

## 2016 Medicines in Development for Autoimmune Diseases

### Autoimmune Arthritis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
ABBV-257 (IL-17/TNF inhibitor)	AbbVie North Chicago, IL	rheumatoid arthritis	Phase I completed <a href="http://www.abbvie.com">www.abbvie.com</a>
ABP 501 (adalimumab biosimilar)	Amgen Thousand Oaks, CA	rheumatoid arthritis	application submitted <a href="http://www.amgen.com">www.amgen.com</a>
ABP 798 (rituximab biosimilar)	Amgen Thousand Oaks, CA	rheumatoid arthritis	Phase III <a href="http://www.amgen.com">www.amgen.com</a>
ABT-122 (IL-17 / TNF-alpha inhibitor)	AbbVie North Chicago, IL	psoriatic arthritis, rheumatoid arthritis	Phase II completed <a href="http://www.abbvie.com">www.abbvie.com</a>
ABT-494 (JAK inhibitor)	AbbVie North Chicago, IL	rheumatoid arthritis	Phase III <a href="http://www.abbvie.com">www.abbvie.com</a>
acalabrutinib (BTK inhibitor)	Acerta Pharma Oss, Netherlands	rheumatoid arthritis	Phase II
<b>Actemra</b> <sup>®</sup> tocilizumab	Genentech South San Francisco, CA	early rheumatoid arthritis	Phase III <a href="http://www.gene.com">www.gene.com</a>
ALX-0061 (IL-6 receptor antagonist/modulator)	AbbVie North Chicago, IL Ablynx Ghent, Belgium	rheumatoid arthritis	Phase II <a href="http://www.abbvie.com">www.abbvie.com</a> <a href="http://ablynx.com">ablynx.com</a>

## Autoimmune Arthritis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
ARG301 (immunomodulator)	arGentis Pharmaceuticals Collierville, TN	rheumatoid arthritis	Phase I <a href="http://www.argentisrx.com">www.argentisrx.com</a>
ASP015K (JAK inhibitor)	Astellas Pharma US Northbrook, IL	rheumatoid arthritis	Phase II <a href="http://www.astellas.com">www.astellas.com</a>
ASP5094	Astellas Pharma US Northbrook, IL	rheumatoid arthritis	Phase I <a href="http://www.astellas.com">www.astellas.com</a>
AZD9567 (selective glucocorticoid receptor modulator)	AstraZeneca Wilmington, DE	rheumatoid arthritis	Phase I <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
baricitinib (JAK1/JAK2 inhibitor)	Incyte Wilmington, DE Eli Lilly Indianapolis, IN	rheumatoid arthritis	application submitted <a href="http://www.incyte.com">www.incyte.com</a> <a href="http://www.lilly.com">www.lilly.com</a>
BAX2200/CHS-0214 (etanercept biosimilar)	Shire Lexington, MA Coherus Biosciences Redwood City, CA	rheumatoid arthritis	Phase III <a href="http://www.shire.com">www.shire.com</a> <a href="http://www.coherus.com">www.coherus.com</a>
BAX2923/M923 (adalimumab biosimilar)	Shire Lexington, MA Momenta Pharmaceuticals Cambridge, MA	rheumatoid arthritis	Phase III <a href="http://www.shire.com">www.shire.com</a> <a href="http://www.momentapharma.com">www.momentapharma.com</a>

## Autoimmune Arthritis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
BI-655066 (risankizumab)	AbbVie North Chicago, IL Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	ankylosing spondylitis, psoriatic arthritis	Phase II <a href="http://www.abbvie.com">www.abbvie.com</a> <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>
BI-695500 (rituximab biosimilar)	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	rheumatoid arthritis	Phase III <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>
BI-695501 (adalimumab biosimilar)	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	rheumatoid arthritis	Phase III <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>
BMS-986104 (SIP1 receptor modulator)	Bristol-Myers Squibb Princeton, NJ	rheumatoid arthritis	Phase I completed <a href="http://www.bms.com">www.bms.com</a>
BMS-986142 (BTK inhibitor)	Bristol-Myers Squibb Princeton, NJ	rheumatoid arthritis	Phase II <a href="http://www.bms.com">www.bms.com</a>
CCX354 (CCR1 receptor antagonist)	ChemoCentryx Mountain View, CA	rheumatoid arthritis	Phase II <a href="http://www.chemocentryx.com">www.chemocentryx.com</a>
CF101 (adenosine A3 receptor agonist)	Can-Fite BioPharma Petah-Tikva, Israel	rheumatoid arthritis	Phase II <a href="http://www.canfite.com">www.canfite.com</a>
<b>Cimzia®</b> certolizumab pegol	UCB Smyrna, GA	axial spondyloarthritis, juvenile idiopathic arthritis	Phase III <a href="http://www.ucb.com">www.ucb.com</a>

## Autoimmune Arthritis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
clazakizumab (IL-6 inhibitor)	Alder Biopharmaceuticals Bothell, WA Vitaeris Vancouver, Canada	rheumatoid arthritis	Phase II completed <a href="http://www.alderbio.com">www.alderbio.com</a>
CNTO 6785 (IL-17 receptor modulator)	Janssen Research & Development Raritan, NJ	rheumatoid arthritis	Phase II completed <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
<b>Cosentyx</b> <sup>®</sup> secukinumab	Novartis Pharmaceuticals East Hanover, NJ	non-radiographic axial spondyloarthritis	Phase III <a href="http://www.novartis.com">www.novartis.com</a>
<b>Dekavil</b> interleukin 10	Pfizer New York, NY	rheumatoid arthritis	Phase II <a href="http://www.pfizer.com">www.pfizer.com</a>
<b>Enbrel</b> <sup>®</sup> etanercept	Amgen Thousand Oaks, CA	psoriatic arthritis (monotherapy), rheumatoid arthritis (monotherapy to maintain remission)	Phase III <a href="http://www.amgen.com">www.amgen.com</a>
filgotinib (JAK1 inhibitor)	Gilead Sciences Foster City, CA	rheumatoid arthritis	Phase II <a href="http://www.gilead.com">www.gilead.com</a>
FKB327 (adalimumab biosimilar)	Fujifilm Kyowa Kirin Biologics Tokyo, Japan	rheumatoid arthritis	Phase III <a href="http://www.fujifilmkyowakirin-biologics.com">www.fujifilmkyowakirin-biologics.com</a>
gerilimzumab (Interleukin-6 modulator)	Bird Rock Bio La Jolla, CA	rheumatoid arthritis	Phase I <a href="http://www.birdrockbio.com">www.birdrockbio.com</a>

## Autoimmune Arthritis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
GP2013 (rituximab biosimilar)	Sandoz Holzkirchen, Germany	rheumatoid arthritis	Phase II <a href="http://www.sandoz-biosimilars.com">www.sandoz-biosimilars.com</a>
GP2015 (etanercept biosimilar)	Sandoz Holzkirchen, Germany	ankylosing spondylitis, juvenile rheumatoid arthritis, psoriatic arthritis, rheumatoid arthritis	application submitted <a href="http://www.sandozbiosimilars.com">www.sandozbiosimilars.com</a>
GP2017 (adalimumab biosimilar)	Sandoz Holzkirchen, Germany	rheumatoid arthritis	Phase III <a href="http://www.sandoz-biosimilars.com">www.sandoz-biosimilars.com</a>
GS-4059 (BTK inhibitor)	Gilead Sciences Foster City, CA	rheumatoid arthritis	Phase I <a href="http://www.gilead.com">www.gilead.com</a>
GS-5745 (MMP9 mAb inhibitor)	Gilead Sciences Foster City, CA	rheumatoid arthritis	Phase I <a href="http://www.gilead.com">www.gilead.com</a>
GS-9876 (Syk kinase inhibitor)	Gilead Sciences Foster City, CA	rheumatoid arthritis	Phase I <a href="http://www.gilead.com">www.gilead.com</a>
GSK2982772 (RIP1 kinase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	rheumatoid arthritis	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
GSK3050002 (CCL20 maybe)	GlaxoSmithKline Research Triangle Park, NC	psoriatic arthritis	Phase I <a href="http://www.gsk.com">www.gsk.com</a>

## Autoimmune Arthritis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
GSK3117391 (macrophage targeted histone deacetylase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	rheumatoid arthritis	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
GSK3196165 (GMCSF mAb)	GlaxoSmithKline Research Triangle Park, NC	rheumatoid arthritis	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
guselkumab (IL-23 subunit p19 inhibitor)	Janssen Research & Development Raritan, NJ	active psoriatic arthritis	Phase II <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
<b>Humira®</b> adalimumab	AbbVie North Chicago, IL	axial spondyloarthritis	application submitted <a href="http://www.abbvie.com">www.abbvie.com</a>
<b>Humira®</b> adalimumab (new formulation)	AbbVie North Chicago, IL	psoriatic arthritis, rheumatoid arthritis	Phase III <a href="http://www.abbvie.com">www.abbvie.com</a>
juvenile rheumatoid arthritis therapeutic	Marathon Pharmaceuticals Northbrook, IL	polyarticular juvenile idiopathic arthritis	Phase III <a href="http://www.marathonpharma.com">www.marathonpharma.com</a>
KD025 (ROCK2 inhibitor)	Kadmon New York, NY	psoriatic arthritis	Phase I <a href="http://www.kadmon.com">www.kadmon.com</a>
LX2931 (S1P inhibitor)	Lexicon Pharmaceuticals The Woodlands, TX	rheumatoid arthritis	Phase II <a href="http://www.lexpharma.com">www.lexpharma.com</a>

