancer Advances Durham, NC	gastric, pancreatic (see also other)	Phase III www.canceradvancesinc.com
		colorectal	Phase II www.canceradvancesinc.com
Prophage™ heat shock protein vaccine ORPHAN DRUG	Agenus Lexington, MA	newly-diagnosed glioblastoma	Phase II www.agenusbio.com
Proscavax™ PSA/IL-2/GM-CSF vaccine	OncBioMune Pharmaceuticals Baton Rouge, LA	prostate cancer	Phase I www.oncbiomune.com
PROSTVAC rilimogene galvacirepvec- rilimogene glafolivec	Bavarian Nordic Morrisville, NC Bristol-Myers Squibb Princeton, NJ	prostate cancer (combination therapy) (Fast Track)	Phase II www.bavarian-nordic.com www.bms.com
PSMA VRP (viral vector vaccine)	AlphaVax Durham, NC	prostate	Phase I www.alphavax.com

Cancer Drug Name	Organization	Indication	Development Phase
PT 107 (allogeneic B7.1/HLA-A1 transfected tumor cell vaccine)	Pique Therapeutics Durham, NC	NSCLC	Phase II www.piquetherapeutics.com
PVX-410 (multi-peptide cancer vaccine) ORPHAN DRUG	OncoPep North Andover, MA	smoldering multiple myeloma	Phase II www.oncopep.com
REIC gene therapy vaccine	Momotaro-Gene Okayama, Japan	localized prostate	Phase I/II www.mt-gene.com
RG6180 (personalized mRNA cancer vaccine)	Genentech South San Francisco, CA	cancer	Phase I www.gene.com
rocapuldencel-T (dendritic cell vaccine)	Argos Therapeutics Durham, NC	renal cell (Fast Track)	Phase III www.argostherapeutics.com
seviprotimut-L (polyvalent antigen vaccine) ORPHAN DRUG	Polynoma San Diego, CA	melanoma	Phase III www.polynoma.com
SL-701 (alpha-type 1 dendritic cell-based vaccine) ORPHAN DRUG	Stemline Therapeutics New York, NY	glioblastoma (adults)	Phase II www.stemline.com
stapuldencel-T (autologous dendritic cell vaccine)	SOTIO Prague, Czech Republic	prostate	Phase III www.sotio.com

Cancer Drug Name	Organization	Indication	Development Phase
SurVaxM peptide mimic vaccine	MimiVax Rochester, NY	glioblastoma	Phase II www.mimivax.com
		multiple myeloma	Phase I www.mimivax.com
tergenpumatu cel-L + indoximod + chemotherapy (tumor cell vaccine)	NewLink Genetics Ames, IA	NSCLC (combination therapy)	Phase I www.newlinkgenetics.com
TG4010 (MVA-MUC1-IL2 cancer vaccine)	Transgene Paris, France Bristol-Myers Squibb Princeton, NJ	NSCLC (with nivolumab)	Phase II www.transgene.fr
TLPLDC (tumor lysate particle loaded dendritic cell vaccine)	Cancer Insight San Antonio, TX Elios Therapeutics Austin, TX	melanoma	Phase II/III www.cancerinsight.com
		ovarian	Phase I/II www.cancerinsight.com
TPIV 100/110 (HER2/neu peptide vaccine)	TapImmune Jacksonville, FL	HER2/neu-positive breast	Phase I www.tapimmune.com
TPIV 200 (folate receptor-alpha peptide vaccine) ORPHAN DRUG	TapImmune Jacksonville, FL	platinum-sensitive ovarian (Fast Track), platinum-resistant ovarian combination therapy), triple negative breast	Phase II www.tapimmune.com

Cancer Drug Name	Organization	Indication	Development Phase
TV-Brain-1 (personalized cancer cell vaccine and killer T-cell therapy)	TVAX Biomedical Olathe, KS	glioblastoma	Phase II www.tvaxbiomedical.com
TV-Kidney-1 (personalized cancer cell vaccine and killer T-cell therapy)	TVAX Biomedical Olathe, KS	renal cell	Phase II www.tvaxbiomedical.com
TVGV-1 vaccine (fusion protein vaccine)	TheVax Cape Canaveral, FL	HPV-related cancers	Phase II www.thevaxgenetics.com
VGX-3100 (therapeutic DNA vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	cervical dysplasia (HPV type 16/18)	Phase III www.inovio.com

		vuval neoplasia (HPV type 16/18)	Phase II www.inovio.com
viagenpumatucl-L (HS-110) (allogeneic vaccine)	Heat Biologics Durham, NC	NSCLC (with nivolumab)	Phase II www.heatbio.com

