

Medicines in Development for Women – 2022

Arthritis/Musculoskeletal Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
1805 (chaperonin BiP analogue)	Revalo Biotherapeutics New Orleans, LA	rheumatoid arthritis	Phase II www.revalobio.com
abaloparatide-TD (synthetic peptide analogue of human parathyroid hormone-related protein)	Radius Health Boston, MA	postmenopausal osteoporosis (transdermal patch)	Phase III www.radiuspharm.com
ABBV-154 (anti-TNF GRM ADC)	AbbVie North Chicago, IL	rheumatoid arthritis	Phase II www.abbvie.com
Ajovy [®] fremanezumab	Teva Pharmaceuticals USA Parsippany, NJ	fibromyalgia	Phase II www.tevausea.com
AMT-101 (oral IL-10)	Applied Molecular Transport South San Francisco, CA	rheumatoid arthritis (+anti-TNFa)	Phase II www.appliedmt.com
AVT02 (adalimumab biosimilar)	Alvotech Reykjavik, Iceland	rheumatoid arthritis	application submitted www.alvotech.com
AXS-14 (esreboxetine) (NE reuptake inhibitor)	Axsome Therapeutics New York, NY	fibromyalgia	Phase III www.axsome.com

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BAY1830839 (IRAK4 inhibitor 2)	Bayer Pharmaceuticals Whippany, NJ	rheumatoid arthritis	Phase I www.bayer.com
BAY1834845 (zabedostertib) (IRAK4 inhibitor 1)	Bayer Pharmaceuticals Whippany, NJ	rheumatoid arthritis	Phase I www.bayer.com
BIIB800 (tocilizumab biosimilar)	Biogen Cambridge, MA	rheumatoid arthritis	Phase III www.biogen.com
branebrutinib (tyrosine kinase inhibitor)	Bristol-Myers Squibb Princeton, NJ	rheumatoid arthritis	Phase II www.bms.com
cevidoplenib (Syk kinase inhibitor)	Genosco Billerica, MA	rheumatoid arthritis	Phase II www.genosco.com
dazodalibep (HZN-4920) (CD40 ligand inhibitor)	Horizon Therapeutics Deerfield, IL	rheumatoid arthritis	Phase II www.horizontherapeutics.com
Dekavil (PF-06687234) (IL-10)	Pfizer New York, NY	rheumatoid arthritis	Phase II www.pfizer.com
EQ 121 (JAK1 inhibitor)	EQRx Cambridge, MA	rheumatoid arthritis	Phase I www.eqrx.com

Arthritis/Musculoskeletal Diseases

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GP2411 (denosumab biosimilar)	Sandoz Princeton, NJ	postmenopausal osteoporosis	Phase III www.sandoz.com
GS-5718 (IRAK4 inhibitor)	Gilead Sciences Foster City, CA	rheumatoid arthritis	Phase I www.gilead.com
HB-adMSC (autologous adipose derived mesenchymal stem cells)	Hope Biosciences Sugar Land, TX	rheumatoid arthritis	Phase I/II completed www.hope.bio
IMC-1 (celecoxib/famciclovir)	Virios Therapeutics Alpharetta, GA	fibromyalgia (Fast Track)	Phase II www.virios.com
JNJ-67484703 (hulG1k antibody)	Janssen Research & Development Raritan, NJ	rheumatoid arthritis	Phase I www.janssen.com
JTE-051 (IL-1 inducible T cell kinase inhibitor)	Akros Pharma (JT Pharma) Princeton, NJ	rheumatoid arthritis	Phase II www.akrospharma.com
KER-012 (TGF beta inhibitor)	Keros Therapeutics Lexington, MA	osteoporosis	Phase I www.kerostx.com
KPL-404 (CD40 antigen inhibitor)	Kiniksa Pharmaceuticals Lexington, MA	rheumatoid arthritis	Phase II www.kiniksa.com

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LABP-104 (LANCL2 protein stimulant)	Landos Biopharma Blacksburg, VA	rheumatoid arthritis	Phase I www.landosbiopharma.com
nipocalimab (Fc receptor antagonist)	Janssen Research & Development Raritan, NJ	rheumatoid arthritis	Phase II www.janssen.com
NYX-2925 (NMDA receptor modulator)	Aptinyx Evanston, IL	fibromyalgia	Phase II www.aptinyx.com
olokizumab (IL-6 inhibitor)	R-Pharm US Princeton, NJ	rheumatoid arthritis	Phase III completed www.rpharm-us.com
ORTD 1 (orynotide)	Oryn Therapeutics Vacaville, CA	rheumatoid arthritis	Phase I www.oryntherapeutics.com
otilimab (GSK3196165) (GM-CSF inhibitor)	GlaxoSmithKline Research Triangle Park, NC	rheumatoid arthritis	Phase III www.gsk.com
peresolimab (LY3462817) (PD-1 antibody agonist)	Lilly Indianapolis, IN	rheumatoid arthritis	Phase II www.lilly.com
PF-06835375 (CXCR5 receptor antagonist)	Pfizer New York, NY	rheumatoid arthritis	Phase I www.pfizer.com

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ritilecitinib (JAK3/TEC inhibitor)	Pfizer New York, NY	rheumatoid arthritis (+/- PF-0650833) (+tofacitinib)	Phase II www.pfizer.com
rituximab biosimilar	Dr. Reddy's Laboratories Princeton, NJ	rheumatoid arthritis	Phase III www.drreddys.com
TNX-102 SL (cyclobenzaprine sublingual tablets)	Tonix Pharmaceuticals Chatham, NJ	fibromyalgia	Phase III www.tonixpharma.com
TVB-009P (denosumab biosimilar)	Teva Pharmaceuticals USA Parsippany, NJ	postmenopausal osteoporosis	Phase III www.tevausea.com
VAY736 (ilanalumab) (BAFF-R modulator)	Novartis East Hanover, NJ	rheumatoid arthritis	Phase I www.novartis.com
zunsemetinib (ATI-450) (MK2 inhibitor)	Aclaris Therapeutics Wayne, PA	rheumatoid arthritis	Phase II www.aclaristx.com

Autoimmune Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ABBV-599 (BTK inhibitor and JAK1 inhibitor)	AbbVie North Chicago, IL	systemic lupus erythematosus	Phase II www.abbvie.com

Autoimmune Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ACE-1334 (TGF-beta-1/beta-3 inhibitor) ORPHAN DRUG	Acceleron Pharma Cambridge, MA	scleroderma (systemic sclerosis) associated interstitial lung disease (Fast Track)	Phase I/II www.acceleronpharma.com
afimetonan (TLR 7/8 inhibitor)	Bristol-Myers Squibb Princeton, NJ	systemic lupus erythematosus	Phase II www.bms.com
		cutaneous lupus erythematosus	Phase I www.bms.com
ALPN-101 (acazicolcept) (ICOS/CD28 antagonist)	AbbVie North Chicago, IL Alpine Immune Sciences Seattle, WA	systemic lupus erythematosus	Phase II www.abbvie.com www.alpineimmunesciences.com
ALPN-303 (dual B cell cytokine antagonist)	Alpine Immune Sciences Seattle, WA	B cell-mediated diseases, including Sjogren's syndrome and systemic lupus erythematosus	Phase I www.alpineimmunesciences.com
ALXN1720 (complement C5 inhibitor)	Alexion AstraZeneca Rare Disease Boston, MA	myasthenia gravis	Phase I www.alexion.com
ALXN2050 (vemircopan) (factor D inhibitor)	Alexion AstraZeneca Rare Disease Boston, MA	myasthenia gravis	Phase II www.alexion.com

Autoimmune Diseases

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AMG 570 (rozibafusp alfa) (BAFF x ICOSL bispecific antibody)	Amgen Thousand Oaks, CA	systemic lupus erythematosus	Phase II www.amgen.com
ANX-005 (complement C1 inhibitor)	Annexon Biosciences Brisbane, CA	autoimmune hemolytic anemia	Phase II www.annexonbio.com
avizakimab (IL-21 mAb)	Boston Pharmaceuticals Cambridge, MA	systemic lupus erythematosus	Phase II www.bostonpharmaceuticals.com
batoclimab (IMVT-1401) (neonatal Fc receptor antagonist) ORPHAN DRUG	Immunovant New York, NY	myasthenia gravis (Breakthrough Therapy)	Phase II completed www.immunovant.com
BIIB059 (litifilimab) (anti-BDCA2)	Biogen Cambridge, MA	systemic lupus erythematosus	Phase III www.biogen.com
BMS-986325 (CD40 antigen inhibitor)	Bristol-Myers Squibb Princeton, NJ	Sjogren's syndrome	Phase I www.bms.com
branebrutinib (tyrosine kinase inhibitor)	Bristol-Myers Squibb Princeton, NJ	Sjogren's syndrome, systemic lupus erythematosus	Phase II www.bms.com

Autoimmune Diseases

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cemdisiran + pozelimab (C5 siRNA and C5 antibody)	Alnylam Pharmaceuticals Cambridge, MA Regeneron Tarrytown, NY	myasthenia gravis	Phase III www.alnylam.com www.regeneron.com
cenerimod (S1P1 receptor modulator)	Idorsia Pharmaceuticals Allschwil, Switzerland	systemic lupus erythematosus (Fast Track)	Phase II www.idorsia.com
cevidoplenib (Syk kinase inhibitor)	Genosco Billerica, MA	idiopathic thrombocytopenic purpura	Phase II www.genosco.com
CFZ53 (iscalimab) (CD40 inhibitor)	Novartis East Hanover, NJ	Sjogren's syndrome, systemic lupus erythematosus	Phase II www.novartis.com
CiVi030 (iloprost) (epoprostenol agonist) ORPHAN DRUG	CiVi Biopharma Chevy Chase, MD	scleroderma (systemic sclerosis)	Phase III www.civibio.com
CMK389 (IL-18 inhibitor)	Novartis East Hanover, NJ	pulmonary sarcoidosis	Phase II www.novartis.com
Cosentyx® secukinumab	Novartis East Hanover, NJ	thyroid eye disease	Phase III www.novartis.com

Autoimmune Diseases

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dapirolizumab pegol (BIIB133) (CD40 ligand inhibitor)	Biogen Cambridge, MA UCB Smyrna, GA	systemic lupus erythematosus	Phase III www.biogen.com www.ucb.com
DAS-001 (ondansetron/pyridostigmine)	DAS Therapeutics Boston, MA	myasthenia gravis	Phase II www.dasterapeutics.com
daxdilimab (HZN-7734) (anti-ILT7 mAb)	Horizon Therapeutics Deerfield, IL	dermatomyositis, discoid lupus erythematosus, systemic lupus erythematosus	Phase II www.horizontherapeutics.com
dazodalibep (HZN-4920) (CD40 ligand inhibitor)	Horizon Therapeutics Deerfield, IL	Sjogren's syndrome	Phase II www.horizontherapeutics.com
dersimelagon (MT-7117) (melanocortin type 1 receptor agonist)	Mitsubishi Tanabe Pharma Jersey City, NJ	scleroderma (systemic sclerosis) (Fast Track)	Phase II www.mt-pharma.co.jp
Descartes-08 CAR-T cell therapy	Cartesian Therapeutics Gaithersburg, MD	myasthenia gravis	Phase I/II www.cartesiantherapeutics.com
deucravacitinib (BMS-986165) (TYK2 kinase inhibitor)	Bristol-Myers Squibb Princeton, NJ	discoid lupus erythematosus, systemic lupus erythematosus	Phase II www.bms.com

Autoimmune Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
DS-7011a (TLR7 antagonist)	Daiichi Sankyo Basking Ridge, NJ	systemic lupus erythematosus	Phase I www.daichiisankyo.com
efavaleukin alfa (IL-2 mutein Fc fusion protein)	Amgen Thousand Oaks, CA	systemic lupus erythematosus	Phase II www.amgen.com
efzofitimod (ATYR1923) (neuropilin-2 modulator) ORPHAN DRUG	aTyr Pharma San Diego, CA	pulmonary sarcoidosis	Phase II www.atyrpharma.com
EHP-101 (dual PPAR-gamma/CB2) agonist) ORPHAN DRUG	Emerald Health Pharmaceuticals San Diego, CA	diffuse cutaneous scleroderma (systemic sclerosis) (Fast Track)	Phase II www.emeraldpharma.com
Enjaymo [®] sutimlimab-jome ORPHAN DRUG	Sanofi Bridgewater, NJ	immune thrombocytopenic purpura	Phase II www.sanofi.com
enpatoran (TLR7/8 antagonist)	EMD Serono Rockland, MA	discoid lupus erythematosus, systemic lupus erythematosus	Phase I www.emdserono.com
Enspryng [®] satralizumab-mwge	Roche/Genentech South San Francisco, CA	myasthenia gravis	Phase III www.roche.com