## Autoimmune Arthritis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
M2951 (BTK inhibitor)	EMD Serono Rockland, MA	rheumatoid arthritis	Phase II <a href="http://www.emdserono.com">www.emdserono.com</a>
mavrilimumab (GM-CSF antagonist)	MedImmune Gaithersburg, MD	rheumatoid arthritis	Phase II <a href="http://www.medimmune.com">www.medimmune.com</a>
MEDI4920 (CD40 ligand inhibitor)	MedImmune Gaithersburg, MD	rheumatoid arthritis	Phase I <a href="http://www.medimmune.com">www.medimmune.com</a>
MORAb-022 (IgG1 mAb)	Eisai Woodcliff Lake, NJ	rheumatoid arthritis	Phase I <a href="http://www.eisai.com">www.eisai.com</a>
MPC-300-IV (rexlemestrocel-L; allogeneic mesenchymal precursor cells)	Mesoblast New York, NY	rheumatoid arthritis	Phase II <a href="http://www.mesoblast.com">www.mesoblast.com</a>
neihulizumab (P-selectin ligand protein inhibitor)	AbGenomics International Los Altos, CA	psoriatic arthritis	Phase II <a href="http://www.abgenomics.com">www.abgenomics.com</a>
olokizumab (anti-IL-6 mAb)	R-Pharm US Princeton, NJ	rheumatoid arthritis	Phase III <a href="http://www.rpharm-us.com">www.rpharm-us.com</a>
ONS-3010 (adalimumab biosimilar)	Oncobiologics Cranbury, NJ	rheumatoid arthritis	Phase I <a href="http://www.oncobiologics.com">www.oncobiologics.com</a>

## Autoimmune Arthritis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
<b>Orencia®</b> abatacept	Bristol-Myers Squibb Princeton, NJ	treatment-resistant active polyarticular juvenile idiopathic arthritis, psoriatic arthritis, early rheumatoid arthritis	Phase III <a href="http://www.bms.com">www.bms.com</a>
<b>Otezla®</b> apremilast	Celgene Summit, NJ	ankylosing spondylitis	Phase III <a href="http://www.celgene.com">www.celgene.com</a>
PF-06410293 (adalimumab biosimilar)	Pfizer New York, NY	rheumatoid arthritis	Phase III <a href="http://www.pfizer.com">www.pfizer.com</a>
PF-06438179 (infliximab biosimilar)	Pfizer New York, NY	rheumatoid arthritis	Phase III <a href="http://www.pfizer.com">www.pfizer.com</a>
PRTX-100 (Staphylococcal protein A)	Protalex Florham Park, NJ	rheumatoid arthritis	Phase I/II <a href="http://www.protalex.com">www.protalex.com</a>
<b>Ravax®</b> rheumatoid arthritis vaccine (IR-501)	Immune Response BioPharma Atlantic City, NJ	rheumatoid arthritis	Phase III <a href="http://www.immuneresponsebiopharma.com">www.immuneresponsebiopharma.com</a>
RG6125 (osteoblast cadherin inhibitor)	Roche Basel, Switzerland	rheumatoid arthritis	Phase I <a href="http://www.roche.com">www.roche.com</a>
SAN-300 (integrin alpha1-beta1 antagonist)	Valeant Pharmaceuticals Bridgewater, NJ	rheumatoid arthritis	Phase II <a href="http://www.valeant.com">www.valeant.com</a>



## Autoimmune Arthritis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
sarilumab (anti-IL-6R mAb)	Sanofi US Bridgewater, NJ	rheumatoid arthritis	application submitted <a href="http://www.sanofi.com">www.sanofi.com</a>
SB2 (infliximab biosimilar)	Merck Kenilworth, NJ Samsung Bioepis Incheon, South Korea	ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis	application submitted <a href="http://www.merck.com">www.merck.com</a> <a href="http://www.samsungbioepis.com">www.samsungbioepis.com</a>
<b>Simponi® Aria®</b> golimumab	Janssen Research & Development Raritan, NJ	ankylosing spondylitis (treatment-experienced), juvenile idiopathic arthritis, psoriatic arthritis	Phase III <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
sirukumab (IL-6 human mAb)	GlaxoSmithKline Research Triangle Park, NC Janssen Research & Development Raritan, NJ	rheumatoid arthritis	Phase III <a href="http://www.gsk.com">www.gsk.com</a> <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
SKI-O-703 (Syk kinase inhibitor)	Oscotec Chonan, South Korea	rheumatoid arthritis	Phase I
<b>Stelara®</b> ustekinumab	Janssen Research & Development Raritan, NJ	axial spondylitis	Phase III <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>

## Autoimmune Arthritis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
STI-002 (infliximab biobetter)	Mabtech Shanghai, China Sorrento Therapeutics San Diego, CA	rheumatoid arthritis	Phase III <a href="http://www.sorrentotherapeutics.com">www.sorrentotherapeutics.com</a>
TAK-020 (BTK inhibitor)	Takeda Pharmaceuticals Deerfield, IL	rheumatoid arthritis	Phase I <a href="http://www.takeda.com">www.takeda.com</a>
<b>Taltz</b> <sup>®</sup> ixekizumab	Eli Lilly Indianapolis, IN	radiographic axial spondyloarthritis	Phase III <a href="http://www.lilly.com">www.lilly.com</a>
VAL BRO 03	Valeant Pharmaceuticals Bridgewater, NJ	psoriatic arthritis	Phase III <a href="http://www.valeant.com">www.valeant.com</a>
VBP15 (glucocorticoid receptor agonist)	ReveraGen BioPharma Rockville, MD	rheumatoid arthritis	Phase I <a href="http://www.reveragen.com">www.reveragen.com</a>
VAY736 (BAFF-R receptor modulator)	Novartis Pharmaceuticals East Hanover, NJ	rheumatoid arthritis	Phase II <a href="http://www.novartis.com">www.novartis.com</a>
<b>Xeljanz</b> <sup>®</sup> tofacitinib	Pfizer New York, NY	juvenile idiopathic arthritis, psoriatic arthritis	Phase III <a href="http://www.pfizer.com">www.pfizer.com</a>

## Celiac Disease

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
AMG 714 (IL-15 inhibitor)	Celimmune Lebanon, NJ	diet non-responsive celiac disease	Phase II <a href="http://www.celimmune.com">www.celimmune.com</a>
IMGX003 (latiglutenase)	ImmunogenX Newport Beach, CA	celiac disease (Fast Track)	Phase II <a href="http://www.immunogenx.com">www.immunogenx.com</a>
INN-202 (larazotide acetate)	Innovate Biopharmaceuticals Raleigh, NC	celiac disease (Fast Track)	Phase II completed <a href="http://www.innovatebiopharma.com">www.innovatebiopharma.com</a>
RG7625 (cathepsin S inhibitor)	Roche Basel, Switzerland	celiac disease	Phase I <a href="http://www.roche.com">www.roche.com</a>
<b>Nexvax2</b> <sup>®</sup> HLA-DQ2 peptide vaccine	ImmusanT Cambridge, MA	celiac disease	Phase I <a href="http://www.immusant.com">www.immusant.com</a>

## Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
<b>Gilenya</b> <sup>®</sup> fingolimod	Novartis Pharmaceuticals East Hanover, NJ	chronic inflammatory demyelinating polyneuropathy	Phase III <a href="http://www.novartis.com">www.novartis.com</a>
<b>Hizentra</b> <sup>®</sup> immune globulin subcutaneous 20%	CSL Behring King of Prussia, PA	chronic inflammatory demyelinating polyradiculoneuropathy	Phase III <a href="http://www.cslobehring.com">www.cslobehring.com</a>

## Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
<b>Hyqvia® + Kiovia®</b> immune globulin infusion 10% (human) with recombinant human hyaluronidase ORPHAN DRUG	Shire Lexington, MA	chronic inflammatory demyelinating polyradiculoneuropathy	Phase III <a href="http://www.shire.com">www.shire.com</a>

## Dermatomyositis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
IMO-8400 (toll-like receptor antagonists)	Idera Pharmaceuticals Cambridge, MA	dermatomyositis	Phase II <a href="http://www.iderapharma.com">www.iderapharma.com</a>
<b>Resunab</b> ajulemic acid	Corbus Pharmaceuticals Norwood, MA	dermatomyositis	Phase II <a href="http://www.corbuspharma.com">www.corbuspharma.com</a>
siponimod (sphingosine-1-phosphate receptor modulator)	Novartis East Hanover, NJ	dermatomyositis, polymyositis	Phase II <a href="http://www.novartis.com">www.novartis.com</a>

## Diabetes

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
BIOD-123 (ultra-rapid-acting insulin)	Biodel Danbury, CT	type 1 diabetes	Phase II <a href="http://www.biodel.com">www.biodel.com</a>

## Diabetes

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
CLBS03 (Treg cell-based therapy) ORPHAN DRUG	Caladrius Biosciences Basking Ridge, NJ	type 1 diabetes	Phase II <a href="http://www.caladrius.com">www.caladrius.com</a>
Dance-501 (inhaled recombinant human insulin)	Dance Biopharma Brisbane, CA	type 1 diabetes	Phase II <a href="http://www.dancebiopharma.com">www.dancebiopharma.com</a>
<b>Diamyd</b> <sup>®</sup> autoimmune diabetes vaccine ORPHAN DRUG	Diamyd Medical Stockholm, Sweden University of Alabama at Birmingham Birmingham, AL	type 1 diabetes	Phase I <a href="http://www.diamyd.com">www.diamyd.com</a>
DV-100 (autologous dendritic cell immunotherapy) ORPHAN DRUG	DiaVacs Edgewater, NJ	type 1 diabetes	Phase I <a href="http://www.diaivacs.us.com">www.diaivacs.us.com</a>
<b>Farixga</b> <sup>®</sup> dapagliflozin	AstraZeneca Wilmington, DE	type 1 diabetes	Phase III <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
HDV insulin (hepatocyte directed vesicles)	Diasome Pharmaceuticals Cleveland, OH	type 1 diabetes	Phase II <a href="http://www.diasomepharmaceuticals.com">www.diasomepharmaceuticals.com</a>
IN-105 (insulin tregopil)	Biocon Bangalore, India	type 1 diabetes	Phase I/II <a href="http://www.biocon.com">www.biocon.com</a>