Cancer
Drug Name

Organization

Indication

Development Phase

Vigil™
genetically-modified autologous
tumor cell vaccine

Gradalis
Dallas, TX

advanced ovarian

Phase III
www.gradalisinc.com

advanced breast

Phase II/III
www.gradalisinc.com

Ewing's sarcoma (adults, children,
elderly), advanced NSCLC,
advanced, melanoma, gynecological

Phase I
www.gradalisinc.com

WT2725
(peptide cancer vaccine)

Sunovion Pharmaceuticals
Marlborough, MA

hematological malignancies,
solid tumors

Phase I
www.sunovion.com

Infectious Diseases
Drug Name

Organization

Indication

Development Phase

Adacel+
tetanus, diphtheria, acellular
pertussis (Tdap) booster vaccine

Sanofi Pasteur
Swiftwater, PA

Tdap booster (prevention)

Phase II
www.sanofi.com

Afluria Quadrivalent®
influenza vaccine

Seqirus
Cambridge, MA

influenza (prevention)
(6-59 months of age)

Phase III completed
www.seqirus.com

AGS-004
(autologous dendritic cell vaccine)

Argos Therapeutics
Durham, NC
University of North Carolina
Chapel Hill, NC

HIV-1 infections (combination
therapy)

Phase I
www.argostherapeutics.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
AGS-v (protein-based vaccine)	Imutex London, United Kingdom National Institute of Allergy and Infectious Diseases Bethesda, MD	mosquito-transmitted viral infections (prevention)	Phase I www.imutex.com
antifungal multivalent oral vaccine	Immunitor Vancouver, Canada	fungal infections (prevention and treatment)	Phase I/II www.immunitor.com
antimicrobial oral vaccine	Immunitor Vancouver, Canada	bacterial infections (treatment)	Phase I/II www.immunitor.com
ASP0113 (bivalent plasmid DNA-based vaccine) ORPHAN DRUG	Astellas Northbrook, IL Vical San Diego, CA	cytomegalovirus (CMV) infections in transplant patients (prevention)	Phase III www.vical.com
AV0328 (conjugated oligosaccharide vaccine against dPNAG [deacetylated polymeric- N-acetyl glucosamine])	Alopexx Vaccine Concord, MA	PNAG-expressing bacterial infections (prevention and treatment)	Phase I/II www.alopexx.com
Chikungunya vaccine (virus-like particle vaccine)	PaxVax Redwood City, CA	Chikungunya infections (prevention)	Phase II www.paxvax.com
Clostridium difficile toxoid vaccine	Sanofi Pasteur Swiftwater, PA	<i>Clostridium difficile</i> infections (prevention) (Fast Track)	Phase III www.sanofi.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
CodaVax® influenza A virus H1N1 vaccine	Codagenix Farmingdale, NY	multi-season influenza (prevention)	Phase I www.codagenix.com
deltaFLU-LAIV (influenza virus delta NS1 vaccine)	Vivaldi Biosciences Fort Collins, CO	influenza (prevention)	Phase II www.vivaldibiosciences.com
Dengvaxia® dengue tetravalent vaccine	Sanofi Pasteur Swiftwater, PA	dengue (prevention) (Fast Track)	Phase II www.sanofi.com
DNA-C (DNA HIV vaccine)	EuroVacc Amsterdam, Netherlands National Institute of Allergy and Infectious Diseases Rockville, MD	HIV infections (prevention) (combination with other HIV vaccines)	Phase I/II
Ebola recombinant viral vector vaccine	GlaxoSmithKline Research Triangle Park, NC	Ebola virus infections (prevention)	Phase II www.gsk.com
Ebola virus vaccine (Ad26 EBOV vaccine)	Janssen Vaccines & Prevention Leiden, Netherlands	Ebola virus infections (prevention)	Phase III www.janssen.com
Ebola virus vaccine + Matrix-M™	Novavax Gaithersburg, MD	Ebola virus infections (prevention)	Phase I www.novavax.com
Fluarix® Quadrivalent influenza vaccine	GlaxoSmithKline Research Triangle Park, NC	seasonal influenza subtypes A and B (prevention) (6-35 months of age)	application submitted www.gsk.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
Flucelvax® influenza vaccine	Seqirus Cambridge, MA	influenza (prevention) (6-<48 months of age)	Phase I/II completed www.seqirus.com
FluNhanche™ recombinant influenza vaccine	Protein Sciences Meriden, CT	influenza (prevention)	Phase II www.proteinsciences.com
Fluzone® QIV HD quadrivalent inactivated influenza vaccine - high dose	Sanofi Pasteur Swiftwater, PA	influenza (prevention) (elderly)	Phase III www.sanofi.com
GEN-003 (protein subunit T cell-enabled vaccine)	Genocea Biosciences Cambridge, MA	herpes simplex virus (HSV) infections (treatment)	Phase II www.genocea.com
