

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 www.abbvie.com
ABP 501 (adalimumab biosimilar)	Amgen Thousand Oaks, CA	rheumatoid arthritis	application submitted www.amgen.com
ABP 798 (rituximab biosimilar)	Amgen Thousand Oaks, CA	rheumatoid arthritis	Phase III www.amgen.com
ABT-122 (IL-17 / TNF-alpha inhibitor)	AbbVie North Chicago, IL	psoriatic arthritis, rheumatoid arthritis	Phase II completed www.abbvie.com
ABT-494 (JAK inhibitor)	AbbVie North Chicago, IL	rheumatoid arthritis	Phase III www.abbvie.com
acalabrutinib (BTK inhibitor)	Acerta Pharma Oss, Netherlands	rheumatoid arthritis	Phase II
Actemra® tocilizumab	Genentech South San Francisco, CA	early rheumatoid arthritis	Phase III www.gene.com
ALX-0061 (IL-6 receptor antagonist/modulator)	AbbVie North Chicago, IL Ablynx Ghent, Belgium	rheumatoid arthritis	Phase II www.abbvie.com ablynx.com

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

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

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

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GP2013 (rituximab biosimilar)	Sandoz Holzkirchen, Germany	rheumatoid arthritis	Phase II www.sandoz-biosimilars.com
GP2015 (etanercept biosimilar)	Sandoz Holzkirchen, Germany	ankylosing spondylitis, juvenile rheumatoid arthritis, psoriatic arthritis, rheumatoid arthritis	application submitted www.sandozbiosimilars.com
GP2017 (adalimumab biosimilar)	Sandoz Holzkirchen, Germany	rheumatoid arthritis	Phase III www.sandoz-biosimilars.com
GS-4059 (BTK inhibitor)	Gilead Sciences Foster City, CA	rheumatoid arthritis	Phase I www.gilead.com
GS-5745 (MMP9 mAb inhibitor)	Gilead Sciences Foster City, CA	rheumatoid arthritis	Phase I www.gilead.com
GS-9876 (Syk kinase inhibitor)	Gilead Sciences Foster City, CA	rheumatoid arthritis	Phase I www.gilead.com
GSK2982772 (RIP1 kinase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	rheumatoid arthritis	Phase I www.gsk.com
GSK3050002 (CCL20 maybe)	GlaxoSmithKline Research Triangle Park, NC	psoriatic arthritis	Phase I www.gsk.com

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

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

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

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

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

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 www.celimmune.com
IMGX003 (latiglutenase)	ImmunogenX Newport Beach, CA	celiac disease (Fast Track)	Phase II www.immunogenx.com
INN-202 (larazotide acetate)	Innovate Biopharmaceuticals Raleigh, NC	celiac disease (Fast Track)	Phase II completed www.innovatebiopharma.com
RG7625 (cathepsin S inhibitor)	Roche Basel, Switzerland	celiac disease	Phase I www.roche.com
Nexvax2® HLA-DQ2 peptide vaccine	ImmusanT Cambridge, MA	celiac disease	Phase I www.immusant.com

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

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

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

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

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 www.iderapharma.com
Resunab ajulemic acid	Corbus Pharmaceuticals Norwood, MA	dermatomyositis	Phase II www.corbuspharma.com
siponimod (sphingosine-1-phosphate receptor modulator)	Novartis East Hanover, NJ	dermatomyositis, polymyositis	Phase II www.novartis.com

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 www.biodel.com

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 www.caladrius.com
Dance-501 (inhaled recombinant human insulin)	Dance Biopharma Brisbane, CA	type 1 diabetes	Phase II www.dancebiopharma.com
Diamyd® autoimmune diabetes vaccine ORPHAN DRUG	Diamyd Medical Stockholm, Sweden University of Alabama at Birmingham Birmingham, AL	type 1 diabetes	Phase I www.diamyd.com
DV-100 (autologous dendritic cell immunotherapy) ORPHAN DRUG	DiaVacs Edgewater, NJ	type 1 diabetes	Phase I www.diavacs.us.com
Farixga® dapagliflozin	AstraZeneca Wilmington, DE	type 1 diabetes	Phase III www.astrazeneca.com
HDV insulin (hepatocyte directed vesicles)	Diasome Pharmaceuticals Cleveland, OH	type 1 diabetes	Phase II www.diasomepharmaceuticals.com
IN-105 (insulin tregopil)	Biocon Bangalore, India	type 1 diabetes	Phase I/II www.biocon.com