## Diabetes

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
insulin glargine biosimilar	Mylan Canonsburg, PA	type 1 diabetes	Phase III <a href="http://www.mylan.com">www.mylan.com</a>
insulin glargine biosimilar	Gan & Lee Pharmaceuticals Beijing, China	type 1 diabetes	Phase I <a href="http://www.ganlee.com">www.ganlee.com</a>
insulin/pramlintide combination	AstraZeneca Wilmington, DE Juvenile Diabetes Research Foundation New York, NY	type 1 diabetes	Phase I <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
<b>Invokana</b> <sup>®</sup> canagliflozin	Janssen Research & Development Raritan, NJ	type 1 diabetes	Phase II <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
<b>Jardiance</b> <sup>®</sup> empagliflozin	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT Eli Lilly Indianapolis, IN	type 1 diabetes	Phase III <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a> <a href="http://www.lilly.com">www.lilly.com</a>
LY900014 (glucose lowering drug)	Eli Lilly Indianapolis, IN	type 1 diabetes	Phase I completed <a href="http://www.lilly.com">www.lilly.com</a>
MER3001 (regulatory T-lymphocyte stimulant)	Mercia Pharma New York, NY	type 1 diabetes	Phase II <a href="http://www.merciapharma.com">www.merciapharma.com</a>
MK-1293 (insulin glargine biosimilar)	Merck Kenilworth, NJ	type 1 diabetes	application submitted <a href="http://www.merck.com">www.merck.com</a>

## Diabetes

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
MK-2640	Merck Kenilworth, NJ	type 1 diabetes	Phase I <a href="http://www.merck.com">www.merck.com</a>
NN1218 (insulin aspart faster-acting)	Novo Nordisk Plainsboro, NJ	type 1 diabetes	application submitted <a href="http://www.novonordisk.com">www.novonordisk.com</a>
NN1406	Novo Nordisk Plainsboro, NJ	type 1 diabetes	Phase I <a href="http://www.novonordisk.com">www.novonordisk.com</a>
NN1953 (oral insulin)	Novo Nordisk Plainsboro, NJ	type 1 diabetes	Phase II <a href="http://www.novonordisk.com">www.novonordisk.com</a>
NN9828 (anti-IL-21 GLP-1 mAb)	Novo Nordisk Plainsboro, NJ	type 1 diabetes	Phase II <a href="http://www.novonordisk.com">www.novonordisk.com</a>
ORMD-0801 (insulin oral)	Oramed Pharmaceuticals Jerusalem, Israel	type 1 diabetes	Phase II <a href="http://www.oramed.com">www.oramed.com</a>
otelixizumab (cluster of differentiation 3) ORPHAN DRUG	GlaxoSmithKline Research Triangle Park, NC	new onset type 1 diabetes	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
PF-06342674 (IL-7 receptor antagonist)	Pfizer New York, NY	type 1 diabetes	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>

## Diabetes

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
<b>Prolastin®-C</b> alpha-1-antitrypsin modified process	Grifols USA Los Angeles, CA	type 1 diabetes	Phase II <a href="http://www.grifolsusa.com">www.grifolsusa.com</a>
REMD-477 (GPCR antagonist)	REMD Biotherapeutics Camarillo, CA	type 1 diabetes	Phase I <a href="http://www.remdbio.com">www.remdbio.com</a>
<b>Ryzodeg®</b> insulin degludec/insulin aspart	Novo Nordisk Plainsboro, NJ	type 1 diabetes (pediatric)	Phase III completed <a href="http://www.novonordisk.com">www.novonordisk.com</a>
SAR342434 (insulin lispro)	Sanofi US Bridgewater, NJ	type 1 diabetes	Phase III <a href="http://www.sanofi.com">www.sanofi.com</a>
SAR440067 (LAPS insulin 115)	Sanofi US Bridgewater, NJ	type 1 diabetes	Phase I <a href="http://www.sanofi.com">www.sanofi.com</a>
sotagliflozin (oral SGLT-1&2 inhibitor)	Sanofi US Bridgewater, NJ	type 1 diabetes	Phase III <a href="http://www.sanofi.com">www.sanofi.com</a>
<b>Tanzeum®</b> albiglutide	GlaxoSmithKline Research Triangle Park, NC	type 1 diabetes	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
teplizumab (anti-CD3 mAb)	MacroGenics Rockville, MD	type 1 diabetes	Phase II <a href="http://www.macrogenics.com">www.macrogenics.com</a>
<b>Toujeo®</b> insulin glargine (300 units/mL)	Sanofi US Bridgewater, NJ	type 1 diabetes (pediatric)	Phase III <a href="http://www.sanofi.com">www.sanofi.com</a>



## Diabetes

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
VC-01 (pancreatic beta cell replacement)	ViaCyte San Diego, CA	type 1 diabetes	Phase I/II <a href="http://www.viacyte.com">www.viacyte.com</a>

## Glomerulonephritis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
ACH-4471 (Factor D inhibitor)	Achillion Pharmaceuticals New Haven, CT	glomerulonephritis	Phase I <a href="http://www.achillion.com">www.achillion.com</a>
<b>Benlysta</b> <sup>®</sup> belimumab (intravenous)	GlaxoSmithKline Research Triangle Park, NC	glomerulonephritis	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
OMS721 (MASP2 protein inhibitor)	Omeros Seattle, WA	glomerulonephritis,	Phase II <a href="http://www.omeros.com">www.omeros.com</a>

## Immune Thrombocytopenic Purpura

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
avatrombopag (thrombopoietin receptor agonist)	Eisai Woodcliff Lake, NJ	idiopathic thrombocytopenic purpura	Phase III <a href="http://www.eisai.com">www.eisai.com</a>
BI-655064 (CD40 antigen inhibitor)	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	immune thrombocytopenic purpura	Phase I completed <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>

## Immune Thrombocytopenic Purpura

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
fostamatinib (SYK kinase inhibitor) ORPHAN DRUG	Rigel Pharmaceuticals South San Francisco, CA	immune thrombocytopenic purpura	Phase III <a href="http://www.rigel.com">www.rigel.com</a>
PRTX-100 (Staphylococcal protein A)	Protalex Florham Park, NJ	immune thrombocytopenic purpura	Phase I/II <a href="http://www.protalex.com">www.protalex.com</a>

## Inflammatory Bowel Disease

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
ABBV-323 (CD40 antagonist)	AbbVie North Chicago, IL	Crohn's disease	Phase I <a href="http://www.abbvie.com">www.abbvie.com</a>
abrilumab (AMG 181) (alpha4/beta7 inhibitor)	Amgen Thousand Oaks, CA AstraZeneca Wilmington, DE	Crohn's disease, ulcerative colitis	Phase II <a href="http://www.amgen.com">www.amgen.com</a> <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
ABT-494 (JAK inhibitor)	AbbVie North Chicago, IL	Crohn's disease, ulcerative colitis	Phase II <a href="http://www.abbvie.com">www.abbvie.com</a>
<b>Alequel™</b> immune regulation therapy	Enzo Biochem New York, NY	Crohn's disease	Phase II <a href="http://www.enzo.com">www.enzo.com</a>

## Inflammatory Bowel Disease

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
alicaforsen (ICAM-1 antagonist)	Atlantic Healthcare Essex, United Kingdom Ionis Pharmaceuticals Carlsbad, CA	ulcerative colitis	Phase II completed <a href="http://www.atlantichc.com">www.atlantichc.com</a> <a href="http://www.ionispharma.com">www.ionispharma.com</a>
APD334 (S1P1 agonist)	Arena Pharmaceuticals San Diego, CA	ulcerative colitis	Phase II <a href="http://www.arenapharm.com">www.arenapharm.com</a>
AVX-470 (TNF inhibitor)	Avaxia Biologics Lexington, MA	ulcerative colitis	Phase I <a href="http://www.avaxiabiologics.com">www.avaxiabiologics.com</a>
bertilimumab (anti-eotaxin mAb)	Immune Pharmaceuticals New York, NY	ulcerative colitis	Phase II <a href="http://www.immunepharma.com">www.immunepharma.com</a>
BI-655066 (risankizumab)	AbbVie North Chicago, IL Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	active moderate to severe Crohn's disease	Phase II <a href="http://www.abbvie.com">www.abbvie.com</a> <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>
CCX507 (CCR9 receptor antagonist)	ChemoCentryx Mountain View, CA	ulcerative colitis	Phase I completed <a href="http://www.chemocentryx.com">www.chemocentryx.com</a>
<b>ChronoVax™</b> Crohn's disease vaccine (IR-777)	Immune Response Biopharma Atlantic City, NJ	Crohn's disease	Phase I <a href="http://www.immuneresponsebiopharma.com">www.immuneresponsebiopharma.com</a>

## Inflammatory Bowel Disease

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
<b>Dekavil</b> interleukin 10	Pfizer New York, NY	inflammatory bowel disease	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
dolcanatide (SP-333) (guanylate cyclase C agonist)	Synergy Pharmaceuticals New York, NY	ulcerative colitis	Phase I <a href="http://www.synergypharma.com">www.synergypharma.com</a>
<b>Entyvio®</b> vedolizumab subcutaneous	Takeda Pharmaceuticals Deerfield, IL	Crohn's disease, ulcerative colitis	Phase III <a href="http://www.takeda.com">www.takeda.com</a>
etrolizumab (humanized IgG1 mAb)	Genentech South San Francisco, CA	Crohn's disease, ulcerative colitis	Phase III <a href="http://www.gene.com">www.gene.com</a>
ETX201 (TNF receptor antagonist)	ETX Pharma Maryland	Crohn's disease	Phase I <a href="http://www.etxpharma.com">www.etxpharma.com</a>
filgotinib (JAK1 inhibitor)	Gilead Foster City, CA	Crohn's disease	Phase II <a href="http://www.gilead.com">www.gilead.com</a>
GS-5745 (MMP9 mAb inhibitor)	Gilead Sciences Foster City, CA	ulcerative colitis	Phase III <a href="http://www.gilead.com">www.gilead.com</a>
		Crohn's disease	Phase II <a href="http://www.gilead.com">www.gilead.com</a>
GSK2982772 (R1P1 kinase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	ulcerative colitis	Phase I <a href="http://www.gsk.com">www.gsk.com</a>