GLS-5300 (DNA vaccine)	GeneOne Life Science Seoul, South Korea Inovio Pharmaceuticals Plymouth Meeting, PA	Middle East respiratory syndrome (MERS) (prevention), coronavirus infections (prevention)	Phase I www.inovio.com
GLS-5700 (DNA-based synthetic vaccine)	GeneOne Life Science Seoul, South Korea Inovio Pharmaceuticals Plymouth Meeting, PA	Zika virus infections (prevention)	Phase I www.inovio.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
GOVX-B11 (clade-B DNA HIV vaccine)	GeoVax Labs Smyrna, GA	HIV infections (prevention)	Phase II www.geovax.com
		HIV infections (treatment)	Phase I www.geovax.com
GS-4774 (T-cell immunity stimulator vaccine)	GlobeImmune Louisville, CO	hepatitis C (treatment) (treatment naïve and virally suppressed)	Phase II www.globeimmune.com
haemophilus recombinant vaccine	GlaxoSmithKline Research Triangle Park, NC	reduction of the frequency of COPD exacerbations associated with non-typeable haemophilus influenza and moreaxella catarrhalis	Phase II www.gsk.com
HBV-002 (recombinant subunit vaccine)	Hawaii Biotech Honolulu, HI	West Nile virus infections (prevention)	Phase I www.hibiotech.com
hepatitis C vaccine (recombinant viral vector vaccine)	GlaxoSmithKline Research Triangle Park, NC	hepatitis C (prevention)	Phase II www.gsk.com
HEPLISAV-B HBsAg-1018 vaccine	Dynavax Technologies Berkeley, CA	hepatitis B (prevention)	application submitted www.dynavax.com
HepTcell peptide vaccine	Altimune Gaithersburg, MD	hepatitis B (treatment)	Phase I www.altimmune.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
HIV recombinant proteins vaccine	GlaxoSmithKline Research Triangle Park, NC	HIV infections (prevention)	Phase II www.gsk.com
HIV vaccine (Ad26 Mos HIV trivalent vaccine)	Janssen Vaccines and Prevention Leiden, Netherlands	HIV infections (prevention)	Phase II www.janssen.com
HIV vaccine (Ad26 Mos HIV vaccine)	Janssen Vaccines and Prevention Leiden, Netherlands	HIV infections (prevention)	Phase II www.janssen.com
HIV vaccine (MVA mosaic HIV vaccine)	Janssen Vaccines and Prevention Leiden, Netherlands	HIV infections (prevention)	Phase I/II www.janssen.com
HIV vaccine (prime-boost vaccine)	Sanofi Pasteur Swiftwater, NJ	HIV infections (prevention)	Phase II www.sanofi.com
HIV vaccine Ad4-Clade C	PaxVax Redwood City, CA	HIV infections (prevention)	Phase I www.paxvax.com
HIV vaccine Ad4-mGag	PaxVax Redwood City, CA	HIV infections (prevention)	Phase I www.paxvax.com
HIVAX™ replication-defective HIV vaccine	GeneCure Biotechnologies Norcross, GA	HIV-1 infections (treatment)	Phase I www.genecure.com
HSV529 (herpes simplex virus type 2 vaccine)	Sanofi Pasteur Swiftwater, PA	HSV-type 2 infections (prevention)	Phase I www.sanofi.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
HTNV/PUUV DNA vaccine	Ichor Medical Systems San Diego, CA United States Army Medical Research and Materiel Command Fort Detrick, MD	hemorrhagic fever caused by hantaan virus and puumala virus (prevention)	Phase II www.ichorms.com
IHV001 (subunit HIV vaccine)	Profectus Biosciences Baltimore, MD	HIV infections (prevention)	Phase I www.profectusbiosciences.com
Imvamune [®] smallpox vaccine	Bavarian Nordic Morrisville, NC	smallpox (prevention) (liquid-frozen)	Phase III www.bavarian-nordic.com
		smallpox (prevention) (freeze-dried)	Phase II www.bavarian-nordic.com
Infanrix Hexa [®] combined diphtheria and tetanus toxoids, acellular pertussis, hepatitis B (recombinant), inactivated polio- myelitis, and adsorbed conjugated <i>Haemophilus influenzae</i> type b vaccine	GlaxoSmithKline Research Triangle Park, NC	diphtheria, haemophilus, hepatitis B, pertussis, polio, tetanus (prevention)	Phase III www.gsk.com
influenza A virus vaccine H1N1 (li-key hybrid cancer vaccine)	Antigen Express Wellesley, MA	influenza (prevention)	Phase I www.antigenexpress.com
influenza A virus vaccine H5N1 (li-key hybrid cancer vaccine)	Antigen Express Wellesley, MA	influenza (prevention)	Phase I www.antigenexpress.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
influenza A virus H5N1 vaccine	Seqirus Cambridge, MA	influenza (prevention) (adults, elderly)	Phase III www.seqirus.com
influenza A virus H5N8 vaccine	Seqirus Cambridge, MA	influenza (prevention)	Phase I www.seqirus.com