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

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 www.merck.com
NN1218 (insulin aspart faster-acting)	Novo Nordisk Plainsboro, NJ	type 1 diabetes	application submitted www.novonordisk.com
NN1406	Novo Nordisk Plainsboro, NJ	type 1 diabetes	Phase I www.novonordisk.com
NN1953 (oral insulin)	Novo Nordisk Plainsboro, NJ	type 1 diabetes	Phase II www.novonordisk.com
NN9828 (anti-IL-21 GLP-1 mAb)	Novo Nordisk Plainsboro, NJ	type 1 diabetes	Phase II www.novonordisk.com
ORMD-0801 (insulin oral)	Oramed Pharmaceuticals Jerusalem, Israel	type 1 diabetes	Phase II www.ored.com
otelixizumab (cluster of differentiation 3) ORPHAN DRUG	GlaxoSmithKline Research Triangle Park, NC	new onset type 1 diabetes	Phase II www.gsk.com
PF-06342674 (IL-7 receptor antagonist)	Pfizer New York, NY	type 1 diabetes	Phase I www.pfizer.com

Diabetes

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

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 www.viacyte.com

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 www.achillion.com
Benlysta® belimumab (intravenous)	GlaxoSmithKline Research Triangle Park, NC	glomerulonephritis	Phase II www.gsk.com
OMS721 (MASP2 protein inhibitor)	Omeros Seattle, WA	glomerulonephritis,	Phase II www.omeros.com

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 www.eisai.com
BI-655064 (CD40 antigen inhibitor)	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	immune thrombocytopenic purpura	Phase I completed www.boehringer-ingelheim.com

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 www.rigel.com
PRTX-100 (Staphylococcal protein A)	Protalex Florham Park, NJ	immune thrombocytopenic purpura	Phase I/II www.protalex.com

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 www.abbvie.com
abrilumab (AMG 181) (alpha4/beta7 inhibitor)	Amgen Thousand Oaks, CA AstraZeneca Wilmington, DE	Crohn's disease, ulcerative colitis	Phase II www.amgen.com www.astrazeneca.com
ABT-494 (JAK inhibitor)	AbbVie North Chicago, IL	Crohn's disease, ulcerative colitis	Phase II www.abbvie.com
Alequel™ immune regulation therapy	Enzo Biochem New York, NY	Crohn's disease	Phase II www.enzo.com

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 www.atlantichc.com www.ionispharma.com
APD334 (S1P1 agonist)	Arena Pharmaceuticals San Diego, CA	ulcerative colitis	Phase II www.arenapharm.com
AVX-470 (TNF inhibitor)	Avaxia Biologics Lexington, MA	ulcerative colitis	Phase I www.avaxiabiologics.com
bertilimumab (anti-eotaxin mAb)	Immune Pharmaceuticals New York, NY	ulcerative colitis	Phase II www.immunepharma.com
BI-655066 (risankizumab)	AbbVie North Chicago, IL Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	active moderate to severe Crohn's disease	Phase II www.abbvie.com www.boehringer-ingelheim.com
CCX507 (CCR9 receptor antagonist)	ChemoCentryx Mountain View, CA	ulcerative colitis	Phase I completed www.chemocentryx.com
ChronoVax™ Crohn's disease vaccine (IR-777)	Immune Response Biopharma Atlantic City, NJ	Crohn's disease	Phase I www.immuneresponsebiopharma.com

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

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<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 www.gsk.com
Humira® adalimumab	AbbVie North Chicago, IL	ulcerative colitis (pediatric)	Phase III www.abbvie.com
Humira® adalimumab (new formulation)	AbbVie North Chicago, IL	Crohn's disease, ulcerative colitis	Phase III www.abbvie.com
INN-108	Innovate Biopharmaceuticals Raleigh, NC	ulcerative colitis	Phase I www.innovatebiopharma.com
IRT-103 (low-dose naltrexone)	Cytocom Orlando, FL	Crohn's disease	Phase II completed www.cytocom.com
JT02 (chemokine CXCL10 inhibitor)	JYANT Technologies Marietta, GA	inflammatory bowel disease	Phase II www.jyanttech.com
KHK4083 (immunomodulator antibody)	Kyowa Kirin USA Princeton, NJ	ulcerative colitis	Phase II www.kyowa-kirin.com
Lialda® mesalazine controlled release	Shire Lexington, MA	ulcerative colitis (pediatric)	Phase III www.shire.com