## Inflammatory Bowel Disease

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
GSK3179106 (RET kinase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	inflammatory bowel disease	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
<b>Humira®</b> adalimumab	AbbVie North Chicago, IL	ulcerative colitis (pediatric)	Phase III <a href="http://www.abbvie.com">www.abbvie.com</a>
<b>Humira®</b> adalimumab (new formulation)	AbbVie North Chicago, IL	Crohn's disease, ulcerative colitis	Phase III <a href="http://www.abbvie.com">www.abbvie.com</a>
INN-108	Innovate Biopharmaceuticals Raleigh, NC	ulcerative colitis	Phase I <a href="http://www.innovatebiopharma.com">www.innovatebiopharma.com</a>
IRT-103 (low-dose naltrexone)	Cytocom Orlando, FL	Crohn's disease	Phase II completed <a href="http://www.cytocom.com">www.cytocom.com</a>
JT02 (chemokine CXCL10 inhibitor)	JYANT Technologies Marietta, GA	inflammatory bowel disease	Phase II <a href="http://www.jyanttech.com">www.jyanttech.com</a>
KHK4083 (immunomodulator antibody)	Kyowa Kirin USA Princeton, NJ	ulcerative colitis	Phase II <a href="http://www.kyowa-kirin.com">www.kyowa-kirin.com</a>
<b>Lialda®</b> mesalazine controlled release	Shire Lexington, MA	ulcerative colitis (pediatric)	Phase III <a href="http://www.shire.com">www.shire.com</a>

## Inflammatory Bowel Disease

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
LT-02 (phosphatidyl choline controlled release)	Nestle Health Science Epalinges, Switzerland Prometheus Laboratories San Diego, CA	ulcerative colitis	Phase III <a href="http://www.nestlehealthscience.com">www.nestlehealthscience.com</a> <a href="http://www.prometheuslabs.com">www.prometheuslabs.com</a>
LY3074828 (IL-23 mAb)	Eli Lilly Indianapolis, IN	ulcerative colitis	Phase II <a href="http://www.lilly.com">www.lilly.com</a>
LYC-30937 (ATPase modulator)	Lycera Ann Arbor, MI	ulcerative colitis	Phase II <a href="http://www.lycera.com">www.lycera.com</a>
MEDI2070 (IL-23 mAb)	MedImmune Gaithersburg, MD	Crohn's disease	Phase II <a href="http://www.medimmune.com">www.medimmune.com</a>
mongersen (GED-0301) (Smad7 protein inhibitor)	Celgene Summit, NJ	Crohn's disease	Phase III <a href="http://www.celgene.com">www.celgene.com</a>
		ulcerative colitis	Phase II <a href="http://www.celgene.com">www.celgene.com</a>
MSC-100-IV (remestemcel-L; mesenchymal stem cells)	Mesoblast New York, NY	Crohn's disease	Phase III <a href="http://www.mesoblast.com">www.mesoblast.com</a>
MT-1303 (amiselimod)	Biogen Cambridge, MA	Crohn's disease	Phase II <a href="http://www.biogen.com">www.biogen.com</a>

## Inflammatory Bowel Disease

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
NN8555 (NK cell lectin-like-receptor subfamily K antagonist)	Janssen Research & Development Raritan, NJ	active Crohn's disease	Phase II completed <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
ONS-3010 (adalimumab biosimilar)	Oncobiologics Cranbury, NJ	Crohn's disease, ulcerative colitis	Phase I <a href="http://www.oncobiologics.com">www.oncobiologics.com</a>
<b>Otezla®</b> apremilast	Celgene Summit, NJ	ulcerative colitis	Phase II <a href="http://www.celgene.com">www.celgene.com</a>
ozanimod (S1P1 receptor agonist)	Celgene Summit, NJ	ulcerative colitis	Phase III <a href="http://www.celgene.com">www.celgene.com</a>
		Crohn's disease	Phase II <a href="http://www.celgene.com">www.celgene.com</a>
<b>Pentasa® Sachet</b> 2g extended release granule formulation	Ferring Pharmaceuticals Saint-Prex, Switzerland	ulcerative colitis	Phase III <a href="http://www.ferring.com">www.ferring.com</a>
PF-04236921 (IL-6 inhibitor)	Pfizer New York, NY	Crohn's disease	Phase II <a href="http://www.pfizer.com">www.pfizer.com</a>
PF-06480605	Pfizer New York, NY	Crohn's disease	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>

## Inflammatory Bowel Disease

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
PF-06651600	Pfizer New York, NY	Crohn's disease	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
PTG-100 (alpha4beta7 antagonist)	Protagonist Therapeutics Milpitas, CA	ulcerative colitis	Phase I <a href="http://www.protagonist-inc.com">www.protagonist-inc.com</a>
RG7880 (IL-22-Fc, UTTR1147A)	Genentech South San Francisco, CA	ulcerative colitis	Phase I <a href="http://www.gene.com">www.gene.com</a>
RHB-104 (clarithromycin/clofazimine/rifabutin) ORPHAN DRUG	RedHill Biopharma Tel-Aviv, Israel	Crohn's disease	Phase III <a href="http://www.redhillbio.com">www.redhillbio.com</a>
rifaximin DR (DNA-directed RNA polymerase inhibitor)	Salix Pharmaceuticals Raleigh, NC	Crohn's disease	Phase III <a href="http://www.salix.com">www.salix.com</a>
SB2 (infliximab biosimilar)	Merck Kenilworth, NJ Samsung Bioepis Incheon, South Korea	Crohn's disease, ulcerative colitis	application submitted <a href="http://www.merck.com">www.merck.com</a> <a href="http://www.samsungbioepis.com">www.samsungbioepis.com</a>
SER-287 (bacteria replacement)	Seres Therapeutics Cambridge, MA	ulcerative colitis	Phase I <a href="http://www.serestherapeutics.com">www.serestherapeutics.com</a>
SGM-1019 (metagenome modulator)	Second Genome South San Francisco, CA	inflammatory bowel disease	Phase I <a href="http://www.secondgenome.com">www.secondgenome.com</a>



## Inflammatory Bowel Disease

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
SGX203 (beclometasone oral) ORPHAN DRUG	Soligenix Princeton, NJ	Crohn's disease (pediatric) (Fast Track)	Phase II <a href="http://www.soligenix.com">www.soligenix.com</a>
SHP647 (mAdCAM inhibitor)	Shire Lexington, MA	Crohn's disease, ulcerative colitis	Phase II <a href="http://www.shire.com">www.shire.com</a>
<b>Simponi® Aria®</b> golimumab	Janssen Research & Development Raritan, NJ	ulcerative colitis (pediatric)	Phase I <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
<b>Stelara®</b> ustekinumab	Janssen Research & Development Raritan, NJ	Crohn's disease	application submitted <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
		ulcerative colitis	Phase III <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
TAK-828 (RORyt inverse agonist)	Takeda Pharmaceuticals Deerfield, IL	Crohn's disease	Phase I <a href="http://www.takeda.com">www.takeda.com</a>
TD-1473 (JAK inhibitor)	Theravance Biopharma South San Francisco, CA	ulcerative colitis	Phase I <a href="http://www.theravance.com">www.theravance.com</a>
VBP15 (glucocorticoid receptor antagonist)	ReveraGen BioPharma Rockville, MD	inflammatory bowel disease	Phase I <a href="http://www.reveragen.com">www.reveragen.com</a>
VBY-129 (cathepsin S inhibitor)	ViroBay Menlo Park, CA	Crohn's disease	Phase I <a href="http://www.virobayinc.com">www.virobayinc.com</a>

## Inflammatory Bowel Disease

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
<b>Xeljanz®</b> tofacitinib	Pfizer New York, NY	ulcerative colitis	Phase III <a href="http://www.pfizer.com">www.pfizer.com</a>

## Lupus

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
ABBV-084	AbbVie North Chicago, IL	systemic lupus erythematosus	Phase I <a href="http://www.abbvie.com">www.abbvie.com</a>
<b>Adcetris®</b> brentuximab vedotin	Seattle Genetics Bothell, WA	systemic lupus erythematosus	Phase II <a href="http://www.seattlegenetics.com">www.seattlegenetics.com</a>
AGS 009 (interferon-alpha neutralizing mAb)	Argos Therapeutics Durham, NC	systemic lupus erythematosus	Phase I completed <a href="http://www.argotherapeutics.com">www.argotherapeutics.com</a>
ALX-0061 (IL-6 receptor antagonist/modulator)	AbbVie North Chicago, IL Ablynx Ghent, Belgium	systemic lupus erythematosus	Phase II <a href="http://www.abbvie.com">www.abbvie.com</a> <a href="http://ablynx.com">ablynx.com</a>
AMG 557/MEDI5872 (B7RP1 mAb)	Amgen Thousand Oaks, CA MedImmune Gaithersburg, MD	systemic lupus erythematosus	Phase II <a href="http://www.amgen.com">www.amgen.com</a> <a href="http://www.medimmune.com">www.medimmune.com</a>