influenza A virus H7N9 vaccine	EpiVax Providence, RI	influenza (prevention)	Phase I www.epivax.com
influenza H3N2 vaccine (intranasal)	FluGen Madison, WI	influenza (prevention)	Phase I www.flugen.com
influenza virus vaccine quadrivalent (plant-based VLP vaccine)	Medicago Durham, NC	seasonal influenza (prevention)	Phase III www.medicago.com
		seasonal influenza (prevention) (elderly)	Phase II www.medicago.com
influenza virus vaccine quadrivalent (aQIV-aQIV)	Seqirus Cambridge, MA	influenza (prevention)	Phase III www.seqirus.com
INO-1800 (multi-antigen vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	hepatitis B (treatment)	Phase I www.inovio.com
INO-4212 (polyvalent DNA based vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	Ebola virus infections (prevention)	Phase I www.inovio.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
INO-8000 (multi-antigen DNA vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	hepatitis C (treatment)	Phase I www.inovio.com
ITV-1 (inactivated pepsin fraction vaccine)	Immunotech Laboratories Monrovia, CA	HIV infections (treatment)	Phase II www.immunotechlab.com
JNJ-61187165 (RSV vaccine)	Janssen Vaccines and Prevention Leiden, Netherlands	respiratory syncytial virus (RSV) infections (prevention)	Phase I completed www.janssen.com
JNJ-61187191 (RSV vaccine)	Janssen Vaccines and Prevention Leiden, Netherlands	RSV infections (prevention)	Phase I completed www.janssen.com
JNJ-63871860 (multivalent glycoprotein conjugate vaccine)	Janssen Vaccines and Prevention Leiden, Netherlands	<i>Escherichia coli</i> infections (prevention)	Phase II completed www.janssen.com
JNJ-64400141 (RSV vaccine)	Janssen Vaccines and Prevention Leiden, Netherlands	RSV infections (prevention) (elderly)	Phase I www.janssen.com
M-001 (universal influenza vaccine)	BiondVax Ness Ziona, Israel National Institute of Allergy and Infectious Diseases Bethesda, MD	influenza (prevention)	Phase II www.biondvax.com
malaria next generation vaccine (recombinant)	GlaxoSmithKline Research Triangle Park, NC	malaria (prevention) (plasmodium falciparum)	Phase II www.gsk.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
MEDI8897/SP0232 (monoclonal antibody vaccine)	MedImmune Gaithersburg, MD Sanofi Pasteur Swiftwater, PA	RSV infections (prevention) (infants)	Phase II/III www.medimmune.com www.sanofi.com
Men ABCWY vaccine	GlaxoSmithKline Research Triangle Park, NC	meningococcal A,B,C,W and Y disease (prevention) (adolescents)	Phase II www.gsk.com
Men Quad TT (second-generation meningococcal ACYW conjugate vaccine)	Sanofi Pasteur Swiftwater, PA	meningococcal A,C,W,Y disease (prevention) (adults, children, elderly)	Phase III www.sanofi.com
MER4101 (MAS-1-adjuvanted seasonal inactivated influenza vaccine)	Mercia Pharma New York, NY	influenza (prevention) (elderly)	Phase I www.merciapharma.com
MMR vaccine	GlaxoSmithKline Research Triangle Park, NC	measles, mumps, rubella (prevention) (pediatric)	Phase III www.gsk.com
mRNA-1325 (messenger RNA vaccine)	Moderna Therapeutics Cambridge, MA	Zika virus infections (prevention)	Phase I/II www.modernatx.com
mRNA-1388 (messenger RNA vaccine)	Moderna Therapeutics Cambridge, MA	Chikungunya virus infections (prevention)	Phase I www.modernatx.com
mRNA-1440 (influenza virus H10N8 messenger RNA vaccine)	Moderna Therapeutics Cambridge, MA	influenza (prevention)	Phase I www.modernatx.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
mRNA-1851 (influenza virus H7N9 messenger RNA vaccine)	Moderna Therapeutics Cambridge, MA	influenza (prevention)	Phase I www.modernatx.com
mRNA MRK-1777 (messenger RNA vaccine)	Merck Kenilworth, NJ Moderna Therapeutics Cambridge, MA	infections (prevention)	Phase I www.modernatx.com
MVA-BN Filo (monovalent vaccine)	Bavarian Nordic Morrisville, NC Janssen Vaccines and Prevention Leiden, Netherlands	Ebola virus infections (prevention)	Phase III www.bavarian-nordic.com
MVA-BN Filo (multivalent vaccine)	Bavarian Nordic Morrisville, NC Janssen Vaccines and Prevention Leiden, Netherlands	Ebola virus infections (prevention), Marburg virus infections (prevention) (adults, elderly)	Phase II www.bavarian-nordic.com
MVA-BN RSV (recombinant RSV vaccine)	Bavarian Nordic Morrisville, NC	RSV infections (prevention) (adults, elderly)	Phase II www.bavarian-nordic.com