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

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

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

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 www.soligenix.com
SHP647 (mAdCAM inhibitor)	Shire Lexington, MA	Crohn's disease, ulcerative colitis	Phase II www.shire.com
Simponi® Aria® golimumab	Janssen Research & Development Raritan, NJ	ulcerative colitis (pediatric)	Phase I www.janssenrnd.com
Stelara® ustekinumab	Janssen Research & Development Raritan, NJ	Crohn's disease	application submitted www.janssenrnd.com
		ulcerative colitis	Phase III www.janssenrnd.com
TAK-828 (RORγt inverse agonist)	Takeda Pharmaceuticals Deerfield, IL	Crohn's disease	Phase I www.takeda.com
TD-1473 (JAK inhibitor)	Theravance Biopharma South San Francisco, CA	ulcerative colitis	Phase I www.theravance.com
VBP15 (glucocorticoid receptor antagonist)	ReveraGen BioPharma Rockville, MD	inflammatory bowel disease	Phase I www.reveragen.com
VBY-129 (cathepsin S inhibitor)	ViroBay Menlo Park, CA	Crohn's disease	Phase I www.virobayinc.com

Inflammatory Bowel Disease

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
Xeljanz® tofacitinib	Pfizer New York, NY	ulcerative colitis	Phase III www.pfizer.com

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 www.abbvie.com
Adcetris® brentuximab vedotin	Seattle Genetics Bothell, WA	systemic lupus erythematosus	Phase II www.seattlegenetics.com
AGS 009 (interferon-alpha neutralizing mAb)	Argos Therapeutics Durham, NC	systemic lupus erythematosus	Phase I completed www.argostherapeutics.com
ALX-0061 (IL-6 receptor antagonist/modulator)	AbbVie North Chicago, IL Ablynx Ghent, Belgium	systemic lupus erythematosus	Phase II www.abbvie.com ablynx.com
AMG 557/MEDI5872 (B7RP1 mAb)	Amgen Thousand Oaks, CA MedImmune Gaithersburg, MD	systemic lupus erythematosus	Phase II www.amgen.com www.medimmune.com

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 www.amgen.com www.medimmune.com
anifrolumab (interferon alpha beta receptor antagonist)	MedImmune Gaithersburg, MD	systemic lupus erythematosus (Fast Track)	Phase III www.medimmune.com
		lupus nephritis	Phase II www.medimmune.com
		systemic lupus erythematosus (subcutaneous treatment)	Phase I www.medimmune.com
atacept (anti-Blys/anti-APRIL fusion protein)	EMD Serono Rockland, MA	systemic lupus erythematosus	Phase II www.emdserono.com
baricitinib (JAK1/JAK2 inhibitor)	Incyte Wilmington, DE Eli Lilly Indianapolis, IN	systemic lupus erythematosus	Phase II www.incyte.com www.lilly.com

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 www.gsk.com
		lupus nephritis (intravenous)	Phase III www.gsk.com
BI-655064 (CD40 antigen inhibitor)	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	lupus nephritis	Phase II www.boehringer-ingelheim.com
BIIB059 (anti-BDCA2 mAb)	Biogen Cambridge, MA	systemic lupus erythematosus	Phase I www.biogen.com
BIIB068 (BTK inhibitor)	Biogen Cambridge, MA	systemic lupus erythematosus	Phase I www.biogen.com
blisibimod (B-cell activating factor inhibitor)	Anthera Pharmaceuticals Hayward, CA	systemic lupus erythematosus	Phase III www.anthera.com
BMS-931699 (anti-CD28 mAb)	Bristol-Myers Squibb Princeton, NJ	systemic lupus erythematosus	Phase II www.bms.com
CC-220 (immunomodulatory therapeutic)	Celgene Summit, NJ	systemic lupus erythematosus	Phase II www.celgene.com
cenerimod (lysophingolipid receptor agonist)	Actelion Pharmaceuticals South San Francisco, CA	systemic lupus erythematosus	Phase II www.actelion.com