Autoimmune Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
FCR001 (cell therapy)	Talaris Therapeutics Louisville, KY	scleroderma (systemic sclerosis)	Phase I www.talaris.com
FCX-013 (gene therapy) ORPHAN DRUG	Castle Creek Biosciences Exton, PA	scleroderma (systemic sclerosis) (Fast Track)	Phase I/II www.castelcreekbio.com
Gazyva [®] obinutuzumab	Roche/Genentech South San Francisco, CA	systemic lupus erythematosus	Phase III www.roche.com
GS-5718 (IRAK4 inhibitor)	Gilead Sciences Foster City, CA	cutaneous lupus erythematosus	Phase I www.gilead.com
GS-9674 (cilofexor) (FXR agonist)	Gilead Sciences Foster City, CA	primary sclerosing cholangitis	Phase III www.gilead.com
Hizentra [®] immujne globulin subcutaneous (human) 20% ORPHAN DRUG	CSL Behring King of Prussia, PA	dermatomyositis	Phase III www.cslbehring.com
		diffuse cutaneous scleroderma (systemic sclerosis) (Fast Track)	Phase II www.cslbehring.coim

Autoimmune Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
HZN-825 (lysophosphatidic acid receptor antagonist)	Horizon Therapeutics Gaithersburg, MD	diffuse scleroderma (systemic sclerosis)	Phase II www.horizontherapeutics.com
iberdomide (ubiquitin protein ligase complex modulator)	Bristol-Myers Squibb Princeton, NJ	systemic lupus erythematosus	Phase II www.bms.com
itolizumab (CD6 antigen inhibitor)	Equillum La Jolla, CA	systemic lupus erythematosus	Phase I www.equilliumbio.com
KPG-818 (CRL4-CRBN E3 modulator)	Kangpu Biopharmaceuticals Shanghai, China	systemic lupus erythematosus	Phase I/II www.kangpugroup.com
KZR-616 (proteasome inhibitor) ORPHAN DRUG	Kezar Life Sciences South San Francisco, CA	dermatomyositis, polymyositis	Phase II www.kezarlifesciences.com
LABP-104 (LANCL2 protein stimulant)	Landos Biopharma Blacksburg, VA	systemic lupus erythematosus	Phase I www.landosbiopharma.com
LAM-001 (rapamycin)	AI Therapeutics Guilford, CT	pulmonary sarcoidosis	Phase II www.ai-therapeutics.com

Autoimmune Diseases

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lenabasum (cannabinoid receptor CB2 agonist) ORPHAN DRUG	Corbus Pharmaceuticals Norwood, MA	dermatomyositis	Phase III www.corbuspharma.com
		systemic lupus erythematosus	Phase II www.corbuspharma.com
LNP023 (iptacopan) (CFB inhibitor)	Novartis East Hanover, NJ	cold agglutinin disease, immune thrombocytopenic purpura	Phase II www.novartis.com
LOU064 (remibrutinib) (BTK inhibitor)	Novartis East Hanover, NJ	Sjogren's syndrome	Phase II www.novartis.com
LY3361237 (BTLA antibody agonist)	Lilly Indianapolis, IN	systemic lupus erythematosus	Phase I completed www.lilly.com
mezagitamab (anti-CD38 antibody)	Takeda Deerfield, IL	idiopathic thrombocytopenic purpura, myasthenia gravis	Phase II www.takeda.com
MHS552	Novartis East Hanover, NJ	systemic lupus erythematosus	Phase I www.novartis.com
MHV370	Novartis East Hanover, NJ	Sjogren's syndrome, systemic lupus erythematosus	Phase I www.novartis.com

Autoimmune Diseases

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mosunetuzumab (RG7828) (CD20xCD3 bispecific antibody)	Roche/Genentech South San Francisco, CA	systemic lupus erythematosus	Phase I www.roche.com
nipocalimab (Fc receptor antagonist) ORPHAN DRUG	Janssen Research & Development Raritan, NJ	warm autoimmune hemolytic anemia (Fast Track), myasthenia gravis	Phase III www.janssen.com
		Sjogren's syndrome, systemic lupus erythematosus	Phase II www.janssen.com
NKTR-358 (LY3471851) (IL-2 T conjugate)	Lilly Indianapolis, IN Nektar Therapeutics San Francisco, CA	systemic lupus erythematosus	Phase II www.lilly.com www.nektar.com
OHB-101 (Fc gamma receptor IIB modulator) ORPHAN DRUG	Oak Hill Bio Cambridge, MA	idiopathic thrombocytopenic purpura (Fast Track)	Phase II www.oakhillbio.com
parsaclisib (PI3K inhibitor)	Incyte Wilmington, DE	warm autoimmune hemolytic anemia	Phase III www.incyte.com
PF-06755347 (immunomodulation)	Pfizer New York, NY	immune thrombocytopenic purpura	Phase I www.pfizer.com

Autoimmune Diseases

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PF-06823859 (IFNβ1 blocker) ORPHAN DRUG	Pfizer New York, NY	dermatomyositis	Phase II www.pfizer.com
PF-06835375 (CXCR5 receptor antagonist)	Pfizer New York, NY	immune thrombocytopenic purpura, systemic lupus erythematosus	Phase I www.pfizer.com
PRV-3279 (Fc gamma receptor antagonists)	Provention Bio Red Bank, NJ	systemic lupus erythematosus	Phase II www.proventionbio.com
Rezurock™ belumosudil ORPHAN DRUG	Kadmon Pharmaceuticals New York, NY	scleroderma (systemic sclerosis)	Phase II www.kadmon.com
RG6315	Roche/Genentech South San Francisco, CA	scleroderma (systemic sclerosis)	Phase I www.roche.com
rilzabrutinib (BTK inhibitor) ORPHAN DRUG	Sanofi Bridgewater, NJ	immune thrombocytopenic purpura (Fast Track)	Phase III www.sanofi.com
rozanolixizumab (neonatal Fc receptor antagonist) ORPHAN DRUG	UCB Smyrna, GA	immune thrombocytopenic purpura, myasthenia gravis	Phase III www.ucb.com

Autoimmune Diseases

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RSLV-132 (nuclease Fc fusion protein)	Resolve Therapeutics St. Petersburg, FL	Sjogren's syndrome, systemic lupus erythematosus	Phase II www.resolvetherapeutics.com
Saphnelo® anifrolumab subcutaneous	AstraZeneca Wilmington, DE	systemic lupus erythematosus	Phase III www.astrazeneca.com
SAR441344 (anti-CD40L mAb)	Immunext Lebanon, NH Sanofi Bridgewater, NJ	Sjogren's syndrome, systemic lupus erythematosus	Phase II www.sanofi.com
SAR443122 (eclitasertib) (RIPK1 inhibitor)	Denali Therapeutics South San Francisco, CA Sanofi Bridgewater, NJ	cutaneous lupus erythematosus	Phase II www.sanofi.com
SAR445088 (complement C1s inhibitor)	Sanofi Bridgewater, NJ	cold agglutinin disease, immune thrombocytopenic purpura	Phase II www.sanofi.com
Sarclisa® isatuximab	Sanofi Bridgewater, NJ	warm autoimmune hemolytic anemia	Phase II www.sanofi.com
SM001 (recombinant DNase I) ORPHAN DRUG	SarcoMed USA Houston, TX	pulmonary sarcoidosis	Phase I www.sarcomedusa.com

Autoimmune Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
SRK001 (anti-inflammatory antibody)	Sarkana Pharma Wilmington, DE	systemic lupus erythematosus	Phase I
Tavalisse® fostamatinib ORPHAN DRUG	Rigel Pharmaceuticals South San Francisco, CA	autoimmune hemolytic anemia (Fast Track)	Phase III www.rigel.com
Tepezza® teprotumumab-trbw (subcutaneous administration)	Horizon Therapeutics Gaithersburg, MD	diffuse cutaneous scleroderma (systemic sclerosis)	Phase I www.horizontherapeutics.com
TLY012 (myofibroblast-targeted DR5 agonist) ORPHAN DRUG	Theraly Fibrosis Germantown, MD	scleroderma (systemic sclerosis)	Phase I www.ddpharmatech.com
tolebrutinib (BTK inhibitor)	Sanofi Bridgewater, NJ	myasthenia gravis	Phase III www.sanofi.com
Ultomiris® ravulizumab-cwvz	Alexion AstraZeneca Rare Disease Boston, MA	myasthenia gravis	application submitted www.alexion.com
		dermatomyositis	Phase II www.alexion.com

Autoimmune Diseases

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Uplizna® inebilizumab	Horizon Therapeutics Gaithersburg, MD	myasthenia gravis	Phase III www.horizontherapeutics.com
VAY736 (ianalumab) (BAFF-R inhibitor)	Novartis East Hanover, NJ	autoimmune hepatitis, Sjogren's syndrome (Fast Track), systemic lupus erythematosus	Phase II www.novartis.com
VRDN 001 (IGF1R antagonist)	Viridian Therapeutics Waltham, MA	thyroid eye disease	Phase I/II www.viridiantherapeutics.com
Vyvgart™ efgartigimod-fcab ORPHAN DRUG	Argenx US Boston, MA	immune thrombocytopenic purpura, myasthenia gravis	Phase III www.argenx.com
XTMAB-16 (TNF alpha inhibitor) ORPHAN DRUG	Xentria Chicago, IL	sarcoidosis	Phase I www.xentria.com
zilucoplan (macrocylic peptode) ORPHAN DRUG	UCB Smyrna, GA	myasthenia gravis	Phase III www.ucb.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AC0682 (estrogen receptor alpha degradation enhancer)	Accutar Biotechnology Brooklyn, NY	ER-positive breast cancer	Phase I www.accutarbio.com
ACE1702 (HER2 targeting ACC-oNK cell therapy)	Acepodia Alameda, CA	HER2-positive metastatic breast cancer	Phase I www.acepodia.com
ACR-368 (prexasertib) (CHK1/CHK2 inhibitor)	Acrivon Therapeutics Watertown, MA	platinum-resistant ovarian cancer	Phase II www.acrivon.com
adagloxad simolenin (cancer immunotherapy)	OBI Pharma San Diego, CA	triple negative breast cancer	Phase III www.obipharma.com
adavosertib (WEE1 protein inhibitor)	AstraZeneca Wilmington, DE	ovarian cancer, uterine serous cancer	Phase II www.astrazeneca.com
AE37 (li-Key-HER2 immunotherapeutic vaccine)	NuGenerex Immuno-Oncology Miramar, FL	breast cancer	Phase II www.nugenerexio.com
afuresertib (proto-oncogene protein c-akt inhibitor)	Laekna Therapeutics Shanghai, China	platinum-resistant ovarian cancer	Phase II www.laeknatp.com

Cancer

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AGEN1181 + balstilimab (CTLA-4/PD-1 bispecific antibody)	Agenus Lexington, MA	MSS gynecologic cancers	Phase I/II www.agenusbio.com
AK104 (PD-1/CTLA-4 bispecific antibody) ORPHAN DRUG	Akeso Biopharma Fremont, CA	2L/3L cervical cancer (Fast Track)	Phase II www.akesobio.com
AL3818 (catequentinib) (multiple tyrosine kinase inhibitor) ORPHAN DRUG	Advenchen Laboratories Moorpark, CA	cervical cancer, endometrial cancer, fallopian tube cancer, ovarian cancer, primary peritoneal cancer (combination therapy)	Phase III www.advenchen.com
amcenenstrant (SERD)	Sanofi Bridgewater, NJ	1L metastatic breast cancer (+palbociclib)	Phase III www.sanofi.com
		early breast cancer, 2L/3L metastatic breast cancer	Phase II www.sanofi.com
AMXI-5001 (bifunctional PARP and microtubule polymerization inhibitor)	AtlasMedx San Francisco, CA	breast cancer, ovarian cancer	Phase I www.atlasmedx.com
Anktiva™ + PD-L1 t-haNK (inbakicept + PD-L1 t-haNK)	ImmunityBio Culver City, CA	3L+ triple negative breast cancer	Phase II www.immunitybio.com