## Lupus

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
AMG 570/MEDI0700 (BAFF/B7RP1 bispecific mAb)	Amgen Thousand Oaks, CA MedImmune Gaithersburg, MD	systemic lupus erythematosus	Phase I <a href="http://www.amgen.com">www.amgen.com</a> <a href="http://www.medimmune.com">www.medimmune.com</a>
anifrolumab (interferon alpha beta receptor antagonist)	MedImmune Gaithersburg, MD	systemic lupus erythematosus (Fast Track)	Phase III <a href="http://www.medimmune.com">www.medimmune.com</a>
		lupus nephritis	Phase II <a href="http://www.medimmune.com">www.medimmune.com</a>
		systemic lupus erythematosus (subcutaneous treatment)	Phase I <a href="http://www.medimmune.com">www.medimmune.com</a>
atacept (anti-Blys/anti-APRIL fusion protein)	EMD Serono Rockland, MA	systemic lupus erythematosus	Phase II <a href="http://www.emdserono.com">www.emdserono.com</a>
baricitinib (JAK1/JAK2 inhibitor)	Incyte Wilmington, DE Eli Lilly Indianapolis, IN	systemic lupus erythematosus	Phase II <a href="http://www.incyte.com">www.incyte.com</a> <a href="http://www.lilly.com">www.lilly.com</a>

## Lupus

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
Benlysta® belimumab	GlaxoSmithKline Research Triangle Park, NC	systemic lupus erythematosus (subcutaneous)	Phase III <a href="http://www.gsk.com">www.gsk.com</a>
		lupus nephritis (intravenous)	Phase III <a href="http://www.gsk.com">www.gsk.com</a>
BI-655064 (CD40 antigen inhibitor)	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	lupus nephritis	Phase II <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>
BIIB059 (anti-BDCA2 mAb)	Biogen Cambridge, MA	systemic lupus erythematosus	Phase I <a href="http://www.biogen.com">www.biogen.com</a>
BIIB068 (BTK inhibitor)	Biogen Cambridge, MA	systemic lupus erythematosus	Phase I <a href="http://www.biogen.com">www.biogen.com</a>
blisibimod (B-cell activating factor inhibitor)	Anthera Pharmaceuticals Hayward, CA	systemic lupus erythematosus	Phase III <a href="http://www.anthera.com">www.anthera.com</a>
BMS-931699 (anti-CD28 mAb)	Bristol-Myers Squibb Princeton, NJ	systemic lupus erythematosus	Phase II <a href="http://www.bms.com">www.bms.com</a>
CC-220 (immunomodulatory therapeutic)	Celgene Summit, NJ	systemic lupus erythematosus	Phase II <a href="http://www.celgene.com">www.celgene.com</a>
cenerimod (lysosphingolipid receptor agonist)	Actelion Pharmaceuticals South San Francisco, CA	systemic lupus erythematosus	Phase II <a href="http://www.actelion.com">www.actelion.com</a>

## Lupus

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
dapirolizumab pegol (CD40 ligand inhibitor)	Biogen Cambridge, MA UCB Smyrna, GA	systemic lupus erythematosus	Phase II <a href="http://www.biogen.com">www.biogen.com</a> <a href="http://www.ucb.com">www.ucb.com</a>
<b>Gazyva</b> <sup>®</sup> obinutuzumab	Genentech South San Francisco, CA	lupus nephritis	Phase II <a href="http://www.gene.com">www.gene.com</a>
INV103 (immunomodulator)	Invion Brisbane, Australia	systemic lupus erythematosus	Phase II <a href="http://www.inviongroup.com">www.inviongroup.com</a>
ixazomib (proteasome inhibitor)	Takeda Pharmaceuticals Deerfield, IL	lupus nephritis	Phase I <a href="http://www.takeda.com">www.takeda.com</a>
JNJ-55920839 (immunomodulator)	Janssen Research & Development Raritan, NJ	systemic lupus erythematosus	Phase I <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
KD025 (ROCK2 inhibitor)	Kadmon New York, NY	systemic lupus erythematosus	Phase I <a href="http://www.kadmon.com">www.kadmon.com</a>
KPP203 (S1P receptor agonist)	Novartis Pharmaceuticals East Hanover, NJ	subacute cutaneous lupus erythematosus	Phase II <a href="http://www.novartis.com">www.novartis.com</a>
lulizumab pegol (CD28 antigen modulator)	Bristol-Myers Squibb Princeton, NJ	systemic lupus erythematosus	Phase II <a href="http://www.bms.com">www.bms.com</a>

## Lupus

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
<b>Lupuzor™</b> forigerimod	ImmuPharma London, United Kingdom	systemic lupus erythematosus (Fast Track)	Phase III <a href="http://www.immupharma.org">www.immupharma.org</a>
milatuzumab (anti-CD74 mAb)	Immunomedics Morris Plains, NJ	systemic lupus erythematosus	Phase I <a href="http://www.immunomedics.com">www.immunomedics.com</a>
M2951 (BTK inhibitor)	EMD Serono Rockland, MA	systemic lupus erythematosus	Phase I <a href="http://www.emdserono.com">www.emdserono.com</a>
MEDI0700 (BAFF/B7RP1 bispecific mAb)	MedImmune Gaithersburg, MD	systemic lupus erythematosus	Phase I <a href="http://www.medimmune.com">www.medimmune.com</a>
OMS721 (MASP2 protein inhibitor)	Omeros Seattle, WA	lupus nephritis	Phase II <a href="http://www.omeros.com">www.omeros.com</a>
<b>Orencia®</b> abatacept	Bristol-Myers Squibb Princeton, NJ	lupus nephritis	Phase III <a href="http://www.bms.com">www.bms.com</a>
PF-06650833	Pfizer New York, NY	lupus	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
PF-06823859	Pfizer New York, NY	lupus	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
<b>Resunab</b> ajulemic acid	Corbus Pharmaceuticals Norwood, MA	systemic lupus erythematosus	Phase II <a href="http://www.corbuspharma.com">www.corbuspharma.com</a>

## Lupus

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
RSLV-132 (B cell inhibitor)	Resolve Therapeutics Seattle, WA	systemic lupus erythematosus	Phase II <a href="http://www.resolvebio.com">www.resolvebio.com</a>
SM101 (human soluble Fc-gamma receptor IIB)	Shire Lexington, MA	systemic lupus erythematosus	Phase II <a href="http://www.shire.com">www.shire.com</a>
<b>Stelara®</b> ustekinumab	Janssen Research & Development Raritan, NJ	systemic lupus erythematosus	Phase II <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
voclosporin (calcineurin inhibitor)	Aurinia Pharmaceuticals Victoria, Canada	lupus nephritis (Fast Track)	Phase II <a href="http://www.auriniapharma.com">www.auriniapharma.com</a>
XmAb5871 (intravenous anti-CD19 mAb)	Xencor Monrovia, CA	systemic lupus erythematosus	Phase II <a href="http://www.xencor.com">www.xencor.com</a>

## Multiple Sclerosis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
ABT-555 (myelin protein stimulant)	AbbVie North Chicago, IL	multiple sclerosis	Phase I <a href="http://www.abbvie.com">www.abbvie.com</a>
ALKS 8700 (immunomodulator)	Alkermes Waltham, MA	multiple sclerosis	Phase III <a href="http://www.alkermes.com">www.alkermes.com</a>

## Multiple Sclerosis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
ARN-6039 (ROR $\gamma$ t inverse agonist)	Arrien Pharmaceuticals Salt Lake City, UT	multiple sclerosis	Phase I <a href="http://www.arrienpharma.com">www.arrienpharma.com</a>
AX-024 (Nck protein modulator/ T cell activation inhibitor)	Artax Biopharma Cambridge, MA	multiple sclerosis	Phase I <a href="http://www.artaxbiopharma.com">www.artaxbiopharma.com</a>
BIIB061 (oral remyelination)	Biogen Cambridge, MA	multiple sclerosis	Phase I <a href="http://www.biogen.com">www.biogen.com</a>
CHS-131 (PPAR-gamma selective modulator and partial agonist)	Coherus Biosciences Redwood City, CA	multiple sclerosis	Phase II <a href="http://www.intekrin.com">www.intekrin.com</a>
cladribine tablets (lymphocyte targeting agent)	EMD Serono Rockland, MA	relapsing-remitting multiple sclerosis (Fast Track)	Phase III <a href="http://www.emdserono.com">www.emdserono.com</a>
FLX-787 (TRP activator)	Flex Pharma Boston, MA	multiple sclerosis associated cramps, spasms and/or spasticity	Phase II <a href="http://www.flex-pharma.com">www.flex-pharma.com</a>
<b>Gilenya</b> <sup>®</sup> fingolimod ORPHAN DRUG	Novartis Pharmaceuticals East Hanover, NJ	multiple sclerosis (pediatric)	Phase III <a href="http://www.novartis.com">www.novartis.com</a>
GZ402668 (anti-CD52 mAb)	Genzyme Cambridge, MA	relapsing multiple sclerosis	Phase I <a href="http://www.genzyme.com">www.genzyme.com</a>



## Multiple Sclerosis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
Humira® adalimumab (new formulation)	AbbVie North Chicago, IL	multiple sclerosis	Phase III <a href="http://www.abbvie.com">www.abbvie.com</a>
laquinimod (neuron stimulant)	Teva Pharmaceutical North Wales, PA	relapsing remitting multiple sclerosis (Fast Track)	Phase III <a href="http://www.tevapharm.com">www.tevapharm.com</a>
		primary progressive multiple sclerosis (Fast Track)	Phase II <a href="http://www.tevapharm.com">www.tevapharm.com</a>
M2736 (ATX-MS-1467) (immune tolerizing agent)	EMD Serono Rockland, MA	multiple sclerosis	Phase II <a href="http://www.emdserono.com">www.emdserono.com</a>
masatinib (tyrosine kinase inhibitor)	AB Science USA Chatham, NJ	progressive forms of multiple sclerosis	Phase III <a href="http://www.ab-science.com">www.ab-science.com</a>
MN-166 (oral anti-inflammatory)	MediciNova La Jolla, CA National Institute of Neurological Disorders and Stroke Bethesda, MD	progressive multiple sclerosis (Fast Track)	Phase II <a href="http://www.medicinova.com">www.medicinova.com</a>
MRF-008 (guanabenz)	Myelin Repair Foundation Saratoga, CA National Institute of Neurological Disorders and Stroke Bethesda, MD	multiple sclerosis	Phase I <a href="http://www.myelinrepair.org">www.myelinrepair.org</a>