Na-APR-1 (hookworm monovalent vaccine)	Sabin Vaccine Institute Washington, DC	hookworm infections (prevention)	Phase I completed www.sabin.org
Nanoflu™ seasonal influenza nanoparticle vaccine	Novavax Gaithersburg, MD	seasonal influenza (prevention) (elderly)	Phase I www.novavax.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
NasoVAX™ recombinant influenza vaccine (intranasal)	Altimmune Gaithersburg, MD	seasonal influenza (prevention), pandemic influenza (prevention)	Phase II www.altimmune.com
NB-1008 (influenza intranasal vaccine)	NanoBio Ann Arbor, MI	seasonal influenza (prevention)	Phase I www.nanobio.com
NDV-3 (alum-adjuvanted recombinant protein vaccine)	NovaDigm Therapeutics Brookline, MA	recurrent vulvovaginal candidiasis (prevention)	Phase I/II www.novadigm.net
NmVac-4 A/C/Y/W-135 DT (meningococcal conjugate vaccine)	JN-International Medical Oakland, Nebraska	meningococcal A,C,W,Y disease	Phase II completed www.jn-vaccines.com
NuThrax™ anthrax vaccine adsorbed with CPG 7909 adjuvant	Emergent BioSolutions Gaithersburg, MD	anthrax (pre-exposure prevention) (Fast Track)	Phase II www.emergentbiosolutions.com
PanBlok influenza virus vaccine	Protein Sciences Meriden, CT	pandemic influenza (prevention)	Phase II www.proteinsciences.com
PBSVax™ HIV-MAG DNA vaccine	Profectus Biosciences Baltimore, MD	HIV infections (treatment)	Phase I www.profectusbiosciences.com
		HIV infections (prevention)	Phase I www.profectusbiosciences.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
PENNVAX®-GP Clade A, B, C, D HIV DNA vaccine	Inovio Pharmaceuticals Plymouth Meeting, PA	HIV infection (prevention)	Phase I www.inovio.com
Pepvax cytomegalovirus peptide vaccine	Helocyte New York, NY	CMV infections in patients under- going stem cell transplantation (prevention)	Phase II www.helocyte.com
PF-06290510 (4-antigen <i>Staphylococcus aureus</i> vaccine)	Pfizer New York, NY	invasive <i>Staphylococcus aureus</i> infections in surgical populations (prevention) (Fast Track)	Phase II www.pfizer.com
PF-06425090 (adjuvant-formulated modified vaccine) vaccine)	Pfizer New York, NY	primary <i>clostridium difficile</i> infection (prevention) (Fast Track) (adults, elderly)	Phase III www.pfizer.com
PF-06482077 (pneumococcal vaccine)	Pfizer New York, NY	invasive and non-invasive pneumococcal infections	Phase I www.pfizer.com
PF-06760805 (multivalent vaccine)	Pfizer New York, NY	invasive Group B Streptococcus infections (prevention)	Phase I www.pfizer.com
PF-06886992	Pfizer New York, NY	serogroups ABCWY meningococcal infections (prevention)	Phase I www.pfizer.com
PfSPZ-Cvac (live unattenuated malaria vaccine plus chloroquine)	Sanaria Rockville, MD	Falciparum malaria (prevention)	Phase I www.sanaria.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
PfSPZ-GA1 (live attenuated malaria vaccine)	Sanaria Rockville, MD	Falciparum malaria (prevention) (Fast Track)	Phase II www.sanaria.com
plague injectable vaccine ORPHAN DRUG	DynPort Vaccine Falls Church, VA	Yersinia infections (prevention)	Phase II www.csra.com/dvc
PR5i (V419) (pediatric hexavalent combination vaccine)	Merck Kenilworth, NJ Sanofi Pasteur Swiftwater, PA	DTP-HepB-polio-Hib infections (prevention) (infants)	application submitted www.merck.com www.sanofi.com
pre-pandemic Avian influenza vaccine (oral tablet)	Vaxart South San Francisco, CA	avian influenza (treatment)	Phase I www.vaxart.com
Px563L (recombinant protective antigen vaccine)	Pfenex San Diego, CA	anthrax (prevention)	Phase I www.pfenex.com
PXVX0047 (adenovirus type 4 and type 7 vaccine)	PaxVax Redwood City, CA	adenovirus infections (prevention)	Phase I www.paxvax.com
Rabies VRVg (purified vero rabies vaccine)	Sanofi Pasteur Swiftwater, PA	rabies (prevention)	Phase II www.sanofi.com
Remune [®] GP120-depleted HIV-1 vaccine ORPHAN DRUG	Immune Response BioPharma Atlantic City, NJ	HIV-1 infections (adult and pediatrics) (treatment)	application submitted www.immuneresponsebiopharma.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
RemuneX[®] HIV combination vaccine	Immune Response BioPharma Atlantic City, NJ	HIV-1 infections (treatment)	Phase III www.immuneresponsebiopharma.com