Cancer

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anti-folate receptor alpha CAR-T cell therapy	Tmunity Therapeutics Philadelphia, PA	ovarian cancer	Phase I www.tmunity.com
anti-TnMUC-1 CAR-T cell therapy	Tmunity Therapeutics Philadelphia, PA	ovarian cancer, triple negative breast cancer	Phase I www.tmunity.com
APG-2575 (Bcl-2 inhibitor)	Ascentage Pharma Rockville, MD	breast cancer	Phase I/II www.ascentagepharma.com
ARV-471 (estrogen receptor alpha degradation enhancer)	Arvinas New Haven, CT Pfizer New York, NY	ER+/HER2- metastatic breast cancer	Phase II www.arvinas.com www.pfizer.com
ARX788 (tubulin inhibitor)	Ambrx San Diego, CA	HER2+ metastatic breast cancer (Fast Track)	Phase III www.ambrx.com
axalimogene filolisbac (gene vaccine) ORPHAN DRUG	Advaxis Monmouth Junction, NJ	cervical cancer (Fast Track)	Phase III www.advaxis.com
balixafortide (CXCR4 receptor antagonist)	Spexis Allschwil, Switzerland	breast cancer (Fast Track)	Phase III www.spexisbio.com

Cancer

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balstilimab (AGEN2034) (anti-PD-1 antibody)	Agenus Lexington, MA	cervical cancer (Fast Track)	Phase II www.agenusbio.com
batiraxcept (GAS6-AXL pathway inhibitor)	Aravive Houston, TX	platinum-resistant recurrent ovarian cancer (Fast Track)	Phase III www.aravive.com
bevacizumab biosimilar	Biocon Bengaluru, India Viatrix Canonsburg, PA	recurrent/metastatic cervical cancer	application submitted www.viatrix.com
bevacizumab biosimilar	Bio-Thera Solutions Guangzhou, China Sandoz Princeton, NJ	cervical cancer	application submitted www.sandoz.com
bintrafusp alfa (TGFbeta trap/anti-PD-L1)	EMD Serono Rockland, MA	2L cervical cancer	Phase II www.emdserono.com
breast cancer vaccine	Anixa Biosciences San Jose, CA Cleveland Clinic Cleveland, OH	breast cancer	Phase I www.anixa.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Bria-IMT™ (SV-BR-1-GM cancer vaccine)	BriaCell Therapeutics Philadelphia, PA	breast cancer	Phase I/II www.briacell.com
cabozatinib (multiple kinase inhibitor)	Exelixis Alameda, CA	endometrial cancer, ovarian cancer, triple negative breast cancer (+atezolizumab)	Phase I/II www.exelixis.com
camizestrant (SERD)	AstraZeneca Wilmington, DE	1L HR+ ESR1m breast cancer (combination therapy), 1L HR+ HER2- breast cancer (combination therapy)	Phase III www.astrazeneca.com
		ER+ breast cancer	Phase II www.astrazeneca.com
capivasertib (proto oncogene protein c-akt inhibitor)	AstraZeneca Wilmington, DE	1L metastatic triple negative breast cancer (combination therapy), 2L+ AI-resistant locally advanced or metastatic breast cancer (combination therapy), 1L early relapse/ET-resistant breast cancer (triple combination therapy)	Phase III www.astrazeneca.com
CDX-527 (anti-PD-L1/CD27 bispecific antibody)	Celldex Therapeutics Hampton, NJ	ovarian cancer	Phase I www.celldex.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ceralasertib (ATR protein inhibitor)	AstraZeneca Wilmington, DE	breast cancer, ovarian cancer (combination therapy)	Phase I/II www.astrazeneca.com
Cosela® trilaciclib	G1 Therapeutics Research Triangle Park, NC	1L/2L triple negative breast cancer (Fast Track)	Phase III www.g1therapeutics.com
		triple negative breast cancer	Phase II www.g1therapeutics.com
CX-072 + CX-2009 (PD-L1 prodrug immunotherapy + CD166 probody drug conjugate)	CytomX Therapeutics South San Francisco, CA	triple negative breast cancer	Phase II www.cytomx.com
CX-2009 (praluzatamab raptansine) (CD166 probody drug conjugate)	CytomX Therapeutics South San Francisco, CA	ER+/PR+ HER2- breast cancer	Phase II www.cytomx.com
D-0502 (SERD)	InventisBio Shanghai, China	breast cancer	Phase I www.inventisbio.com
DAN-222 (DNA topoisomerase 1 inhibitor)	Dantari Thousand Oaks, CA	HER2- metastatic breast cancer	Phase I www.dantari.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
datopotamab deruxtecan (Dato-DXd) (DNA topoisomerase I inhibitor)	AstraZeneca Wilmington, DE Daiichi Sankyo Basking Ridge, NJ	2/3L HR+ breast cancer	Phase III www.astrazeneca.com www.daiichisankyo.com
		HR+ breast cancer, triple negative breast cancer	Phase I www.astrazeneca.com www.daiichisankyo.com
DKN-01 (DKK1 protein inhibitor)	Leap Therapeutics Cambridge, MA	endometrial cancer	Phase II www.leaptx.com
DKY709 (novel immunomodulatory agent)	Novartis Morris Plains, NJ	triple negative breast cancer (monotherapy and PD-1 combination)	Phase I www.novartis.com
DPV-001 (immunostimulant cancer vaccine)	UbiVac Portland, OR	1/2L triple negative breast cancer	Phase I www.ubivac.com
DS-6000 (CDH6-directed ADC)	Daiichi Sankyo Basking Ridge, NJ	ovarian cancer	Phase I www.daiichisankyo.com
DZD1516 (ERBB 2 receptor antagonist)	Dizal Pharmaceutical Shanghai, China	breast cancer	Phase I www.dizalpharma.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
eganelisib (PI3K inhibitor)	Infinity Pharmaceuticals Cambridge, MA	1L metastatic triple negative breast cancer (Fast Track)	Phase III www.infi.com
elacestrant (RAD1901) (SERD)	Radius Health Boston, MA	ER+ breast cancer (Fast Track)	Phase III www.radiuspharm.com
ELI-002 (mKRAS cancer vaccine)	Elicio Therapeutics Boston, MA	ovarian cancer	Phase I www.elicio.com
elimusertib (BAY1895344) (ATR inhibitor)	Bayer Pharmaceuticals Whippany, NJ	ovarian cancer	Phase I www.bayer.com
ENB003 (endothelin B receptor antagonist)	ENB Therapeutics New York, NY	ovarian cancer	Phase I www.enbpharma.com
encequidar/paclitaxel + dostarlimab	Athenex Buffalo, NY	neoadjuvant breast cancer	Phase II www.athenex.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Enhertu® fam-trastuzumab deruxtecan-nxki	AstraZeneca Wilmington, DE Daiichi Sankyo Basking Ridge, NJ	2L HER2+ breast cancer	application submitted www.astrazeneca.com www.daiichisankyo.com
		3L HER2+ breast cancer, HER2 low breast cancer (post-chemo), HER2+ breast cancer (post neoadjuvant), HER2 low breast cancer (chemo naïve), 1L HER2+ breast cancer, HER2+ breast cancer (neoadjuvant)	Phase III www.astrazeneca.com www.daiichisankyo.com
		triple negative breast cancer	Phase II www.astrazeneca.com www.daiichisankyo.com
		2L HER2+ breast cancer, HER2 low breast cancer (chemo naïve/ post chemo), breast cancer (+nivolumab), breast cancer (+pembrolizumab)	Phase I www.astrazeneca.com www.daiichisankyo.com
enobosarm (selective androgen receptor targeting agonist)	Veru Miami, FL	metastatic breast cancer (monotherapy and combination therapy) (Fast Track)	Phase III www.verupharma.com
entinostat (HDAC inhibitor)	Syndax Biosciences Waltham, MA	breast cancer	Phase II completed www.syndax.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
EP0057 (nanoparticle drug conjugate)	Ellipses Pharma London, United Kingdom	ovarian cancer	Phase II www.ellipses.life
evorpcept (CD47 antigen inhibitor)	ALX Oncology South San Francisco, CA	breast cancer (+zanidatamab)	Phase I www.alxoncology.com
fruquintinib (VEGFR inhibitor)	HUTCHMED Hong Kong	triple negative breast cancer	Phase I/II www.hutch-med.com
fulvestrant (estrogen receptor antagonist)	Eagle Pharmaceuticals Woodcliff Lake, NJ	breast cancer	Phase I www.eagleus.com
futibatinib (FGFR 1-4 inhibitor)	Taiho Oncology Princeton, NJ	breast cancer with FGFR 1/2 amplification	Phase II www.taihooncology.com
galinpepimut-S (cancer peptide vaccine)	Sellas Life Sciences New York, NY	ovarian cancer (+nivolumab)	Phase I completed www.sellaslifesciences.com
gavocabtagene autoleucel (gavo-cel) (T-cell therapy targeting mesothelin-positive tumors)	TCR2 Therapeutics Cambridge, MA	ovarian cancer	Phase I www.tcr2.com
GEN-1 (IL-12 gene therapy) ORPHAN DRUG	Celsion Lawrenceville, NJ	ovarian cancer (Fast Track)	Phase II www.celsion.com

Cancer**Drug Name****Sponsor****Indication****Development Phase**giredestrant (RG6171)
(SERD)Roche/Genentech
South San Francisco, CAER+ HER2- metastatic breast cancer,
ER+ breast cancer (adjuvant)Phase III
www.roche.com-----
ER+ breast cancer (neoadjuvant),
2/3L ER+ HER2- breast cancer
(Fast Track)Phase II
www.roche.comGLSI-100
(GP2 immunotherapy)Greenwich Life Sciences
Stafford, TX

breast cancer

Phase II completed
www.greenwichlifesciences.comGMI-1359
(dual E-selectin and CXCR4 antagonist)GlycoMimetics
Rockville, MD

breast cancer

Phase I
www.glycomimetics.comGRN 300
(SIK2 inhibitor)Green3Bio
Austin, TX

ovarian cancer

Phase I
www.greenfirebio.comH3B-6545
(ER-alpha inhibitor)Eisai
Woodcliff Lake, NJ

breast cancer (monotherapy)

Phase I/II
www.eisai.com-----
breast cancer (+palbociclib)Phase I
www.eisai.comHB-201
(immunostimulant)Hookipa Pharma
New York, NY

HPV-16+ cervical cancer

Phase I
www.hookipapharma.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
HC-5404 (PERK inhibitor)	HiberCell New York, NY	metastatic breast cancer (Fast Track)	Phase I www.hibercell.com
HPN536 (T lymphocyte stimulant)	Harpoon Therapeutics South San Francisco, CA	ovarian cancer	Phase I www.harpoontx.com
huMNC2-CAR44 (CAR-T cell therapy)	Minerva Biotechnologies Waltham, MA	breast cancer	Phase I/II www.minervabio.com
Ibrance® palbociclib	Pfizer New York, NY	ER+ HER2+ metastatic breast cancer	Phase III www.pfizer.com
		ER+ HER2- metastatic breast cancer (+ARV-471)	Phase I www.pfizer.com
ICT01 (anti-BTN3A mAb)	ImCheck Therapeutics Marseille, France	breast cancer, ovarian cancer	Phase I/II www.imchecktherapeutics.com
Imfinzi® durvalumab	AstraZeneca Wilmington, DE	locally-advanced cervical cancer, 1L metastatic triple negative breast cancer	Phase III www.astrazeneca.com