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 www.biogen.com www.ucb.com
Gazyva® obinutuzumab	Genentech South San Francisco, CA	lupus nephritis	Phase II www.gene.com
INV103 (immunomodulator)	Invion Brisbane, Australia	systemic lupus erythematosus	Phase II www.inviongroup.com
ixazomib (proteasome inhibitor)	Takeda Pharmaceuticals Deerfield, IL	lupus nephritis	Phase I www.takeda.com
JNJ-55920839 (immunomodulator)	Janssen Research & Development Raritan, NJ	systemic lupus erythematosus	Phase I www.janssenrnd.com
KD025 (ROCK2 inhibitor)	Kadmon New York, NY	systemic lupus erythematosus	Phase I www.kadmon.com
KPP203 (S1P receptor agonist)	Novartis Pharmaceuticals East Hanover, NJ	subacute cutaneous lupus erythematosus	Phase II www.novartis.com
lulizumab pegol (CD28 antigen modulator)	Bristol-Myers Squibb Princeton, NJ	systemic lupus erythematosus	Phase II www.bms.com

Lupus

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

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 www.resolvebio.com
SM101 (human soluble Fc-gamma receptor IIB)	Shire Lexington, MA	systemic lupus erythematosus	Phase II www.shire.com
Stelara® ustekinumab	Janssen Research & Development Raritan, NJ	systemic lupus erythematosus	Phase II www.janssenrnd.com
voclosporin (calcineurin inhibitor)	Aurinia Pharmaceuticals Victoria, Canada	lupus nephritis (Fast Track)	Phase II www.auriniapharma.com
XmAb5871 (intravenous anti-CD19 mAb)	Xencor Monrovia, CA	systemic lupus erythematosus	Phase II www.xencor.com

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 www.abbvie.com
ALKS 8700 (immunomodulator)	Alkermes Waltham, MA	multiple sclerosis	Phase III www.alkermes.com

Multiple Sclerosis

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

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 www.abbvie.com
laquinimod (neuron stimulant)	Teva Pharmaceutical North Wales, PA	relapsing remitting multiple sclerosis (Fast Track)	Phase III www.tevapharm.com
		primary progressive multiple sclerosis (Fast Track)	Phase II www.tevapharm.com
M2736 (ATX-MS-1467) (immune tolerizing agent)	EMD Serono Rockland, MA	multiple sclerosis	Phase II www.emdserono.com
masatinib (tyrosine kinase inhibitor)	AB Science USA Chatham, NJ	progressive forms of multiple sclerosis	Phase III www.ab-science.com
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 www.medicinova.com
MRF-008 (guanabenz)	Myelin Repair Foundation Saratoga, CA National Institute of Neurological Disorders and Stroke Bethesda, MD	multiple sclerosis	Phase I www.myelinrepair.org

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

Multiple Sclerosis

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

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 www.reveragen.com

Myasthenia Gravis

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

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 www.medimmune.com
neuromyelitis optica therapeutic	Marathon Pharmaceuticals Northbrook, IL	neuromyelitis optica	Phase II www.marathonpharma.com
SA237/RG6168 (anti-IL-6 receptor humanized mAb)	Chugai Pharma USA Berkeley Heights, NJ Roche Basel, Switzerland	neuromyelitis optica	Phase III www.chugai-pharm.com www.roche.com
SHP616 (complement C1 inhibitor)	Shire Lexington, MA	neuromyelitis optica	Phase I www.shire.com
Soliris® eculizumab ORPHAN DRUG	Alexion Pharmaceuticals New Haven, CT	relapsing neuromyelitis optica spectrum disorder	Phase III www.alexion.com

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 www.immunepharma.com

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 www.principiabio.com
Rituxin® rituximab	Genentech South San Francisco, CA	pemphigus vulgaris	Phase III www.roche.com
TNT009 (complement C1s inhibitor)	True North Therapeutics South San Francisco, CA	bullous pemphigoid	Phase I www.truenorthrx.com
VAY736 (BAFF-R receptor modulator)	Novartis East Hanover, NJ	pemphigus vulgaris	Phase II www.novartis.com