## Multiple Sclerosis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
multiple sclerosis therapeutic	Marathon Pharmaceuticals Northbrook, IL	multiple sclerosis	Phase I <a href="http://www.marathonpharma.com">www.marathonpharma.com</a>
<b>NeuroVax®</b> immunostimulant vaccine ORPHAN DRUG	Immune Response BioPharma Atlantic City, NJ	secondary progressive multiple sclerosis (Fast Track)	Phase II <a href="http://www.immuneresponsebiopharma.com">www.immuneresponsebiopharma.com</a>
ocrelizumab (CD20 antigen inhibitor)	Genentech South San Francisco, CA	primary progressive multiple sclerosis, relapsing remitting multiple sclerosis	application submitted <a href="http://www.gene.com">www.gene.com</a>
OMB157	Novartis Pharmaceuticals East Hanover, NJ	relapsing multiple sclerosis	in clinical trials <a href="http://www.novartis.com">www.novartis.com</a>
opicinumab (anti-LINGO)	Biogen Cambridge, MA	multiple sclerosis	Phase II <a href="http://www.biogen.com">www.biogen.com</a>
ozanimod (S1P1 receptor agonist)	Celgene Summit, NJ	relapsing multiple sclerosis	Phase III <a href="http://www.celgene.com">www.celgene.com</a>
PF530 (interferon beta-1b biosimilar)	Pfenex San Diego, CA	multiple sclerosis	Phase I <a href="http://www.pfenex.com">www.pfenex.com</a>
ponesimod (S1P1 receptor agonist)	Actelion Pharmaceuticals South San Francisco, CA	multiple sclerosis	Phase III <a href="http://www.actelion.com">www.actelion.com</a>

## Multiple Sclerosis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
<b>Raxone®</b> idebenone	Santhera Pharmaceuticals Liestal, Switzerland National Institutes of Health Bethesda, MD	primary progressive multiple sclerosis	Phase II <a href="http://www.santhera.com">www.santhera.com</a>
rHlgM22 (remyelinating antibody)	Acorda Therapeutics Ardsley, NY	acute relapsing multiple sclerosis	Phase I <a href="http://www.acorda.com">www.acorda.com</a>
RPI-78M (nicotinic receptor antagonist) ORPHAN DRUG	Nutra Pharma Coral Springs, FL	multiple sclerosis	Phase I completed <a href="http://www.nutrapharma.com">www.nutrapharma.com</a>
RTL-1000 (T lymphocyte modulator) ORPHAN DRUG	Artielle ImmunoTherapeutics San Mateo, CA	multiple sclerosis	Phase I completed <a href="http://www.artielle.com">www.artielle.com</a>
siponimod (sphingosine-1-phosphate receptor modulator)	Novartis East Hanover, NJ	secondary progressive multiple sclerosis	Phase III <a href="http://www.novartis.com">www.novartis.com</a>
<b>Tcelna®</b> imilecleucel-T	Opexa Therapeutics The Woodlands, TX	secondary progressive multiple sclerosis (Fast Track)	Phase II <a href="http://www.opexatherapeutics.com">www.opexatherapeutics.com</a>
TG-1101 (ublituximab)	TG Therapeutics New York, NY	multiple sclerosis	Phase II <a href="http://www.tgtherapeutics.com">www.tgtherapeutics.com</a>

## Multiple Sclerosis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
VBP15 (glucocorticoid receptor agonist)	ReveraGen BioPharma Rockville, MD	multiple sclerosis	Phase I <a href="http://www.reveragen.com">www.reveragen.com</a>

## Myasthenia Gravis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
<b>Benlysta</b> <sup>®</sup> belimumab (intravenous)	GlaxoSmithKline Research Triangle Park, NC	myasthenia gravis	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
CFZ533 (CD40 antigen inhibitor)	Novartis Pharmaceuticals East Hanover, NJ	severe myasthenia gravis	Phase II <a href="http://www.novartis.com">www.novartis.com</a>
<b>Firdapse</b> <sup>®</sup> amifampridine	Catalyst Pharmaceuticals Coral Gables, FL	myasthenia gravis	Phase II completed <a href="http://www.catalystpharma.com">www.catalystpharma.com</a>
<b>Gamunex</b> <sup>®</sup> -C immune globulin injection (human), 10% caprylate/chromatography purified	Grifols USA Los Angeles, CA	generalized myasthenia gravis	Phase II <a href="http://www.grifolsusa.com">www.grifolsusa.com</a>
<b>Soliris</b> <sup>®</sup> eculizumab ORPHAN DRUG	Alexion Pharmaceuticals New Haven, CT	refractory myasthenia gravis	Phase III <a href="http://www.alexion.com">www.alexion.com</a>

## Neuromyelitis Optica

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
inebilizumab (MEDI-551) (anti-CD19 mAb) ORPHAN DRUG	MedImmune Gaithersburg, MD	neuromyelitis optica	Phase II <a href="http://www.medimmune.com">www.medimmune.com</a>
neuromyelitis optica therapeutic	Marathon Pharmaceuticals Northbrook, IL	neuromyelitis optica	Phase II <a href="http://www.marathonpharma.com">www.marathonpharma.com</a>
SA237/RG6168 (anti-IL-6 receptor humanized mAb)	Chugai Pharma USA Berkeley Heights, NJ Roche Basel, Switzerland	neuromyelitis optica	Phase III <a href="http://www.chugai-pharm.com">www.chugai-pharm.com</a> <a href="http://www.roche.com">www.roche.com</a>
SHP616 (complement C1 inhibitor)	Shire Lexington, MA	neuromyelitis optica	Phase I <a href="http://www.shire.com">www.shire.com</a>
<b>Soliris®</b> eculizumab ORPHAN DRUG	Alexion Pharmaceuticals New Haven, CT	relapsing neuromyelitis optica spectrum disorder	Phase III <a href="http://www.alexion.com">www.alexion.com</a>

## Pemphigoid/Pemphigus

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
bertilimumab (anti-eotaxin mAb)	Immune Pharmaceuticals New York, NY	bullous pemphigoid	Phase II <a href="http://www.immunepharma.com">www.immunepharma.com</a>

## Pemphigoid/Pemphigus

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
PRN1008 (BTK inhibitor)	Principia Biopharma South San Francisco, CA	pemphigus vulgaris	Phase II <a href="http://www.principiabio.com">www.principiabio.com</a>
<b>Rituxin®</b> rituximab	Genentech South San Francisco, CA	pemphigus vulgaris	Phase III <a href="http://www.roche.com">www.roche.com</a>
TNT009 (complement C1s inhibitor)	True North Therapeutics South San Francisco, CA	bullous pemphigoid	Phase I <a href="http://www.truenorthrx.com">www.truenorthrx.com</a>
VAY736 (BAFF-R receptor modulator)	Novartis East Hanover, NJ	pemphigus vulgaris	Phase II <a href="http://www.novartis.com">www.novartis.com</a>

## Primary Biliary Cholangitis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
LJN452 (farnesoid X-activated receptor agonist)	Novartis Pharmaceuticals East Hanover, NJ	primary biliary cholangitis	Phase II <a href="http://www.novartis.com">www.novartis.com</a>
MBX-8025 (PPAR-delta agonist)	CymaBay Therapeutics Newark, CA	primary biliary cholangitis	Phase II <a href="http://www.cymabay.com">www.cymabay.com</a>
SHP625 (sodium-bile acid cotransporter inhibitor)	Shire Lexington, MA	primary biliary cholangitis	Phase II <a href="http://www.shire.com">www.shire.com</a>

## Primary Biliary Cholangitis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
ursodeoxycholic acid	Retrophin San Diego, CA	primary biliary cholangitis	in clinical trials <a href="http://www.retrophin.com">www.retrophin.com</a>

## Psoriasis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
122-0551 foam	Therapeutics San Diego, CA	plaque psoriasis	Phase III <a href="http://www.therapeuticsinc.com">www.therapeuticsinc.com</a>
ABP 501 (adalimumab biosimilar)	Amgen Thousand Oaks, CA	plaque psoriasis	application submitted <a href="http://www.amgen.com">www.amgen.com</a>
ALX-0761 (M1095) (anti-IL-17 A/F nanobody)	Ablynx Ghent, Belgium EMD Serono Rockland, MA	psoriasis	Phase I <a href="http://www.ablynx.com">www.ablynx.com</a> <a href="http://www.emdserono.com">www.emdserono.com</a>
ARN-6039 (RORyt inverse agonist)	Arrien Pharmaceuticals Salt Lake City, UT	psoriasis	Phase I <a href="http://www.arrienpharma.com">www.arrienpharma.com</a>
AST-005 (tumour necrosis factor modulator)	Exicure Skokie, IL	psoriasis	Phase I <a href="http://www.exicuretx.com">www.exicuretx.com</a>

## Psoriasis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
BAX2200/CHS-0214 (etanercept biosimilar)	Shire Lexington, MA Coherus Biosciences Redwood City, CA	plaque psoriasis	Phase III <a href="http://www.shire.com">www.shire.com</a> <a href="http://www.coherus.com">www.coherus.com</a>
BAX2923/M923 (adalimumab biosimilar)	Shire Lexington, MA Momenta Pharmaceuticals Cambridge, MA	plaque psoriasis	Phase III <a href="http://www.shire.com">www.shire.com</a> <a href="http://www.momentapharma.com">www.momentapharma.com</a>
bertilimumab (anti-eotaxin mAb)	Immune Pharmaceuticals New York, NY	psoriasis	Phase II <a href="http://www.immunepharma.com">www.immunepharma.com</a>
BI-655066 (risankizumab)	AbbVie North Chicago, IL Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	moderate to severe chronic plaque psoriasis	Phase III <a href="http://www.abbvie.com">www.abbvie.com</a> <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>
BMS-986020 (LPA1 receptor antagonist)	Bristol-Myers Squibb Princeton, NJ	psoriasis	Phase I <a href="http://www.bms.com">www.bms.com</a>
BMS-986165	Bristol-Myers Squibb Princeton, NJ	plaque psoriasis	Phase I <a href="http://www.bms.com">www.bms.com</a>