rotavirus vaccine	PATH Seattle, WA SK Chemicals Gyeonggi-do, Korea	rotavirus infections (prevention)	Phase II www.path.org
RSV F protein vaccine	Novavax Gaithersburg, MD	RSV infections (prevention) (maternal immunization) (Fast Track)	Phase III www.novavax.com
		RSV infections (prevention) (elderly) (Fast Track)	Phase II www.novavax.com
		RSV infections (prevention) (6 months-5 years of age) (Fast Track)	Phase I www.novavax.com
RSV recombinant vaccine	GlaxoSmithKline Research Triangle Park, NC	RSV (prevention) (maternal immunization)	Phase II www.gsk.com
RSV vaccine (replication-defective recombinant vaccine)	GlaxoSmithKline Research Triangle Park, NC	RSV infections (prevention)	Phase II www.gsk.com
RSV vaccine	Sanofi Pasteur Swiftwater, PA	RSV infections in infants (prevention)	Phase I www.sanofi.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
S. pneumococcal next-generation vaccine	GlaxoSmithKline Research Triangle Park, NC	streptococcus pneumonia disease (prevention) (infants)	Phase II www.gsk.com
Shan 6 (DTP-HepB-Polio-Hib pediatric hexavalent vaccine)	Sanofi Pasteur Swiftwater, PA	hepatitis B, diphtheria, tetanus, pertussis (DTP), haemophilus infections, poliomyelitis (prevention)	Phase II www.sanofi.com
Shigella conjugated and outer membrane vaccine	GlaxoSmithKline Research Triangle Park, NC	Shigella diarrhea (prevention)	Phase II www.gsk.com
Shigella vaccine (Flexyn2a)	LimmaTech Biologics Schlieren, Switzerland	Shigella infections (prevention) (Fast Track)	Phase II www.lmtbio.com
STEBVax recombinant detoxified SEB vaccine	Integrated Biotherapeutics Rockville, MD	toxic shock syndrome from Staphylococcus enterotoxin B exposure (prevention)	Phase I www.integratedbiotherapeutics.com
Streptococcal B conjugated vaccine	GlaxoSmithKline Research Triangle Park, NC	Streptococcal B infections (prevention) (maternal immunization)	Phase II www.gsk.com
TAK-003 (dengue vaccine)	Takeda Pharmaceuticals Deerfield, IL	dengue (prevention)	Phase III www.takeda.com
TAK-021 (EV71 enterovirus A vaccine)	Takeda Pharmaceuticals Deerfield, IL	enterovirus A infections (prevention)	Phase I www.takeda.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
TAK-195 (sabin-strain inactivated polio vaccine)	Takeda Pharmaceuticals Deerfield, IL	poliomyelitis (prevention)	Phase I www.takeda.com
TAK-214 (norovirus vaccine)	Takeda Pharmaceuticals Deerfield, IL	norovirus infections (prevention) (adults, elderly)	Phase II www.takeda.com
TDENV (tetraivalent dengue virus vaccine)	GlaxoSmithKline Research Triangle Park, NC U.S. Army Medical Research and Materiel Command Fort Detrick, MD	dengue (prevention)	Phase I/II www.gsk.com
Triplex cytomegalovirus peptide vaccine	Helocyte New York, NY	CMV infections in patients under- going stem cell transplantation (prevention)	Phase II www.helocyte.com
tuberculosis recombinant subunit vaccine	Sanofi Pasteur Swiftwater, PA	tuberculosis (prevention)	Phase II www.sanofi.com
tuberculosis recombinant vaccine	GlaxoSmithKline Research Triangle Park, NC	tuberculosis (prevention)	Phase II www.gsk.com
UTI vaccine	Sequoia Sciences St. Louis, MO	reduction of recurrent urinary tract infections caused by multi-drug resistant bacteria (Fast Track)	Phase I www.sequoiasciences.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
V114 (pneumoconjugate 15-valent vaccine)	Merck Kenilworth, NJ	pneumococcal infections (prevention) (adults, children, elderly)	Phase II www.merck.com
V160 (CMV vaccine)	Merck Kenilworth, NJ	CMV infections (treatment)	Phase I completed www.merck.com
V180 (tetraivalent subunit vaccine)	Merck Kenilworth, NJ	dengue (prevention)	Phase I completed www.merck.com
V212 (inactivated VZV vaccine)	Merck Kenilworth, NJ	herpes zoster (prevention)	Phase III www.merck.com
V920 (Ebola vaccine)	Merck Kenilworth, NJ	Ebola virus infections (prevention)	Phase III www.merck.com
Vaxchora [®] cholera vaccine, live, oral	PaxVax Redwood City, CA	cholera (prevention) (pediatric)	Phase III www.paxvax.com
VaxiGrip [®] QIV IM quadrivalent inactivated influenza vaccine	Sanofi Pasteur Swiftwater, PA	influenza (prevention) (6-35 months of age)	Phase III www.sanofi.com
VBI-1501A	VBI Vaccines Cambridge, MA	CMV infections (prevention)	Phase I www.vbivaccines.com