Primary Biliary Cholangitis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
LN452 (farnesoid X-activated receptor agonist)	Novartis Pharmaceuticals East Hanover, NJ	primary biliary cholangitis	Phase II www.novartis.com
MBX-8025 (PPAR-delta agonist)	CymaBay Therapeutics Newark, CA	primary biliary cholangitis	Phase II www.cymabay.com
SHP625 (sodium-bile acid cotransporter inhibitor)	Shire Lexington, MA	primary biliary cholangitis	Phase II www.shire.com

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 www.retrophin.com

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 www.therapeuticsinc.com
ABP 501 (adalimumab biosimilar)	Amgen Thousand Oaks, CA	plaque psoriasis	application submitted www.amgen.com
ALX-0761 (M1095) (anti-IL-17 A/F nanobody)	Ablynx Ghent, Belgium EMD Serono Rockland, MA	psoriasis	Phase I www.ablynx.com www.emdserono.com
ARN-6039 (RORyt inverse agonist)	Arrien Pharmaceuticals Salt Lake City, UT	psoriasis	Phase I www.arrienpharma.com
AST-005 (tumour necrosis factor modulator)	Excure Skokie, IL	psoriasis	Phase I www.excuretx.com

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 www.shire.com www.coherus.com
BAX2923/M923 (adalimumab biosimilar)	Shire Lexington, MA Momenta Pharmaceuticals Cambridge, MA	plaque psoriasis	Phase III www.shire.com www.momentapharma.com
bertilimumab (anti-eotaxin mAb)	Immune Pharmaceuticals New York, NY	psoriasis	Phase II www.immunepharma.com
BI-655066 (risankizumab)	AbbVie North Chicago, IL Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	moderate to severe chronic plaque psoriasis	Phase III www.abbvie.com www.boehringer-ingelheim.com
BMS-986020 (LPA1 receptor antagonist)	Bristol-Myers Squibb Princeton, NJ	psoriasis	Phase I www.bms.com
BMS-986165	Bristol-Myers Squibb Princeton, NJ	plaque psoriasis	Phase I www.bms.com

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 www.astrazeneca.com www.valeant.com
CF101 (adenosine A3 receptor agonist)	Can-Fite BioPharma Petah-Tikva, Israel	psoriasis	Phase III www.canfite.com
CHS-1420 (adalimumab biosimilar)	Coherus Biosciences Redwood City, CA	plaque psoriasis	Phase III www.coherus.com
Cimzia® certolizumab pegol	UCB Smyrna, GA	plaque psoriasis	Phase III www.ucb.com
CJM112 (IL-17 inhibitor)	Novartis Pharmaceuticals East Hanover, NJ	chronic plaque psoriasis	Phase I/II completed www.novartis.com
CT327 (TrkA receptor inhibitor)	Creabilis Therapeutics Canterbury, United Kingdom	plaque psoriasis	Phase II completed www.creabilis-sa.com
dalazatide (Kv1.3 potassium channel inhibitor)	Kineta Seattle, WA	plaque psoriasis	Phase I completed www.kinetabio.com
DFD-06	Promius Pharma Princeton, NJ	plaque psoriasis	Phase III www.promiuspharma.com

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 www.amgen.com
GP2015 (etanercept biosimilar)	Sandoz Holzkirchen, Germany	plaque psoriasis	application submitted www.sandozbiosimilars.com
GP2017 (adalimumab biosimilar)	Sandoz Holzkirchen, Germany	plaque psoriasis	Phase III www.sandoz-biosimilars.com
GR-MD-02 (galectin 3 inhibitor)	Galectin Therapeutics Norcross, GA	moderate to severe plaque psoriasis	Phase II www.galectintherapeutics.com
GSK2894512 (non-steroidal anti-inflammatory)	GlaxoSmithKline Research Triangle Park, NC	plaque psoriasis	Phase II www.gsk.com
GSK2981278 (ROR gamma inverse agonist)	GlaxoSmithKline Research Triangle Park, NC	plaque psoriasis	Phase II www.gsk.com
GSK2982772 (RIP1 kinase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	psoriasis	Phase I www.gsk.com
guselkumab (IL-23 subunit p19 inhibitor)	Janssen Research & Development Raritan, NJ	moderate to severe plaque psoriasis, pustular psoriasis, erythrodermic psoriasis	Phase III www.janssenrnd.com