## Psoriasis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
brodalumab (IL-17R mAb)	AstraZeneca Wilmington, DE Valeant Pharmaceuticals Bridgewater, NJ	plaque psoriasis	application submitted <a href="http://www.astrazeneca.com">www.astrazeneca.com</a> <a href="http://www.valeant.com">www.valeant.com</a>
CF101 (adenosine A3 receptor agonist)	Can-Fite BioPharma Petah-Tikva, Israel	psoriasis	Phase III <a href="http://www.canfite.com">www.canfite.com</a>
CHS-1420 (adalimumab biosimilar)	Coherus Biosciences Redwood City, CA	plaque psoriasis	Phase III <a href="http://www.coherus.com">www.coherus.com</a>
<b>Cimzia</b> <sup>®</sup> certolizumab pegol	UCB Smyrna, GA	plaque psoriasis	Phase III <a href="http://www.ucb.com">www.ucb.com</a>
CJM112 (IL-17 inhibitor)	Novartis Pharmaceuticals East Hanover, NJ	chronic plaque psoriasis	Phase I/II completed <a href="http://www.novartis.com">www.novartis.com</a>
CT327 (TrkA receptor inhibitor)	Creabilis Therapeutics Canterbury, United Kingdom	plaque psoriasis	Phase II completed <a href="http://www.creabilis-sa.com">www.creabilis-sa.com</a>
dalazatide (Kv1.3 potassium channel inhibitor)	Kineta Seattle, WA	plaque psoriasis	Phase I completed <a href="http://www.kineta.bio">www.kineta.bio</a>
DFD-06	Promius Pharma Princeton, NJ	plaque psoriasis	Phase III <a href="http://www.promiuspharma.com">www.promiuspharma.com</a>

## Psoriasis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
Enbrel® etanercept	Amgen Thousand Oaks, CA	plaque psoriasis (pediatric)	application submitted <a href="http://www.amgen.com">www.amgen.com</a>
GP2015 (etanercept biosimilar)	Sandoz Holzkirchen, Germany	plaque psoriasis	application submitted <a href="http://www.sandozbiosimilars.com">www.sandozbiosimilars.com</a>
GP2017 (adalimumab biosimilar)	Sandoz Holzkirchen, Germany	plaque psoriasis	Phase III <a href="http://www.sandoz-biosimilars.com">www.sandoz-biosimilars.com</a>
GR-MD-02 (galectin 3 inhibitor)	Galectin Therapeutics Norcross, GA	moderate to severe plaque psoriasis	Phase II <a href="http://www.galectintherapeutics.com">www.galectintherapeutics.com</a>
GSK2894512 (non-steroidal anti-inflammatory)	GlaxoSmithKline Research Triangle Park, NC	plaque psoriasis	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
GSK2981278 (ROR gamma inverse agonist)	GlaxoSmithKline Research Triangle Park, NC	plaque psoriasis	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
GSK2982772 (RIP1 kinase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	psoriasis	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
guselkumab (IL-23 subunit p19 inhibitor)	Janssen Research & Development Raritan, NJ	moderate to severe plaque psoriasis, pustular psoriasis, erythrodermic psoriasis	Phase III <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>

## Psoriasis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
IDP-118 (tazarotene/ulobetasol)	Valeant Pharmaceuticals Bridgewater, NJ	plaque psoriasis	Phase II <a href="http://www.valeant.com">www.valeant.com</a>
IDP-122 (steroid receptor agonist)	Valeant Pharmaceuticals Bridgewater, NJ	plaque psoriasis	Phase III <a href="http://www.valeant.com">www.valeant.com</a>
JNJ-38518168 (histamine H4 receptor antagonist)	Janssen Research & Development Raritan, NJ	plaque psoriasis	Phase II <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
KD025 (ROCK2 inhibitor)	Kadmon New York, NY	psoriasis vulgaris	Phase II <a href="http://www.kadmon.com">www.kadmon.com</a>
M518101 (phosphoric diester hydrolase inhibitor)	Maruho Osaka, Japan	plaque psoriasis	Phase III <a href="http://www.maruho.co.jp">www.maruho.co.jp</a>
MABp1 (anti-IL-1-alpha mAb)	XBiotech Austin, TX	plaque psoriasis	Phase II <a href="http://www.xbiotech.com">www.xbiotech.com</a>
MK-3222 (tildrakizumab)	Merck Kenilworth, NJ	plaque psoriasis	Phase III <a href="http://www.merck.com">www.merck.com</a>
MSB 11022 (adalimumab biosimilar)	EMD Serono Rockland, MA	chronic plaque psoriasis	Phase III <a href="http://www.emdserono.com">www.emdserono.com</a>

## Psoriasis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
NIA-114 (GPR109A/GPR109B receptor agonist)	Niadyne Pharma Fort Worth, TX	plaque psoriasis	in clinical trials <a href="http://www.niadynepharma.com">www.niadynepharma.com</a>
ONS-3010 (adalimumab biosimilar)	Oncobiologics Cranbury, NJ	psoriasis	Phase I <a href="http://www.oncobiologics.com">www.oncobiologics.com</a>
PF-06700841	Pfizer New York, NY	psoriasis	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
PH-10 (rose bengal sodium)	Provectus Biopharmaceuticals Knoxville, TN	psoriasis	Phase II <a href="http://www.pvct.com">www.pvct.com</a>
<b>Prurisol</b> abacavir	Cellceutix Beverly, MA	psoriasis	Phase II <a href="http://www.cellceutix.com">www.cellceutix.com</a>
PRX003 (cell adhesion molecule inhibitor)	Prothena Biosciences South San Francisco, CA	psoriasis	Phase I <a href="http://www.prothena.com">www.prothena.com</a>
santalum album cream	Santalix Healthcare San Antonio, TX	psoriasis	Phase II
SB2 (infliximab biosimilar)	Merck Kenilworth, NJ Samsung Bioepis Incheon, South Korea	plaque psoriasis	application submitted <a href="http://www.merck.com">www.merck.com</a> <a href="http://www.samsungbioepis.com">www.samsungbioepis.com</a>

## Psoriasis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
<b>Sernivo™</b> betamethasone dipropionate	Promius Pharma Princeton, NJ	plaque psoriasis (adolescents)	Phase III <a href="http://www.promiuspharma.com">www.promiuspharma.com</a>
<b>Topicort® Topical Spray</b> desoximetasone topical	Taro Pharmaceuticals USA Hawthorne, NY	plaque psoriasis (pediatric)	Phase III <a href="http://www.taro.com">www.taro.com</a>
VTP-43742 (ROR-gamma inhibitor)	Vitae Pharmaceuticals Fort Washington, PA	psoriasis	Phase II <a href="http://www.vitraepharma.com">www.vitraepharma.com</a>
<b>Zorcell™</b> psoriasis vaccine (IR-502)	Immune Response BioPharma Atlantic City, NJ	plaque psoriasis	Phase II <a href="http://www.immuneresponsebiopharma.com">www.immuneresponsebiopharma.com</a>
ZPL-389 (histamine H4 receptor antagonist)	Ziarco Pharma Sandwich, United Kingdom	plaque psoriasis	Phase II <a href="http://www.ziarcopharma.com">www.ziarcopharma.com</a>

## Scleroderma

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
ACER-003 (free radical inhibitor)	Acer Therapeutics Cambridge, MA	systemic scleroderma	Phase II <a href="http://www.acertx.com">www.acertx.com</a>
<b>Actemra®</b> tocilizumab	Genentech South San Francisco, CA	systemic sclerosis	Phase III <a href="http://www.gene.com">www.gene.com</a>

## Scleroderma

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
<b>Adempas®</b> riociguat ORPHAN DRUG	Bayer HealthCare Pharmaceuticals Parsippany, NJ	systemic scleroderma	Phase II <a href="http://www.bayer.pharma.com">www.bayer.pharma.com</a>
ARG201 (immunomodulator) ORPHAN DRUG	arGentis Pharmaceuticals Collierville, TN	diffuse systemic scleroderma	Phase II <a href="http://www.argentirx.com">www.argentirx.com</a>
C 82 (CBP/ $\beta$ -catenin complex inhibitor)	PRISM Pharma Yokohama, Japan	scleroderma	Phase I/II
ECCS-50 (adipose-derived stem and regenerative cell therapy) ORPHAN DRUG	Cytori Therapeutics San Diego, CA	scleroderma-associated hand dysfunction	Phase III <a href="http://www.cytori.com">www.cytori.com</a>
GSK2330811 (oncostatin M mAb)	GlaxoSmithKline Research Triangle Park, NC	systemic scleroderma	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
KD025 (ROCK2 inhibitor)	Kadmon New York, NY	scleroderma	Phase I <a href="http://www.kadmon.com">www.kadmon.com</a>
MRG-201 (microRNA modulator)	miRagen Therapeutics Boulder, CO	cutaneous scleroderma	Phase I <a href="http://www.miragentherapeutics.com">www.miragentherapeutics.com</a>
<b>Ofev®</b> nintedanib	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	scleroderma-related lung fibrosis	Phase III <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>