Cancer <u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
IMGC936 (ADAM9)	ImmunoGen Waltham, MA MacroGenics Rockville, MD	triple negative breast cancer	Phase I www.immunogen.com www.macrogenics.com
imlunestrant (SERD)	Lilly Indianapolis, IN	ER+ HER2- metastatic breast cancer	Phase III www.lilly.com
inavolisib (RG6114) (PI3K alpha inhibitor)	Roche/Genentech South San Francisco, CA	1L HR+ metastatic breast cancer	Phase III www.roche.com
INT230-6 (cisplatin/vinblastine)	Intensity Therapeutics Westport, CT	early-stage breast cancer, breast cancer (+ipilimumab)	Phase II www.intensitytherapeutics.com
		triple negative breast cancer	Phase I www.intensitytherapeutics.com
IRX4204 (RXR agonist)	Io Therapeutics Santa Ana, CA	HER2+ breast cancer	Phase I www.io-therapeutics.com
Jemperli® dostarlimab	GlaxoSmithKline Research Triangle Park, NC	1L endometrial cancer (monotherapy), 1L endometrial cancer (+niraparib) (Breakthrough Therapy)	Phase III www.gsk.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Kadcyla® ado-trastuzumab emtastine	Roche/Genentech South San Francisco, CA	2L HER2+ PD-L1+ metastatic breast cancer (+atezolizumab), HER2+ early breast cancer high-risk (+atezolizumab)	Phase III www.roche.com
Kevetrin™ thioureidobutyronitrile ORPHAN DRUG	Innovation Pharmaceuticals Wakefield, MA	ovarian cancer	Phase II completed www.ipharminc.com
Keytruda® pembrolizumab	Merck Kenilworth, NJ	MSI-H or dMMR endometrial cancer	application submitted www.merck.com
		ovarian cancer	Phase III www.merck.com
Kisqali® ribociclib	Novartis East Hanover, NJ	HR+ HER2- breast cancer (adjuvant)	Phase III www.novartis.com
ladiratumumab vedotin (dendritic cancer vaccine)	Merck Kenilworth, NJ Seagen Bothell, WA	1L metastatic triple negative breast cancer (+pembrolizumab)	Phase II www.merck.com
		metastatic breast cancer	Phase I www.merck.com
lasofoxifene (SERM)	Sermonix Pharmaceuticals Columbus, OH	breast cancer (combination therapy) (Fast Track)	Phase III www.sermonixpharma.com

Cancer**Drug Name****Sponsor****Indication****Development Phase****Lenvima®**
lenvatinibEisai
Woodcliff Lake, NJ

1L endometrial cancer

Phase III
www.eisai.com-----
endometrial cancerPhase I/II
www.eisai.comlerociclib (EQ132)
(CDK4/6 kinase inhibitor)EQRx
Cambridge, MA

breast cancer

Phase II
www.eqr.comleronlimab
(CCR5 antagonist)CytoDyn
Vancouver, WA

ovarian cancer, uterine cancer

Phase II
www.cytodyn.com-----
triple negative breast cancer
(Fast Track)Phase I/II
www.cytodyn.com**Libtayo®**
cemiplimab
ORPHAN DRUGRegeneron Pharmaceuticals
Tarrytown, NY
Sanofi
Wilmington, DE

2L cervical cancer (Fast Track)

application submitted
www.regeneron.com
www.sanofi.com-----
2L cervical cancer (+ISA101b)Phase II
www.regeneron.com
www.sanofi.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
lifileucel (tumor infiltrating lymphocyte) ORPHAN DRUG	Iovance Biotherapeutics San Carlos, CA	cervical cancer (Fast Track) (Breakthrough Therapy)	Phase III www.iovance.com
		cervical cancer (+pembrolizumab)	Phase II www.iovance.com
LiPlaCis [®] cisplatin in phospholipase A2 modified liposome	Allarity Therapeutics Cambridge, MA Smerud Medical Research Oslo, Norway	metastatic breast cancer	Phase II www.allarity.com
lucitanib (tyrosine kinase inhibitor)	Clovis Oncology Boulder, CO	gynecologic cancer (+nivolumab)	Phase II www.clovisoncology.com
Lynparza [®] olaparib	AstraZeneca Wilmington, DE Merck Kenilworth, NJ	1L endometrial cancer (+durvalumab), 1L ovarian cancer (+durvalumab and bevacizumab), 1L BRCAwt ovarian cancer	Phase III www.astrazeneca.com www.merck.com
magrolimab (anti-CD47 antibody)	Gilead Sciences Foster City, CA	triple negative breast cancer	Phase II www.gilead.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
maveropepimut-S (peptide cancer vaccine) ORPHAN DRUG	IMV Cambridge, MA	ovarian cancer (Fast Track)	Phase II www.imv-inc.com
		breast cancer (neoadjuvant)	Phase I www.imv-inc.com
mecbotamab vedotin (AXL-targeted antibody-drug conjugate)	BioAtla San Diego, CA	ovarian cancer	Phase II www.bioatla.com
MEN1611 (PI3K inhibitor)	Menarini Florence, Italy	metastatic breast cancer	Phase I www.menarini.com
MGC018 (B7-H3)	MacroGenics Rockville, MD	triple negative breast cancer	Phase II www.macrogenics.com
mifepristone (glucocorticoid/progesterone receptor antagonist)	Corcept Therapeutics Menlo Park, CA	metastatic GR+ triple negative breast cancer, HER2- metastatic breast cancer (combination therapy)	Phase II www.corcept.com
mirvetuximab soravtansine (antibody drug conjugate) ORPHAN DRUG	ImmunoGen Waltham, MA	platinum-resistant ovarian cancer	Phase III www.immunogen.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
MK-2140 (zilovetumab vedotin) (antibody-drug conjugate)	Merck Whitehouse Station, NJ	breast cancer	Phase II www.merck.com
MORAb-202 (antibody-drug conjugate)	Eisai Woodcliff Park, NJ	endometrial cancer, ovarian cancer, triple negative breast cancer	Phase I/II www.eisai.com
NanoPac® paclitaxel nanoformulation	Nanology Fort Worth, TX	ovarian cancer, peritoneal cancer	Phase II www.nanology.us
navicixizumab (anti-DLL4/VEGF bispecific antibody)	OncXerna Therapeutics Waltham, MA	fallopian tube cancer, ovarian cancer, primary peritoneal cancer (Fast Track)	Phase I www.oncxerna.com
NBE-002 (immune-stimulatory antibody drug conjugate)	NBE Therapeutics Basel, Switzerland	triple negative breast cancer	Phase I/II www.nbe-therapeutics.com
nelipepimut-S	Sellas Life Sciences New York, NY	breast cancer (Fast Track)	Phase II completed www.sellaslifesciences.com
nemvaleukin alfa (interleukin-2 receptor agonist)	Alkermes Waltham, MA	platinum-resistant ovarian cancer (+pembrolizumab) (Fast Track)	Phase III www.alkermes.com
Nerlynx® neratinib	Puma Biotechnology Los Angeles, CA	HER2-mutant breast cancer, HER2-mutant cervical cancer	Phase II www.pumabiotechnology.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
NUV-422 (CDK 2/4/6 inhibitor)	Nuvation Bio New York, NY	breast cancer	Phase I www.nuvationbio.com
NZV930 (CD73 antagonist)	Novartis East Hanover, NJ	triple negative breast cancer, ovarian cancer (monotherapy and combination therapy)	Phase II www.novartis.com
odetiglucon (Dectin-1)	HiberCell New York, NY	metastatic breast cancer (+pembrolizumab)	Phase II www.hibercell.com
ofranergene obadenovec (gene therapy)	VBL Therapeutics Pearl River, NY	platinum-resistant ovarian cancer	Phase III www.vblrx.com
olvimulogene nanivacirepvec (Olvi-Vec) (oncolytic vaccinia virus)	Genelux Westlake Village, CA	ovarian cancer	Phase II www.genelux.com
onapristone (ONA-XR) (progesterone receptor antagonist)	Context Therapeutics Philadelphia, PA	1L metastatic breast cancer 2L/3L metastatic breast cancer	Phase II www.cntexttherapeutics.com
OP-1250 (CERAN and SERD)	Olema Pharmaceuticals San Francisco, CA	breast cancer	Phase I/II www.olema.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Opdivo® nivolumab	Bristol-Myers Squibb Princeton, NJ	ER+ HER2- breast cancer (neoadjuvant)	Phase III www.bms.com
		ER+ HER2- breast cancer (neoadjuvant) (+ CD4/6 inhibitor)	Phase II www.bms.com
oregovomab (anti-idiotypic mAb) ORPHAN DRUG	OncoQuest Pharmaceuticals Edmonton, Canada	ovarian cancer	Phase III www.oncoquestinc.com
ORIN1001 (ERN2 protein inhibitor)	Orinove Newbury Park, CA	breast cancer (Fast Track)	Phase I/II www.orinove.com
osugacestat (AL101) (gamma secretase inhibitor)	Ayala Pharmaceuticals Wilmington, DE	triple negative breast cancer	Phase II www.ayalapharma.com
OTS167 (MELK inhibitor)	OncoTherapy Science Kawasaki City, Japan	breast cancer	Phase I www.oncotherapy.co.jp
ozuriftamab vedotin (ROR2 antibody drug conjugate)	BioAtla San Diego, CA	ovarian cancer	Phase II www.bioatla.com
paclitaxel liposomal	Sun Pharma USA Princeton, NJ	breast cancer	application submitted www.sunpharma.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
patritumab deruxtecan (HER3-DXd) (DNA topoisomerase I inhibitor)	Daiichi Sankyo Basking Ridge, NJ	HER3+ breast cancer	Phase I www.daiichi.com
PDS0101 (cancer immunotherapy)	PDS Biotechnology Florham Park, NY	1L cervical cancer, HPV+ cervical cancer, vaginal cancer, vulvar cancer	Phase II www.pdsbiotech.com
pelareorep (immuno-oncolytic reovirus)	Oncolytics Biotech Calgary, Canada	HR+ HER2- metastatic breast cancer (+avelumab) (Fast Track), triple negative breast cancer (+INCMGA00012)	Phase II www.oncolyticsbiotech.com
		early stage breast cancer (+atezolizumab)	Phase I www.oncolyticsbiotech.com
PF-06873600 (ebvaciclib) (CDK 2,4,6 inhibitor)	Pfizer New York, NY	metastatic breast cancer	Phase I www.pfizer.com
PF-07104091 (CDK2 inhibitor)	Pfizer New York, NY	metastatic breast cancer	Phase I www.pfizer.com
PF-07220060 (CDK4 inhibitor)	Pfizer New York, NY	metastatic breast cancer	Phase I www.pfizer.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
PF-07248144 (KAT6A epigenetic modifier)	Pfizer New York, NY	metastatic breast cancer	Phase I www.pfizer.com
PF-07257876 (CD47cPD-LA bispecific antibody)	Pfizer New York, NY	ovarian cancer	Phase I www.pfizer.com
PF-07260437 (B7H4xCD3 bispecific antibody)	Pfizer New York, NY	metastatic breast cancer	Phase I www.pfizer.com
pidnarulex (CX-5461) (G-quadruplex stabilizer)	Senhwa Biosciences San Diego, CA	breast and ovarian cancers BRCA1/2, PALB2 or other HRD mutations (Fast Track)	Phase II www.senhwabio.com
Piqray® alpelisib	Novartis East Hanover, NJ	ovarian cancer, triple negative breast cancer, HER2+ advanced breast cancer	Phase III www.novartis.com
PLX2853 (BET inhibitor)	Daiichi Sankyo Basking Ridge, NJ	gynecologic cancer, ovarian cancer	Phase I www.daiichisankyo.com
PMD-026 (ribosomal protein S6 kinase inhibitor)	Phoenix Molecular Designs Vancouver, Canada	breast cancer	Phase I www.phoenixmd.ca