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

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 www.niadynepharma.com
ONS-3010 (adalimumab biosimilar)	Oncobiologics Cranbury, NJ	psoriasis	Phase I www.oncobiologics.com
PF-06700841	Pfizer New York, NY	psoriasis	Phase I www.pfizer.com
PH-10 (rose bengal sodium)	Provectus Biopharmaceuticals Knoxville, TN	psoriasis	Phase II www.pvct.com
Prurisol abacavir	Cellceutix Beverly, MA	psoriasis	Phase II www.cellceutix.com
PRX003 (cell adhesion molecule inhibitor)	Prothena Biosciences South San Francisco, CA	psoriasis	Phase I www.prothena.com
santalum album cream	Santalus Healthcare San Antonio, TX	psoriasis	Phase II
SB2 (infliximab biosimilar)	Merck Kenilworth, NJ Samsung Bioepis Incheon, South Korea	plaque psoriasis	application submitted www.merck.com www.samsungbioepis.com

Psoriasis

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

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 www.acertx.com
Actemra® tocilizumab	Genentech South San Francisco, CA	systemic sclerosis	Phase III www.gene.com

Scleroderma

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
Adempas® riociguat ORPHAN DRUG	Bayer HealthCare Pharmaceuticals Parsippany, NJ	systemic scleroderma	Phase II www.bayer.pharma.com
ARG201 (immunomodulator) ORPHAN DRUG	arGentis Pharmaceuticals Collierville, TN	diffuse systemic scleroderma	Phase II www.argentixrx.com
C 82 (CBP/β-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 www.cytori.com
GSK2330811 (oncostatin M mAb)	GlaxoSmithKline Research Triangle Park, NC	systemic scleroderma	Phase I www.gsk.com
KD025 (ROCK2 inhibitor)	Kadmon New York, NY	scleroderma	Phase I www.kadmon.com
MRG-201 (microRNA modulator)	miRagen Therapeutics Boulder, CO	cutaneous scleroderma	Phase I www.miragentherapeutics.com
Ofev® nintedanib	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	scleroderma-related lung fibrosis	Phase III www.boehringer-ingelheim.com

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 www.celgene.com
Resunab ajulemic acid	Corbus Pharmaceuticals Norwood, MA	systemic sclerosis	Phase II www.corbuspharma.com
SAR100842 (LPA1 receptor antagonist)	Sanofi US Bridgewater, NJ	systemic sclerosis	Phase II www.sanofi.com

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 www.amgen.com www.medimmune.com
Benlysta® + Rituxan® belimumab (subcutaneous) + rituximab	GlaxoSmithKline Research Triangle Park, NC	Sjögren's syndrome	Phase II www.gsk.com
BIIB063 (anti-CD40)	Biogen Cambridge, MA	Sjögren's syndrome	Phase I www.biogen.com
CFZ533 (CD40 antigen inhibitor)	Novartis Pharmaceuticals East Hanover, NJ	primary Sjögren's syndrome	Phase II www.novartis.com

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 www.gsk.com
LY3090106	Eli Lilly Indianapolis, IN	Sjögren's syndrome	Phase I www.lilly.com
MEDI4920 (CD40 ligand inhibitor)	MedImmune Gaithersburg, MD	primary Sjögren's syndrome	Phase I www.medimmune.com
RG7625 (cathepsin S inhibitor)	Roche Basel, Switzerland	Sjögren's syndrome	Phase II www.roche.com
RSLV-132 (B cell inhibitor)	Resolve Therapeutics Seattle, WA	Sjögren's syndrome	Phase II www.resolvebio.com