Infectious Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
VCL-HB01 (naked plasmid DNA vaccine)	Vical San Diego, CA	HSV-2 infections (treatment)	Phase II www.vical.com
VesiculoVax™ Ebola virus vaccine	Profectus Biosciences Baltimore, MD	Ebola/Marburg virus infections (prevention)	Phase I www.profectusbiosciences.com
VLA15-101 (hexavalent protein subunit vaccine)	Valneva Lyon, France	Lyme disease (prevention) (Fast Track)	Phase I www.valneva.com
VLA-84 (recombinant fusion protein vaccine)	Valneva Lyon, France	<i>Clostridium difficile</i> infections (prevention)	Phase II www.valneva.com
VXA-A1.1-H1 (H1N1) (oral influenza vaccine)	Vaxart South San Francisco, CA	influenza (prevention)	Phase II www.vaxart.com
VXA-G1.1-NN (oral norovirus vaccine)	Vaxart South San Francisco, CA	norovirus infections (prevention)	Phase I www.vaxart.com
VXA-RSV-f (oral RSV vaccine)	Vaxart South San Francisco, CA	RSV infections (prevention)	Phase I www.vaxart.com
Zika virus vaccine (inactivated Zika vaccine)	Sanofi Pasteur Swiftwater, PA	Zika virus infections (prevention)	Phase I www.sanofi.com