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
poziotinib (pan-HER and EGFR inhibitor)	Spectrum Pharmaceuticals Henderson, NV	EGFR or HER2 activating mutations in breast cancer	Phase II www.sppirx.com
PRGN-3005 (CAR-T cell therapy)	Precigen Germantown, MA	ovarian cancer	Phase I www.precigen.com
REGN4018 (MUC16xCD3 bispecific antibody)	Regeneron Pharmaceuticals Tarrytown, NY	platinum-resistant ovarian cancer	Phase I www.regeneron.com
REGN5668 (MUC16xCD28 bispecific antibody)	Regeneron Pharmaceuticals Tarrytown, NY	ovarian cancer	Phase I www.regeneron.com
relacorilant (glucocorticoid receptor antagonist)	Corcept Therapeutics Menlo Park, CA	ovarian cancer (+Nab-paclitaxel)	Phase II completed www.corcept.com
retifanlimab (anti-PD-1 mAb)	Incyte Wilmington, De	MSI-H endometrial cancer (Fast Track)	Phase II www.incyte.com
rintatolimod (mismatched double-stranded RNA)	AIM ImmunoTech Ocala, FL	breast cancer, ovarian cancer	Phase II www.aimimmuno.com

Cancer**Drug Name****Sponsor****Indication****Development Phase**rintodestrant
(SERD)G1 Therapeutics
Research Triangle Park, NC

ER+ HER2- breast cancer (+palbociclib)

Phase II

www.g1therapeutics.comER+ HER2- breast cancer
(monotherapy)

Phase I

www.g1therapeutics.comrostaporfin (REM-001)
(photodynamic therapeutic)Kintara Therapeutics
San Diego, CA

cutaneous metastatic breast cancer

Phase III

www.kintara.comRPTR-168
(T cell therapy)Repertoire Immune Medicines
Cambridge, MA

cervical cancer

Phase I

www.repertoire.comRTX-321
(red blood cell therapy)Rubius Therapeutics
Cambridge, MA

HPV16+ cervical cancer

Phase I

www.rubiustx.com**Rubraca®**
rucaparibClovis Oncology
Boulder, CO1L maintenance ovarian cancer
(monotherapy and +nivolumab)

Phase III

www.clovisoncology.comrunimotamab (RG6194)
(HER2 x CD3 bispecific antibody)Roche/Genentech
South San Francisco, CA

breast cancer

Phase I

www.roche.comsamuraciclib (CT7001)
(CDK7 inhibitor)Carrick Therapeutics
Dublin, Ireland

HR+ HER2- breast cancer (Fast Track)

Phase I/II

www.carricktherapeutics.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
SBT6050 (TLR8 agonist)	Silverback Therapeutics Seattle, WA	breast cancer	Phase I www.silverbacktx.com
SL-172154 (recombinant fusion protein)	Shattuck Labs Austin, TX	ovarian cancer	Phase I www.shattuckslabs.com
sotigalimab (CD40 agonistic antibody)	Apexigen San Carlos, CA	ovarian cancer	Phase II www.apexigen.com
spartalizumab (PDR001) (PD-1 inhibitor)	Novartis East Hanover, NJ	ovarian cancer (combination therapy), triple negative breast cancer (combination therapy)	Phase I www.novartis.com
SPL-108 (immunomodulator)	Splash Pharmaceuticals San Diego, CA	ovarian epithelial cancer	Phase I completed www.splashpharma.com
stenoparib (2X-121) (PARP inhibitor)	Allarity Therapeutics Cambridge, MA	ovarian cancer	Phase II www.allarity.com
STI-3031 (PD-L1)	Sorrento Therapeutics San Diego, CA	cervical cancer	Phase III www.sorrentotherapeutics.com
STRO-002 (antibody drug conjugate)	Sutro Biopharma South San Francisco, CA	endometrial cancer, ovarian cancer (Fast Track)	Phase I www.sutrobio.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
SY5609 (CDK7 inhibitor)	Syros Pharmaceuticals Cambridge, MA	breast cancer	Phase I www.syros.com
SYD985 (trastuzumab duocarmazine) (antibody drug conjugate)	Byondis Nijmegen, the Netherlands	HER2+ metastatic breast cancer (Fast Track)	Phase III www.byondis.com
		HER2-expressing uterine serous cancer	Phase II www.byondis.com
TAC01-HER2 (T cell therapy)	Triumvira Immunologics Austin, TX	breast cancer	Phase I www.triumvira.com
TAEK-VAC-HerBy (cancer vaccine)	Bavarian Nordic Morrisville, NC	breast cancer, ovarian cancer	Phase I www.bavarian-nordic.com
TAK-676 (MPYS protein stimulant)	Takeda Deerfield, IL	triple negative breast cancer	Phase I www.takeda.com
TAS2940 (ERBB inhibitor)	Taiho Oncology Princeton, NJ	breast cancer	Phase I www.taihooncology.com
TAVO™ tavokinogene telseplasmid	OncoSec Medical Pennington, NJ	triple negative breast cancer (combination therapy)	Phase II www.oncosec.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
TCR T-cell therapy	Alaunos Therapeutics Houston, TX	endometrial cancer, ovarian cancer	Phase I www.alaunos.com
Tecentriq® atezolizumab	Roche/Genentech South San Francisco, CA	1L triple negative breast cancer (+capecitabine or carbo/gem). triple negative breast cancer (+paclitaxel)	Phase III www.roche.com
TG4050 (viral-based neoantigen vaccine)	Transgene France	ovarian cancer, fallopian tube cancer, peritoneal cancer	Phase I www.transgene.fr
tiragolumab (RG6058) (TIGIT inhibitor)	Roche/Genentech South San Francisco, CA	cervical cancer (combination therapy)	Phase II www.roche.com
Tivdak® tisotumab vedotin	Seagen Bothell, WA	2L/3L metastatic/recurrent cervical cancer	Phase III www.seagen.com
		1L/2L recurrent or metastatic cervical cancer, 2L platinum-resistant ovarian cancer	Phase II www.seagen.com
TJ004309 (uliledlimab) (anti-CD73 mAb)	I-MAB Biopharma Gaithersburg, MD	ovarian cancer, triple negative breast cancer	Phase II www.i-mabbioharma.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
TOL2506 (leuprorelin)	Tolmar Fort Collins, CO	breast cancer	Phase III www.tolmar.com
tomivosertib (MNK inhibitor)	Effector Therapeutics Solana Beach, CA	metastatic breast cancer	Phase II www.effector.com
toripalimab (PD-1 inhibitor)	Coherus BioSciences Redwood City, CA Junshi Biosciences Shanghai, China	triple negative breast cancer (+albumin-bound paclitaxel)	Phase III www.coherus.com
trastuzumab biosimilar (EG12014)	Sandoz Princeton, NJ	breast cancer	application submitted www.sandoz.com
trastuzumab biosimilar (TX05)	Tanvex BioPharma Irvine, CA	breast cancer	application submitted www.tanvex.com
Trodelvy® sacituzumab govitecan-hziy	Gilead Sciences Foster City, CA	HR+ HER2- metastatic breast cancer 1L PD-L1+ metastatic triple negative breast cancer, 1L PD-L1- metastatic triple negative breast cancer	Phase III www.gilead.com
TT-00420 (multiple kinase inhibitor)	TransThera Biosciences Nanjing, China	breast cancer	Phase I/II www.transtherabio.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Tukysa® tucatinib	Merck Kenilworth, NJ Seagen Bothell, WA	1L/2L metastatic HER2+ breast cancer, high-risk HER2+ breast cancer (adjuvant)	Phase III www.seagen.com
		2L HER2+ metastatic breast cancer, cervical cancer, endometrial cancer	Phase II www.seagen.com
upifitamab rilsodotin (NaPi2b targeting antibody drug conjugate)	Mersana Therapeutics Cambridge, MA	platinum-resistant ovarian cancer (Fast Track)	Phase II www.mersana.com
V937 (CD55 antigen inhibitor)	Merck Kenilworth, NJ	breast cancer	Phase II www.merck.com
veliparib (PARP inhibitor)	AbbVie North Chicago, IL	BRCA breast cancer, 1L ovarian cancer	Phase III www.abbvie.com
VGX-3100 (DNA cancer immunotherapy)	Inovio Pharmaceuticals Plymouth Meeting, PA	precancerous cervical dysplasia	Phase III www.inovio.com
		precancerous vulvar dysplasia	Phase II www.inovio.com
vibostolimab/pembrolizumab (TIGIT inhibitor/PD-1 antagonist)	Merck Kenilworth, NJ	breast cancer, cervical cancer, endometrial cancer	Phase II www.merck.com

Cancer**Drug Name****Sponsor****Indication****Development Phase**

Vigil™
(genetically-modified autologous
tumor cell vaccine and bi-shRNAfurin)

Gradalis
Dallas, TX

ovarian cancer (monotherapy),
ovarian cancer (combination therapy)

Phase II
www.gradalisinc.com

BRCA-wt ovarian cancer
(combination therapy), triple negative
breast cancer (combination therapy)
triple negative breast cancer

Phase I
www.gradalisinc.com

Voyager V1
(cell death stimulant)

Vyriad
Rochester, MN

endometrial cancer
(combination therapy)

Phase II
www.vyriad.com

VS6766
(dual RAF/MEK inhibitor)
ORPHAN DRUG

Verastem Oncology
Needham, MA

low-grade serous ovarian cancer
(Breakthrough Therapy)

Phase II
www.verastem.com

low-grade serous ovarian cancer
(+defactinib), endometrial cancer

Phase I
www.verastem.com

VT101
(alpha-tocopherolxyacetic acid)

Veana Therapeutics
Portland, OR

refractory HER2+ breast cancer

Phase I
www.veana-therapeutics.com

vudalimab
(PD-1 x CTLA4)

Xencor
Monrovia, CA

gynecologic cancers

Phase II
www.xencor.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
WNT974 (procupine inhibitor)	Novartis East Hanover, NJ	cervical cancer, triple negative breast cancer	Phase I www.novartis.com
xentuzumab (IgG1 mAb)	Boehringer Ingelheim Ridgefield, CT	breast cancer (combination therapy)	Phase II www.boehringer-ingelheim.com
XMT-1592 (antibody drug conjugate)	Mersana Therapeutics Cambridge, MA	ovarian cancer	Phase I www.mersana.com
Xpovio® selinexor	Karyopharm Therapeutics Newton, MA	endometrial cancer	Phase III www.karyopharm.com
zalifrelimab + balstilimab (CTLA-4 + PD-1)	Agenus Lexington, MA	recurrent/metastatic cervical cancer	Phase II www.agenusbio.com
zanidatamab (IgG1 bi-specific antibody)	Zymeworks Vancouver, Canada	HER2+ HR+ breast cancer	Phase II www.zymeworks.com
Zejula® niraparib	GlaxoSmithKline Research Triangle Park, NC	1L maintenance ovarian cancer (+dostarlimab), pre-metastatic select biomarker population breast cancer	Phase III www.gsk.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ZEN-3694 (BET inhibitor)	Zenith Epigenetics San Francisco, CA	triple negative breast cancer	Phase II www.zenithepigenetics.com
zenocutuzumab (MCLA-128) (IgG1 bispecific antibody)	Merus Cambridge, MA	breast cancer	Phase II www.merus.nl
zilovertamab (ROR1 mAb)	Oncternal Therapeutics San Diego, CA	breast cancer	Phase I www.oncternal.com
ZN-c3 (Weel1 inhibitor)	Zentalis Pharmaceuticals New York, NY	uterine serous carcinoma (Fast Track), ovarian cancer	Phase II www.zentalis.com
ZN-c5 (oral SERD)	Zentalis Pharmaceuticals New York, NY	breast cancer	Phase II www.zentalis.com
zotatifin (eIF4A inhibitor)	Effector Therapeutics Solana Beach, CA	ER+ breast cancer	Phase I www.effector.com

Eye Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
A197 (T-lymphocyte inhibitor)	Aramis Biosciences Medfield, MA	dry eye disease	Phase I www.aramisbio.com

Eye Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AGN-231868 (chemokine receptor antagonist)	AbbVie North Chicago, IL	dry eye disease	Phase II www.abbvie.com
AGN-242428 (ROR)	AbbVie North Chicago, IL	dry eye disease	Phase II www.abbvie.com
ALG-1007 (integrin inhibitor)	Allegro Ophthalmics San Juan Capistrano, CA	dry eye disease	Phase II www.allegroeye.com
ALY688 (adiponectin analogue)	Allysta Pharmaceuticals Bellevue, WA	dry eye disease	Phase III www.allysta.com
AR-15512 (TRPM8 protein stimulant)	Aerie Pharmaceuticals Durham, NC	dry eye disease	Phase II www.aeriepharma.com
AXR-159 (eye drop) (integrin antagonist)	AxeroVision Carlsbad, CA	chronic dry eye disease	Phase II www.axerovision.com
AXR-270 (cream) (SeGRA)	AxeroVision Carlsbad, CA	acute dry eye disease	Phase II www.axerovision.com
BRM 421 (peptide drug molecule)	BRIM Biotechnology Taipei, Taiwan	dry eye disease	Phase II/III completed www.brimbiotech.com