Other Autoimmune Diseases

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

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 www.araimpharma.com
CFZ533 (CD40 antigen inhibitor)	Novartis Pharmaceuticals East Hanover, NJ	Graves disease	Phase II www.novartis.com
CTP-543 (JAK1/JAK2 inhibitor)	Concert Pharmaceuticals Lexington, MA	alopecia areata	Phase I www.concertpharma.com
Firdapse® amifampridine ORPHAN DRUG	Catalyst Pharmaceuticals Coral Gables, FL	Lambert-Eaton myasthenic syndrome (Breakthrough Therapy)	Phase III www.catalystpharma.com
fostamatinib (SYK kinase inhibitor)	Rigel Pharmaceuticals South San Francisco, CA	autoimmune hemolytic anemia	Phase II www.rigel.com
LEO 124249 ointment	LEO Pharma Parsippany, NJ	alopecia areata	Phase II www.leo-pharma.com
Nucala® mepolizumab ORPHAN DRUG	GlaxoSmithKline Research Triangle Park, NC	eosinophilic granulomatosis with polyangiitis (Churg-Strauss syndrome)	Phase III www.gsk.com
Optiquel™	Enzo Biochem New York, NY	autoimmune uveitis	Phase I www.enzo.com

Other Autoimmune Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Highest Development Phase</u>
Otezla® apremilast	Celgene Summit, NJ	Behcet's disease	Phase III www.celgene.com
Scenesse® afamelanotide	Clinuvel Pharmaceuticals New York, NY	vitiligo	Phase II www.clinuvel.com
sirukumab (IL-6 human mAb)	GlaxoSmithKline Research Triangle Park, NC	giant cell arteritis	Phase III www.gsk.com
sPIF (preimplantation factor)	BioIncept Cherry Hill, NJ University of Miami Miami, Florida	autoimmune hepatitis (Fast Track)	Phase I www.bioincept.com
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 www.incyte.com
TNT009 (complement C1s inhibitor) ORPHAN DRUG	True North Therapeutics South San Francisco, CA	cold agglutinin disease, warm autoimmune hemolytic anemia	Phase I www.truenorthrx.com
XmAb5871 (anti-CD19 mAb intravenous)	Xencor Monrovia, CA	IgG4-related diseases	Phase II www.xencor.com

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 www.aceabio.com
antibody therapeutic (immunomodulator)	Merck Kenilworth, NJ Xencor Monrovia, CA	autoimmune diseases	Phase I www.merck.com www.xencor.com
BTK inhibitor	AbbVie North Chicago, IL	autoimmune diseases	Phase I www.abbvie.com
BTK inhibitor	Eli Lilly Indianapolis, IN	autoimmune diseases	Phase I www.lilly.com
DV1179 (TLR 7/9 Inhibitor)	Dynavax Technologies Berkeley, CA	autoimmune diseases	Phase I www.dynavax.com
GDC-0853 (BTK inhibitor)	Genentech South San Francisco, CA	autoimmune diseases	Phase I www.gene.com
GSK2831781 (LAG3 protein mAb)	GlaxoSmithKline Research Triangle Park, NC	autoimmune diseases	Phase I www.gsk.com
IMO-9200 (toll-like receptor antagonist)	Idera Pharmaceuticals Cambridge, MA	autoimmune diseases	Phase I completed www.iderapharma.com

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 www.janssenrnd.com
M281 (anti-FcRn antibody)	Momenta Pharmaceuticals Cambridge, MA	autoimmune diseases	Phase I www.momentapharma.com
MGD010 (CD32B and CD79B modulator)	MacroGenics Rockville, MD Takeda Pharmaceuticals	autoimmune diseases	Phase I www.macrogenics.com www.takeda.com
RG7625 (cathepsin S antagonist)	Roche Basel, Switzerland	autoimmune diseases	Phase II www.roche.com
RG7845 (BTK inhibitor)	Roche Basel, Switzerland	autoimmune diseases	Phase I www.roche.com
STI-003 (basiliximab biobetter) (anti-CD 25 mAb)	Sorrento Therapeutics San Diego, CA	autoimmune diseases	Phase II www.sorrentotherapeutics.com
tyrosine kinase 2 inhibitor (TYK2 inhibitor)	Bristol-Myers Squibb Princeton, NJ	autoimmune diseases	Phase I www.bms.com
VTP-43742 (ROR-gamma inhibitor)	Vitae Pharmaceuticals Fort Washington, PA	autoimmune diseases	Phase I www.vitaepharma.com

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 www.xencor.com

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. 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).

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.