## Scleroderma

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
pomalidomide	Celgene Summit, NJ	systemic scleroderma-related lung disease	Phase II <a href="http://www.celgene.com">www.celgene.com</a>
<b>Resunab</b> ajulemic acid	Corbus Pharmaceuticals Norwood, MA	systemic sclerosis	Phase II <a href="http://www.corbuspharma.com">www.corbuspharma.com</a>
SAR100842 (LPA1 receptor antagonist)	Sanofi US Bridgewater, NJ	systemic sclerosis	Phase II <a href="http://www.sanofi.com">www.sanofi.com</a>

## Sjögren's Syndrome

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
AMG 557/MEDI5872 (B7RP1 mAb)	Amgen Thousand Oaks, CA MedImmune Gaithersburg, MD	primary Sjögren's syndrome	Phase II <a href="http://www.amgen.com">www.amgen.com</a> <a href="http://www.medimmune.com">www.medimmune.com</a>
<b>Benlysta® + Rituxan®</b> belimumab (subcutaneous) + rituximab	GlaxoSmithKline Research Triangle Park, NC	Sjögren's syndrome	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
BIIB063 (anti-CD40)	Biogen Cambridge, MA	Sjögren's syndrome	Phase I <a href="http://www.biogen.com">www.biogen.com</a>
CFZ533 (CD40 antigen inhibitor)	Novartis Pharmaceuticals East Hanover, NJ	primary Sjögren's syndrome	Phase II <a href="http://www.novartis.com">www.novartis.com</a>

## Sjögren's Syndrome

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
GSK2618960 (IL-7 receptor mAb)	GlaxoSmithKline Research Triangle Park, NC	Sjögren's syndrome	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
LY3090106	Eli Lilly Indianapolis, IN	Sjögren's syndrome	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
MEDI4920 (CD40 ligand inhibitor)	MedImmune Gaithersburg, MD	primary Sjögren's syndrome	Phase I <a href="http://www.medimmune.com">www.medimmune.com</a>
RG7625 (cathepsin S inhibitor)	Roche Basel, Switzerland	Sjögren's syndrome	Phase II <a href="http://www.roche.com">www.roche.com</a>
RSLV-132 (B cell inhibitor)	Resolve Therapeutics Seattle, WA	Sjögren's syndrome	Phase II <a href="http://www.resolvebio.com">www.resolvebio.com</a>

## Other Autoimmune Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
<b>Actemra</b> <sup>®</sup> tocilizumab	Genentech South San Francisco, CA	giant cell arteritis	Phase III <a href="http://www.gene.com">www.gene.com</a>
ALXN1007	Alexion Pharmaceuticals New Haven, CT	antiphospholipid syndrome	Phase II <a href="http://www.alexion.com">www.alexion.com</a>



## Other Autoimmune Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
ARA 290 (erythropoietin receptor agonist) ORPHAN DRUG	Araim Pharmaceuticals Tarrytown, NY	sarcoidosis pain (Fast Track)	Phase II <a href="http://www.araimpharma.com">www.araimpharma.com</a>
CFZ533 (CD40 antigen inhibitor)	Novartis Pharmaceuticals East Hanover, NJ	Graves disease	Phase II <a href="http://www.novartis.com">www.novartis.com</a>
CTP-543 (JAK1/JAK2 inhibitor)	Concert Pharmaceuticals Lexington, MA	alopecia areata	Phase I <a href="http://www.concertpharma.com">www.concertpharma.com</a>
<b>Firdapse®</b> amifampridine ORPHAN DRUG	Catalyst Pharmaceuticals Coral Gables, FL	Lambert-Eaton myasthenic syndrome (Breakthrough Therapy)	Phase III <a href="http://www.catalystpharma.com">www.catalystpharma.com</a>
fostamatinib (SYK kinase inhibitor)	Rigel Pharmaceuticals South San Francisco, CA	autoimmune hemolytic anemia	Phase II <a href="http://www.rigel.com">www.rigel.com</a>
LEO 124249 ointment	LEO Pharma Parsippany, NJ	alopecia areata	Phase II <a href="http://www.leo-pharma.com">www.leo-pharma.com</a>
<b>Nucala®</b> mepolizumab ORPHAN DRUG	GlaxoSmithKline Research Triangle Park, NC	eosinophilic granulomatosis with polyangiitis (Churg-Strauss syndrome)	Phase III <a href="http://www.gsk.com">www.gsk.com</a>
<b>Optiquel™</b>	Enzo Biochem New York, NY	autoimmune uveitis	Phase I <a href="http://www.enzo.com">www.enzo.com</a>

## Other Autoimmune Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
<b>Otezla®</b> apremilast	Celgene Summit, NJ	Behcet's disease	Phase III <a href="http://www.celgene.com">www.celgene.com</a>
<b>Scenese®</b> afamelanotide	Clinuvel Pharmaceuticals New York, NY	vitiligo	Phase II <a href="http://www.clinuvel.com">www.clinuvel.com</a>
sirukumab (IL-6 human mAb)	GlaxoSmithKline Research Triangle Park, NC	giant cell arteritis	Phase III <a href="http://www.gsk.com">www.gsk.com</a>
sPIF (preimplantation factor)	BioIncept Cherry Hill, NJ University of Miami Miami, Florida	autoimmune hepatitis (Fast Track)	Phase I <a href="http://www.bioincept.com">www.bioincept.com</a>
teprotumumab (RV001) (IGR-1 receptor antagonist) ORPHAN DRUG	River Vision Development New York, NY	Graves ophthalmopathy	Phase II
topical ruxolitinib (JAK inhibitor)	Incyte Wilmington, DE	alopecia areata	Phase II <a href="http://www.incyte.com">www.incyte.com</a>
TNT009 (complement C1s inhibitor) ORPHAN DRUG	True North Therapeutics South San Francisco, CA	cold agglutinin disease, warm autoimmune hemolytic anemia	Phase I <a href="http://www.truenorthrx.com">www.truenorthrx.com</a>
XmAb5871 (anti-CD19 mAb intravenous)	Xencor Monrovia, CA	IgG4-related diseases	Phase II <a href="http://www.xencor.com">www.xencor.com</a>

## Non-Specific Autoimmune Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
AC0058TA (BTK inhibitor)	ACEA Biosciences San Diego, CA	autoimmune diseases	Phase I <a href="http://www.aceabio.com">www.aceabio.com</a>
antibody therapeutic (immunomodulator)	Merck Kenilworth, NJ Xencor Monrovia, CA	autoimmune diseases	Phase I <a href="http://www.merck.com">www.merck.com</a> <a href="http://www.xencor.com">www.xencor.com</a>
BTK inhibitor	AbbVie North Chicago, IL	autoimmune diseases	Phase I <a href="http://www.abbvie.com">www.abbvie.com</a>
BTK inhibitor	Eli Lilly Indianapolis, IN	autoimmune diseases	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
DV1179 (TLR 7/9 Inhibitor)	Dynavax Technologies Berkeley, CA	autoimmune diseases	Phase I <a href="http://www.dynavax.com">www.dynavax.com</a>
GDC-0853 (BTK inhibitor)	Genentech South San Francisco, CA	autoimmune diseases	Phase I <a href="http://www.gene.com">www.gene.com</a>
GSK2831781 (LAG3 protein mAb)	GlaxoSmithKline Research Triangle Park, NC	autoimmune diseases	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
IMO-9200 (toll-like receptor antagonist)	Idera Pharmaceuticals Cambridge, MA	autoimmune diseases	Phase I completed <a href="http://www.iderapharma.com">www.iderapharma.com</a>

## Non-Specific Autoimmune Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
JNJ-61178104 (inflammation mediator modulator)	Janssen Research & Development Raritan, NJ	autoimmune diseases	Phase I <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
M281 (anti-FcRn antibody)	Momenta Pharmaceuticals Cambridge, MA	autoimmune diseases	Phase I <a href="http://www.momentapharma.com">www.momentapharma.com</a>
MGD010 (CD32B and CD79B modulator)	MacroGenics Rockville, MD Takeda Pharmaceuticals	autoimmune diseases	Phase I <a href="http://www.macrogenics.com">www.macrogenics.com</a> <a href="http://www.takeda.com">www.takeda.com</a>
RG7625 (cathepsin S antagonist)	Roche Basel, Switzerland	autoimmune diseases	Phase II <a href="http://www.roche.com">www.roche.com</a>
RG7845 (BTK inhibitor)	Roche Basel, Switzerland	autoimmune diseases	Phase I <a href="http://www.roche.com">www.roche.com</a>
STI-003 (basiliximab biobetter) (anti-CD 25 mAb)	Sorrento Therapeutics San Diego, CA	autoimmune diseases	Phase II <a href="http://www.sorrentotherapeutics.com">www.sorrentotherapeutics.com</a>
tyrosine kinase 2 inhibitor (TYK2 inhibitor)	Bristol-Myers Squibb Princeton, NJ	autoimmune diseases	Phase I <a href="http://www.bms.com">www.bms.com</a>
VTP-43742 (ROR-gamma inhibitor)	Vitae Pharmaceuticals Fort Washington, PA	autoimmune diseases	Phase I <a href="http://www.vitaepharma.com">www.vitaepharma.com</a>

## Non-Specific Autoimmune Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
XmAb5981 (anti-CD19 mAb subcutaneous)	Xencor Monrovia, CA	autoimmune diseases	Phase I <a href="http://www.xencor.com">www.xencor.com</a>

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 August 12, 2016.** 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](http://www.clinicaltrials.gov). The entire series of *Medicines in Development* is available on PhRMA's website, [www.phrma.org](http://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).

**Breakthrough Therapy**—Upon request by a sponsor, the FDA can grant this designation to expedite the development and review of a drug or biologic intended, alone or in combination with one or more other drugs, to treat a serious or life threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically-significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug or biologic is designated as a breakthrough therapy, the FDA will expedite the development and review. With this designation, all Fast Track features convey to the medicine.

**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 fewer than 200,000 people in the United States, or that affects more than 200,000 persons but is not expected to recover the costs of its development and marketing.

**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.