Eye Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
CAM-101 (fibrogen-depleted human platelet lysate cell therapy)	Cambium Medical Technologies Atlanta, GA	dry eye disease	Phase I/II www.cambiumbio.com
CyclASol® cyclosporine A	Novaliq Cambridge, MA	dry eye disease	Phase III www.novaliq.com
IC 265 (Syk kinase inhibitor)	IACTA Pharmaceuticals Guaynabo, PR	dry eye disease	Phase II www.iactapharma.com
iNexin™ (connexin 43 inhibitor)	FirstString Research Mount Pleasant, SC	signs and symptoms associated with dry eye disease	Phase I www.firststringresearch.com
K10-101 (DHODH inhibitor)	Kiora Pharmaceuticals Salt Lake City, UT	dry eye disease	Phase I www.kiorapharma.com
K-161	Kowa Pharma Development Boston, MA	dry eye disease	Phase II www.kowaus.com
NOV03 (perfluorohexyloctane)	Bausch & Lomb Rochester, NY Novaliq Cambridge, MA	dry eye disease	Phase III www.bauschhealth.com www.novaliq.com

Eye Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
NRO-1 (GDNF agonist)	Neuroptika Cambridge, MA	dry eye disease	Phase II www.neuroptika.com
Oxervate™ cenegermin-bkbj	Dompe Farmaceutici Milan, Italy	Sjogren's-related dry eye disease	Phase III www.dompe.com
OTX-CSI (cyclosporine intracanalicular insert)	Ocular Therapeutix Bedford, MA	dry eye disease	Phase II www.ocutx.com
OTX-DED (dexamethasone intracanalicular insert)	Ocular Therapeutix Bedford, MA	episodic dry eye disease	Phase II www.ocutx.com
pilocarpine topical cream	Glaukos San Clemente, CA	dry eye disease	Phase II www.glaukos.com
PL9643 (MCR agonist)	Palatin Technologies Cranbury, NJ	dry eye disease	Phase III www.palatin.com
reproxalap (malondialdehyde inhibitor)	Aldeyra Therapeutics Lexington, MA	dry eye disease	Phase III www.aldeyra.com
RGN-259 eye drops (thymosin beta-4)	RegeneRx Biopharmaceuticals Rockville, MD	dry eye disease	Phase III completed www.regenerx.com

SDP-4 (I-kappa B kinase inhibitor)	SilkTech Biopharmaceuticals Plymouth, MN	dry eye disease	Phase II completed www.silk-tech.com
SkQ1 eye drops (cardiolipin peroxidation inhibitor)	Mitotech Luxembourg, the Netherlands	dry eye disease	Phase III www.mitotechpharma.com
ST-100 (collagen replacement)	Stuart Therapeutics Stuart, FL	dry eye disease	Phase II www.stuarttherapeutics.com
SURF-100 (mycophenolic acid, low concentration betamethasone in Klarity® diluent)	Surface Ophthalmics Pleasanton, California	acute dry eye disease	Phase II www.surfaceophthalmics.com
SURF-200 (low concentration betamethasone in Klarity® diluent)	Surface Ophthalmics Pleasanton, California	acute dry eye disease	Phase II www.surfaceophthalmics.com
synthetic lacritin	TearSolutions Charlottesville, VA	dry eye disease	Phase II www.tearsolutions.com
tanfanercept (TNF-alpha receptor inhibitor)	HanAll Biopharma Seoul, South Korea	dry eye disease	Phase III www.hanall.co.kr
tavilermide (TrkA receptor agonist)	Mimetogen USA Boston, MA	dry eye disease	Phase III www.mimetogen.com

Eye Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
tivanisiran (SYL-1001) (RNA interference)	Sylentis Madrid, Spain	Sjogren's-related dry eye disease	Phase III www.sylentis.com
VVN001 (LFA-1 inhibitor)	VivaVision Biotech Shanghai, China	dry eye disease	Phase II completed www.vivavisionbio.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
bacteriophage therapeutic	Adaptive Phage Therapeutics Gaithersburg, MD	chronic recurrent urinary tract infections	Phase I/II www.aphage.com
Brexafemme® ibrexafungerp ORPHAN DRUG	SCYNEXIS Jersey City, NJ	prevention of recurrent vulvovaginal candidiasis, invasive candidiasis, candidemia	Phase III www.scynexis.com
cefepime/enmetazobactam fixed-dose combination	Allegra Therapeutics Saint-Louis, France	urinary tract infections	Phase III www.allegra.com
cefepime/taniborbactam fixed-dose combination	VenatoRx Pharmaceuticals Malvern, PA	complicated urinary tract infections (Fast Track)	Phase III www.venatorx.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ETX0282CPDP (beta-lactamases inhibitor and cefpodoxime combination)	Entasis Therapeutics Waltham, MA	urinary tract infections	Phase I www.entasistx.com
EVO100 (citric acid/lactic acid/potassium bitartrate)	Evoform Biosciences San Diego, CA	prevention of urogenital chlamydia and gonorrhea in women (Fast Track)	Phase III www.evoform.com
		bacterial vaginosis	Phase I www.evoform.com
fosfomycin intravenous	Nabriva Therapeutics Fort Washington, PA	complicated urinary tract infections (Fast Track)	application submitted www.nabriva.com
gepotidacin (II topoisomerase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	uncomplicated urinary tract infections (acute cystitis)	Phase III www.gsk.com
GSK3882347 (FimH antagonist)	GlaxoSmithKline Research Triangle Park, NC	uncomplicated urinary tract infections	Phase I www.gsk.com
KSP-1007 (beta lactamase inhibitor)	Sumitovant New York, NY Sumitomo Dainippon Pharma Osaka, Japan	complicated urinary tract infections	Phase I www.ds-pharma.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
LACTIN-V (live biotherapeutic)	Osel Mountain View, CA	recurrent bacterial vaginosis, recurrent urinary tract infections	Phase II www.oselinc.com
LBP-EC01 (phage cocktail)	Locus Biosciences Morrisville, NC	urinary tract infections	Phase I www.locus-bio.com
metronidazole gel	Curatek Pharmaceuticals Elk Grove Village, IL	vaginal infections	Phase III www.curatek.com
metronidazole/terconazole gel	Curatek Pharmaceuticals Elk Grove Village, IL	vaginal infections	Phase III www.curatek.com
NDV-3 (recombinant protein vaccine)	NovaDigm Therapeutics Boston, MA	candidiasis	Phase II www.novodigm.net
oteseconazole (14-alpha demethylase inhibitor)	Mycovia Pharmaceuticals Durham, NC	recurrent vulvovaginal candidiasis (Fast Track)	application submitted www.mycovia.com
RBX2660 (microbiome modulator)	Rebiotix Roseville, MN	multi-drug resistant urinary tract infections	Phase I www.rebiotix.com
rezafungin (glucan synthase inhibitor) ORPHAN DRUG	Cidara Therapeutics San Diego, CA	candidiasis, candidemia (Fast Track)	Phase III www.cidara.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
SP0148 (HSV-2 therapeutic vaccine)	Sanofi Bridgewater, NJ	herpes simplex virus type II	Phase I www.sanofi.com
sulopenem (intravenous) (cell wall inhibitor)	Iterum Therapeutics Chicago, IL	complicated urinary tract infections (Fast Track)	Phase III www.iterumtx.com
sulopenem etzadroxil (oral) (cell wall inhibitor)	Iterum Therapeutics Chicago, IL	complicated urinary tract infections (Fast Track), uncomplicated urinary tract infections (Fast Track)	application submitted www.iterumtx.com
tebipenem HBr (cell wall inhibitor)	Spero Therapeutics Cambridge, MA	urinary tract infections (Fast Track)	application submitted www.sperotherapeutics.com
terconazole gel	Curatek Pharmaceuticals Elk Grove Village, IL	vaginal infections	Phase III www.curatek.com

Mental Illness

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ACT-539313 (orexin receptor type 1 antagonist)	Idorsia Pharmaceuticals Allschwil, Switzerland	binge-eating disorder	Phase II www.idorsia.com

Mental Illness

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AL001 (lithium cocrystal)	Alzamend Neuro Atlanta, GA	depression, post-traumatic stress disorder	Phase I www.alzamend.com
ALTO-100 (personalized medicine)	Alto Neuroscience Los Altos, CA	major depressive disorder, post-traumatic stress disorder	Phase II www.altoneuroscience.com
ALTO-300 (personalized medicine)	Alto Neuroscience Los Altos, CA	major depressive disorder, post-traumatic stress disorder	Phase II www.altoneuroscience.com
AXS-05 (bupropion/dextromethorphan)	Axsome Therapeutics New York, NY	major depressive disorder (Fast Track) (Breakthrough Therapy)	application submitted www.axsome.com
BI 1358894 (TRPC4/5 cation channel inhibitor)	Boehringer Ingelheim Ridgefield, CT	major depressive disorder, post-traumatic stress disorder	Phase II www.boehringer-ingelheim.com
BIIB125 (zuranolone) (GABA-A receptor modulator)	Biogen Cambridge, MA Sage Therapeutics Cambridge, MA	major depressive disorder (Fast Track) (Breakthrough Therapy), postpartum depression (Fast Track)	Phase III www.biogen.com www.sagerx.com
BNC210 (negative allosteric modulator)	Bionomics Adelaide, Australia	post-traumatic stress disorder, social anxiety disorder (Fast Track)	Phase II www.bionomics.com.au

Mental Illness

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
BRII-296	Brii Biosciences Durham, NC	postpartum depression	Phase I www.briibio.com
cannabidiol (liquid structure CBD)	ANANDA Scientific Greenwood Village, CO	post-traumatic stress disorder	Phase I/II www.anandascientific.com
cannabidiol technosphere (cannabinoid receptor agonist)	Receptor Life Sciences Seattle, WA	acute panic, anxiety disorder	Phase I www.receptorlife.com
centanafadine (triple reuptake inhibitor)	Otsuka Rockville, MD	binge-eating disorder	Phase II www.otsuka-us.com
COMP360 (psilocybin) (serotonin 2 receptor agonist)	COMPASS Pathways London, United Kingdom	treatment-resistant depression (Breakthrough Therapy)	Phase II www.compasspathways.com
CORT108297 (glucocorticoid receptor antagonist)	Corcept Therapeutics Menlo Park, CA	post-traumatic stress disorder	Phase II www.corcept.com
darigabat (GABA A receptor agonist)	Cerevel Therapeutics Cambridge, MA	anxiety disorder	Phase II www.cerevel.com

Mental Illness

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Exxua™ gepirone ER	Fabre-Kramer Pharmaceuticals Houston, TX	major depressive disorder	application submitted www.fabrekramer.com
		generalized anxiety disorder, hypoactive sexual desire disorder	Phase II completed www.fabrekramer.com
FKW00GA (5HT1A agonist/5HT2 antagonist)	Fabre-Kramer Pharmaceuticals Houston, TX	anxiety disorder, social phobia	Phase II completed www.fabrekramer.com
GRX-917 (etifoxine deuterated)	GABA Therapeutics Newport Beach, CA	anxiety disorder	Phase I www.gabarx.com
JNJ-42165279 (FAAH inhibitor)	Janssen Research & Development Raritan, NJ	social anxiety disorder	Phase II completed www.janssen.com
JZP150 (FAAH inhibitor)	Jazz Pharmaceuticals Dublin, Ireland	post-traumatic stress disorder (Fast Track)	Phase II www.jazzpharma.com
Lorexys™ bupropion/trazodone fixed-dose combination	S1 Biopharma New York, NY	hypoactive sexual desire disorder	Phase II www.s1biopharma.com
Lu AG06466 (MAGL inhibitor)	Lundbeck Deerfield, IL	post-traumatic stress disorder	Phase I www.lundbeck.com