Other Diseases

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
polyclonal antibody stimulator (fusion peptide)	Cancer Advances Durham, NC	gastro-esophageal reflux disease (see also cancer)	Phase II www.canceradvancesinc.com
RiVax® + TVax heat stable recombinant subunit vaccine ORPHAN DRUG	Soligenix Princeton, NJ	ricin poisoning (pre-exposure prevention)	Phase I www.soligenix.com
SELA-070 (immune stimulation 2nd-generation vaccine)	Selecta Biosciences Watertown, MA	tobacco use disorder and relapse prevention	Phase I www.selectabio.com
SELA-212 pegsiticase/synthetic vaccine particle-rapamycin)	Selecta Biosciences Watertown, MA	gout (treatment)	Phase II www.selectabio.com
TA-CD vaccine	Celtic Pharma Bermuda National Institute on Drug Abuse Rockville, MD	cocaine use disorder	Phase II

The content of this report has been obtained through public, government and industry sources, and the Springer "Adis Insight" database based on the latest information. **Report current as of October 23, 2017.** The medicines in this listing include medicines being developed by U.S.-based companies conducting trials in the United States and abroad, PhRMA-member companies conducting trials in the United States and abroad, and foreign companies conducting clinical trials in the United States. Some products may not be in active clinical trials. The information may not be comprehensive. For more, specific information about a particular product, contact the individual company directly or go to www.clinicaltrials.gov. The entire series of *Medicines in Development* is available on PhRMA's website, www.phrma.org.

Definitions

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

Fast Track—Upon request by a sponsor, the FDA can grant this designation to facilitate the development and expedite the review of a drug or biologic to treat a serious condition and fill an unmet medical need. When considering a biopharmaceutical company's request for Fast Track designation for an investigational drug or biologic, the FDA evaluates whether it will affect factors such 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, and whether a condition can be adequately addressed by available therapy. With Fast Track designation, early and frequent communication between the FDA and the biopharmaceutical company is encouraged throughout the entire drug development and review process to help to quickly resolve any questions or issues that arise, potentially leading to an earlier approval and access by patients.

Orphan Designation—Upon request by a sponsor, the FDA can grant special status ("orphan status") to a drug or biologic to treat a rare disease or condition. In order to receive an orphan designation, a qualifying drug or biologic must be intended for the treatment, diagnosis, or prevention of a rare disease or condition that affects usually fewer than 200,000 people in the United States.

Phase I—Researchers test the investigational drug or biologic in a small group of people, usually between 20 and 100 healthy adult volunteers, to evaluate its initial safety and tolerability profile, determine a safe dosage range, and identify potential side effects.

Phase II—The investigational drug or biologic is given to volunteer patients, usually between 100 and 500, to determine whether it is effective, identify an optimal dose, and to further evaluate its short-term safety.

Phase III—The investigational drug or biologic is given to a larger, more diverse patient population, often involving between 1,000 and 5,000 patients (but sometimes many more), to generate statistically significant evidence to confirm its safety and effectiveness. Phase III studies are the longest studies and usually take place in multiple sites around the world.