Mental Illness

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
MIJ821 (NR2B negative allosteric modulator)	Novartis East Hanover, NJ	depression	Phase II www.novartis.com
MK-1942	Merck Kenilworth, NJ	treatment-resistant depression	Phase II www.merck.com
MM-120 (lysergic acid diethylamide)	Mindmed New York, NY	generalized anxiety disorder	Phase II www.mindmed.co
NBI-065845 (AMPA receptor modulator)	Neurocrine Biosciences San Diego, CA	inadequate response in major depressive disorder	Phase II www.neurocrine.com
NBI-065846 (GP139 protein agonist)	Neurocrine Biosciences San Diego, CA	anhedonia in major depressive disorder	Phase II www.neurocrine.com
NBTX-001 (NMDA receptor antagonist)	Nobilis Therapeutics Portland, OR	panic disorder, post-traumatic stress disorder	Phase I www.nobilistx.com
NMRA-140 (KOR antagonist)	Neumora Therapeutics Watertown, MA	major depressive disorder, anhedonia	Phase II www.neumoratrix.com
NMRA-511 (V1aR antagonist)	Neumora Therapeutics Watertown, MA	anxiety disorder	Phase I www.neumoratrix.com

Mental Illness

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
NYX-783 (NMDA receptor modulator)	Aptinyx Evanston, IL	post-traumatic stress disorder (Fast Track)	Phase II www.aptinyx.com
PF-07258669 (MC4R antagonist)	Pfizer New York, NY	geriatric anorexia	Phase I www.pfizer.com
PH10 (chemoreceptor cell modulator)	VistaGen Therapeutics South San Francisco, CA	major depressive disorder	Phase II www.vistagen.com
PH94B nasal spray (chemoreceptor cell modulator)	VistaGen Therapeutics South San Francisco, CA	social anxiety disorder (Fast Track)	Phase III www.vistagen.com
		adjustment disorder with anxiety	Phase II www.vistagen.com
PRAX-114 (GABA modulator)	Praxis Precision Medicines Boston, MA	major depressive disorder	Phase III www.praxismedicines.com
		post-traumatic stress disorder	Phase II www.praxismedicines.com
Rexulti® brexpiprazole	Lundbeck Deerfield, IL Otsuka Rockville, MD	post-traumatic stress disorder	Phase III www.lundbeck.com www.otsuka-us.com

Mental Illness

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
seltorexant (orexin receptor type 2 antagonist)	Janssen Research & Development Raritan, NJ	adjunctive treatment for major depressive disorder with insomnia symptoms	Phase III www.janssen.com
SEP-378614	Sunovion Marlborough, MA	treatment-resistant depression	Phase I www.sunovion.com
sildenafil topical cream (PDE5 inhibitor)	Dare Bioscience San Diego, CA	female sexual arousal disorder	Phase II www.darebioscience.com
SLS-002 (intranasal ketamine)	Seelos Therapeutics New York, NY	major depressive disorder	Phase II www.seelostherapeutics.com
TNX-102 SL (cyclobenzaprine sublingual tablets)	Tonix Pharmaceuticals Chatham, NJ	post-traumatic stress disorder (Breakthrough Therapy)	Phase II www.tonixpharma.com
TNX-601 CR (naloxone/tianeptine)	Tonix Pharmaceuticals Chatham, NJ	major depressive disorder, post-traumatic stress disorder	Phase I www.tonixpharma.com
TS-161 (mGluR2/3 antagonist)	Taisho Pharmaceutical R&D Morristown, NJ	depression	Phase II www.taisho.co.jp

Mental Illness

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
VQW-765 (alpha7 nicotinic acetylcholine receptor agonist)	Vanda Pharmaceuticals Washington, DC	female performance anxiety	Phase II www.vandapharma.com
Vraylar® cariprazine	AbbVie North Chicago, IL	adjunctive treatment for major depressive disorder	Phase III www.abbvie.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AAT-009 (5-HT4 partial agonist)	AskAt Nagoya, Japan	Alzheimer's disease	Phase I completed www.askat-inc.com
ABP-450 (prabotulinumtoxin A)	AEON Biopharma Newport Beach, FL	migraine prevention	Phase II www.aeonbiopharma.com
ACI-35.030 (anti-pTau vaccine)	AC Immune Lausanne, Switzerland Janssen Research & Development Raritan, NJ	early Alzheimer's disease	Phase II www.acimmune.com www.janssen.com
ACU193 (anti-amyloid-beta oligomer mAb)	Acumen Pharmaceuticals Charlottesville, VA	Alzheimer's disease	Phase I www.acumenpharm.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AD-101 (calcium channel antagonist)	Amyriad Los Angeles, CA	Alzheimer's disease	Phase II completed www.amyriadtherapeutics.com
AGB101 (levetiracetam low-dose)	AgenBio Baltimore, MD	mild cognitive impairment due to Alzheimer's disease and control further progression of Alzheimer's dementia	Phase II/III www.agenebio.com
AKST/GRF6019 (neurogenesis stimulant)	Alkahest San Carlos, CA Grifols Barcelona, Spain	mild to moderate Alzheimer's disease, severe Alzheimer's disease	Phase II www.alkahest.com
AL001 (lithium cocrystal)	Alzamend Neuro Atlanta, GA	Alzheimer's disease	Phase I www.alzamend.com
AL002 (TREM2 protein stimulant)	AbbVie North Chicago, IL Alector South San Francisco, CA	early Alzheimer's disease	Phase II www.abbvie.com www.alector.com
AL003 (SIGLEC 3)	AbbVie North Chicago, IL Alector South San Francisco, CA	Alzheimer's disease	Phase I www.abbvie.com www.alector.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ALLOD-2 (naltrexone and acetaminophen)	Allodynic Therapeutics North Miami, FL	acute migraine	Phase II/III www.alodynic.com
ALN-APP (RNA interference targeting amyloid)	Alnylam Pharmaceuticals Cambridge, MA	early onset Alzheimer's disease	Phase I www.alnylam.com
Alpha7 nicotinic (positive allosteric modulator)	Merck Kenilworth, NJ Bionomics Thebarton, Australia	cognitive dysfunction in Alzheimer's disease	Phase I www.merck.com www.bionomics.com.au
ALX-001 (mGluR5 modulator)	Allyx Therapeutics New Haven, CT	Alzheimer's disease	Phase I www.allyxthera.com
ALZ-801 (amyloid beta-protein inhibitor)	Alzheon Framingham, MA	early Alzheimer's disease (APOE4/4 homozygotes) (Fast Track)	Phase III www.alzheon.com
		early Alzheimer's disease (APOE4 carriers), prevention of Alzheimer's disease in asymptomatic patients (APOE4/4 homozygotes)	Phase II www.alzheon.com
ALZT-OP1 (amyloid beta-protein inhibitor/ inflammation mediator inhibitor)	AZTherapies Boston, MA	early Alzheimer's disease	Phase III completed www.aztherapies.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AMX0035 (sodium phenylbutyrate/ tauroursodeoxycholic acid)	Amylyx Pharmaceuticals Cambridge, MA	Alzheimer's disease	Phase II www.amylyx.com
ANAVEX® 2-73 (blarcamesine) (muscarinic receptor agonist/ sigma-1 receptor agonist)	Anavex Life Sciences New York, NY	Alzheimer's disease	Phase III www.anavex.com
ANK-700 (immunomodulator)	Anokion Ecublens, Switzerland	relapsing remitting multiple sclerosis	Phase I www.anokion.com
ANVS301 (bisnorcymserine)	Annovis Bio Berwyn, PA	advanced Alzheimer's disease	Phase I www.annovisbio.com
ANVS401 (R-phenserine)	Annovis Bio Berwyn, PA	Alzheimer's disease	Phase II www.annovisbio.com
		Alzheimer's disease in Down syndrome	Phase I www.annovisbio.com
AR1001 (PDE5 inhibitor)	AriBio Gyeonggi-do, South Korea	Alzheimer's disease	Phase II completed www.aribio.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AstroStem® mesenchymal stem cell therapy	Nature Cell Seoul, South Korea	Alzheimer's disease	Phase I/II completed www.naturecell.co.kr
ATA188 (T-cell immunotherapy)	Atara Biotherapeutics South San Francisco, CA	progressive multiple sclerosis (Fast Track)	Phase II www.atarabio.com
ATH-1017 (HGF stimulant)	Athira Pharma Bothell, WA	Alzheimer's disease	Phase II/III www.athira.com
atuzaginstat (COR388) (lysine gingipain inhibitor)	Cortexyme South San Francisco, CA	Alzheimer's disease	Phase III www.cortexyme.com
AVP-786 (dextromethorphan analogue/ultra-low dose quinidine)	Avanir Pharmaceuticals Aliso Viejo, CA	agitation in Alzheimer's disease (Fast Track)	Phase III www.avanir.com
AXS-05 (bupropion/dextromethorphan)	Axsome Therapeutics New York, NY	agitation in Alzheimer's disease (Fast Track) (Breakthrough Therapy)	Phase III www.axsome.com
AXS-07 (meloxicam/rizatriptan)	Axsome Therapeutics New York, NY	migraine	application submitted www.axsome.com
BAC	Charsire Biotechnology Tainan City, Taiwan	Alzheimer's disease	Phase II completed www.charsire.com.tw

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
BAN2401 (lecanemab) (anti-amyloid beta protofibril antibody)	Biogen Cambridge, MA Eisai Woodcliff Lake, NJ	early Alzheimer's disease (Fast Track) (Breakthrough Therapy)	application submitted www.biogen.com www.eisai.com
		preclinical Alzheimer's disease	Phase III www.biogen.com www.eisai.com
bepranemab (UCB0107) (anti-tau antibody)	UCB Smyrna, GA Roche/Genentech South San Francisco, CA	Alzheimer's disease	Phase II www.ucb.com www.roche.com
BIIB061 (oral remyelination)	Biogen Cambridge, MA	multiple sclerosis	Phase I www.biogen.com
BIIB076 (anti-tau antibody)	Biogen Cambridge, MA	Alzheimer's disease	Phase I www.biogen.com
BIIB080 (tau-targeting protein)	Biogen Cambridge, MA	mild Alzheimer's disease	Phase I www.biogen.com
BIIB091 (BTK inhibitor)	Biogen Cambridge, MA	multiple sclerosis	Phase I www.biogen.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
BIIB107 (integrin alpha4beta1 antagonist)	Biogen Cambridge, MA	multiple sclerosis	Phase I www.biogen.com
BPN14770 (zatozmilast) (PDE4D inhibitor)	Tetra Discovery Partners Grand Rapids, MI Shionogi Florham Park, NJ	Alzheimer's disease	Phase II www.tetradiscovery.com www.shionogi.com
bryostatin 1 (protein kinase C stimulant)	Synaptogenix New York, NY	Alzheimer's disease	Phase II www.synaptogen.com
CL-H1T (promethazine/sumatriptan)	Charleston Laboratories Jupiter, FL	migraine	Phase III www.charlestonlabs.com
CNM-Au8 (nanotherapeutic)	Clene Nanomedicine Salt Lake City, UT	multiple sclerosis	Phase II www.clene.com
crenezumab (RG7412) (anti-amyloid beta antibody)	Roche/Genentech South San Francisco, CA	familial Alzheimer's disease in healthy people	Phase II www.roche.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
CT1812 (amyloid beta oligomer receptor antagonist)	Cognition Therapeutics Pittsburgh, PA	mild to moderate Alzheimer's disease (Fast Track)	Phase II www.cogrx.com
		early Alzheimer's disease	Phase I www.cogrx.com
CY6463 (sGC stimulant)	Cyclerion Therapeutics Cambridge, MA	Alzheimer's disease with vascular pathology	Phase II www.cyclerion.com
donanemab (LY3002813) (N3pG-amyloid beta antibody)	Lilly Indianapolis, IN	early Alzheimer's disease (Breakthrough Therapy)	application submitted www.lilly.com
		preclinical Alzheimer's disease	Phase III www.lilly.com
E2006 (orexin receptor antagonist)	Eisai Woodcliff Lake, NJ	Alzheimer's disease dementia	Phase II www.eisai.com
E2511 (synapse regenerant)	Eisai Woodcliff Lake, NJ	Alzheimer's disease	Phase I www.eisai.com
E2814 (anti-MTBR tau antibody)	Eisai Woodcliff Lake, NJ	Alzheimer's disease	Phase II/III www.eisai.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
EHP-101 (PPAR gamma modulator/ CB2 receptor agonist)	Emerald Health Pharmaceuticals San Diego, CA	relapsing multiple sclerosis	Phase II www.emeraldpharma.life
EI-1071 (CSF-1R inhibitor)	Elixiron Immunotherapeutics San Francisco, CA	Alzheimer's disease	Phase I www.elixiron.com
evobrutinib (BTK inhibitor)	EMD Serono Rockland, MA	relapsing multiple sclerosis	Phase III www.emdserono.com
fenebrutinib (RG7845) (BTK inhibitor)	Roche/Genentech South San Francisco, CA	primary progressive multiple sclerosis, relapsing multiple sclerosis	Phase III www.roche.com
foralumab (regulatory T-lymphocyte stimulant)	Tiziana Life Sciences New York, NY	secondary progressive multiple sclerosis	Phase I www.tizianalifesciences.com
GA depot (glatiramer acetate controlled release)	Mapi Pharma Ness Ziona, Israel	relapsing remitting multiple sclerosis	Phase III www.mapi-pharma.com
gantenerumab (RG1450) (amyloid beta-protein inhibitor)	Roche/Genentech South San Francisco, CA	Alzheimer's disease (Breakthrough Therapy)	Phase III www.roche.com
GSK3888130 (anti-IL7 antibody)	GlaxoSmithKline Research triangle Park, NC	multiple sclerosis	Phase I www.gsk.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
GV-971 (sodium oligomannate)	Green Valley Pharmaceuticals Shanghai, China	Alzheimer's disease	Phase III www.greenvalleypharma.com
HB-adMSC (autologous adipose derived mesenchymal stem cells)	Hope Biosciences Sugar Land, TX	multiple sclerosis	Phase II www.hope.bio
IGC-AD1 (phytocannabinoid therapeutic)	IGC Pharma Potomac, MD	Alzheimer's disease	Phase I www.igcpharma.com
IMS110 (mesenchymal stem cell therapy)	ImStem Biotechnology Farmington, CT	multiple sclerosis	Phase I www.imstem.com
IMU-838 (DHODH inhibitor)	Immunic New York, NY	relapsing multiple sclerosis	Phase III www.imux.com
		progressive multiple sclerosis	Phase II www.imux.com
Injectafer [®] ferric carboxymatose	American Regent Shirley, NY	restless legs syndrome	Phase II www.americanregent.com
JNJ-63733657 (phospho-tau mAb inhibitor)	Janssen Research & Development Raritan, NJ	early Alzheimer's disease	Phase II www.janssen.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
JNS108 (oral capsule of trans-resveratrol)	Jupiter Neurosciences Palm Beach Gardens, FL	early Alzheimer's disease	Phase II www.jupiterneurosciences.com
LM11A-31 (p75 neurotrophin receptor)	Pharmatrophix Menlo Park, CA	mild to moderate Alzheimer's disease	Phase I/II www.pharmatrophix.com
Lomecel-B (mesenchymal stem cell therapy)	Longeveron Miami, FL	Alzheimer's disease	Phase II www.longeveron.com
LOU064 (remibrutinib) (BTK inhibitor)	Novartis East Hanover, NJ	relapsing multiple sclerosis	Phase III www.novartis.com
Lu AF87908 (tau protein inhibitor)	Lundbeck Deerfield, IL	Alzheimer's disease (taupathies)	Phase I www.lundbeck.com
Lu AG06466 (MAGL inhibitor)	Lundbeck Deerfield, IL	multiple sclerosis spasticity	Phase I www.lundbeck.com
Lu AG09222 (anti-PACAP mAb)	Lundbeck Deerfield, IL	migraine prevention	Phase II www.lundbeck.com
LX1001 (AAV-mediated gene therapy)	LEXEO Therapeutics New York, NY	APOE4-associated Alzheimer's disease (Fast Track)	Phase I www.lexeotx.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
LY3372689 (O-GlcNAcase inhibitor)	Lilly Indianapolis, IN	Alzheimer's disease	Phase II www.lilly.com
LY3372993 (N3pG-Ab mAb)	Lilly Indianapolis, IN	Alzheimer's disease	Phase I www.lilly.com
LY3451838 (PACA38 antibody)	Lilly Indianapolis, IN	migraine	Phase II www.lilly.com
M207 (zolmitriptan transdermal microneedle system)	Zosano Pharma Fremont, CA	migraine	application submitted www.zosanopharma.com
MEDI1814 (anti-amyloid beta mAb)	AstraZeneca Wilmington, DE	Alzheimer's disease	Phase I www.astrazeneca.com
mesenchymal stem cell therapy (allogeneic bone marrow-derived)	Longeveron Miami, FL	Alzheimer's disease	Phase I www.longeveron.com
mesenchymal stem cell therapy (ischemic-tolerant stem cells)	Stemedica Cell Technologies San Diego, CA	Alzheimer's disease	Phase II www.stemedica.com
MK-1942	Merck Whitehouse Station, NJ	Alzheimer's disease (+donepezil)	Phase I www.merck.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
MN-166 (ibudilast) (neuroprotective therapeutic)	MediciNova La Jolla, CA	progressive multiple sclerosis (Fast Track)	Phase II www.medicinova.com
MW150 (p38 MAPK inhibitor)	NeuroKine Therapeutics Blue River, WI	Alzheimer's disease	Phase I www.neurokinetp.com
NA-831 (traneurocin) (neurogenesis stimulant)	NeuroActiva San Jose, CA	Alzheimer's disease	Phase II www.neuroactiva.com
natalizimab biosimilar	Polpharma Biologics Gdansk, Poland Sandoz Princeton, NJ	relapsing-remitting multiple sclerosis	Phase III www.polpharmabiologics.com www.sandoz.com
NE3107 (ERK inhibitor)	BioVie Santa Monica, CA	Alzheimer's disease	Phase III www.bioviepharma.com
neflamapimod (VX-745) (p38 mitogen-activated protein kinase inhibitor)	EIP Pharma Cambridge, MA	Alzheimer's disease	Phase II www.eippharma.com
NeuroVax (immunostimulant vaccine) ORPHAN DRUG	Immune Response BioPharma Atlantic City, NJ	multiple sclerosis (Fast Track)	Phase II/III www.immuneresponsebiopharma.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
nilotinib (tyrosine kinase inhibitor)	KeifeRx McLean, VA	Alzheimer's disease	Phase III www.keiferx.com
NLY01-AD (GLP-1R agonist)	Neuraly Gaithersburg, MD	Alzheimer's disease	Phase II www.neuraly.com
NNI-362 (neuron regenerative therapy)	Neuronascent Clarksville, MD	Alzheimer's disease	Phase I www.neuronascent.com
NP001 (macrophage modulator)	Neuvivo Palo Alto, CA	Alzheimer's disease	Phase I www.neuvivo.com
NTRX-07 (cannabinoid receptor CB2 agonist)	NeuroTherapia Gates Mills, OH	Alzheimer's disease	Phase I www.neurotherapia.com
NurOwn® (neurotrophic factor-producing mesenchymal stem cell therapy)	Brainstorm Cell Therapeutics New York, NY	progressive multiple sclerosis	Phase II www.brainstorm-cell.com
Ocrevus® obinutuzumab (high dose)	Roche/Genentech South San Francisco, CA	relapsing multiple sclerosis and primary progressive multiple sclerosis	Phase III www.roche.com
orelabrutinib (BTK inhibitor)	Biogen Cambridge, MA	relapsing remitting multiple sclerosis	Phase II www.biogen.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
pepinemab (anti-SEMA4D mAb)	Vaccinex Rochester, NY	Alzheimer's disease	Phase I/II www.vaccinex.com
PIPE-307 (M1R antagonist)	Pipeline Therapeutics San Diego, CA	multiple sclerosis (myelin restoration)	Phase I www.pipelinetherapeutics.com
PQ912 (QC inhibitor)	Vivoryon Therapeutics Halle, Germany	early Alzheimer's disease	Phase II www.vivoryon.com
protollin (amyloid beta inhibitor)	I-MAB Biopharma Gaithersburg, MD	Alzheimer's disease	Phase I www.i-mabbioharma.com
PRX005 (tau protein inhibitor)	Bristol-Myers Squibb Princeton, NJ Prothena Dublin, Ireland	Alzheimer's disease	Phase I www.bms.com
PU-AD (icapamespib) (HSP90 heat-shock protein inhibitor)	Samus Therapeutics Topsfield, MA	Alzheimer's disease	Phase II www.samustherapeutics.com
Qulipta [®] atogepant	AbbVie North Chicago, IL	chronic migraine prevention	Phase III www.abbvie.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Rexulti® brexpiprazole	Lundbeck Deerfield, IL Otsuka Pharmaceutical Tokyo, Japan	agitation in Alzheimer's disease (Fast Track)	Phase III www.lundbeck.com www.otsuka.com
RG6035 (brain shuttle CD-20 mAb)	Roche/Genentech South San Francisco, CA	multiple sclerosis	Phase I www.roche.com
RG6102 (brain shuttle gantenerumab)	Roche/Genentech South San Francisco, CA	Alzheimer's disease	Phase II www.roche.com
RG6289	Roche/Genentech South San Francisco, CA	Alzheimer's disease	Phase I www.roche.com
rizatriptan intranasal	Benuvia Therapeutics Chandler, AZ	migraine	Phase I www.benuvia.com
RNS60 (intracellular signaling pathway activator)	Revalesio Tacoma, WA	multiple sclerosis	Phase I completed www.revalesio.com
SAGE-718 (NMDA receptor modulator)	Sage Therapeutics Cambridge, MA	mild cognitive impairment and mild dementia due to Alzheimer's disease	Phase II www.sagerx.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
SAR441344 (anti-CD40L mAb)	Immunext Lebanon, NH Sanofi Bridgewater, NJ	multiple sclerosis	Phase II www.sanofi.com
semaglutide oral (GLP-1 receptor agonist)	Novo Nordisk Plainsboro, NJ	early Alzheimer's disease	Phase III www.novonordisk.com
semorinemab (RG6100) (tau protein inhibitor)	AC Immune Lausanne, Switzerland Roche/Genentech South San Francisco, CA	Alzheimer's disease	Phase II www.roche.com
SEP-380135	Sunovion Pharmaceuticals Marlborough, MA	agitation in Alzheimer's disease	Phase I www.sunovion.com
simufilam (microfilament protein modulator)	Cassava Sciences Austin, TX	Alzheimer's disease	Phase II www.cassavasciences.com
SNK01 (autologous NK cell therapy)	NKGen Biotech Irvine, CA	Alzheimer's disease	Phase I www.nkgenbiotech.com
solanezumab (amyloid beta protein inhibitor)	Lilly Indianapolis, IN	preclinical Alzheimer's disease	Phase III www.lilly.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
STS101 (DHE nasal powder)	Satsuma Pharmaceuticals South San Francisco, CA	migraine	Phase III www.satsumarx.com
SUVN-502 (masupirdine) (serotonin 6 receptor antagonist)	Suven Life Sciences Hyderabad, India	moderate Alzheimer's disease (adjunctive treatment)	Phase II completed www.suven.com
T-817MA (edonergic) (amyloid beta-protein inhibitor)	Toyama Chemical Tokyo, Japan	Alzheimer's disease	Phase II completed www.toyama-chemical.co.jp
T3D-959 (PPAR-delta/gamma agonist)	T3D Therapeutics Research Triangle Park, NC	Alzheimer's disease	Phase II www.t3dtherapeutics.com
TB006 (TIM-3)	TrueBinding Foster City, CA	Alzheimer's disease	Phase I www.truebinding.com
TNX-1900 (oxytocin intranasal)	Tonix Pharmaceuticals Chatham, NJ	chronic migraine	Phase II www.tonixpharma.com
tolebrutinib (BTK inhibitor)	Sanofi Bridgewater, NJ	primary progressive multiple sclerosis, relapsing multiple sclerosis, secondary progressive multiple sclerosis	Phase III www.sanofi.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Trappsol® Cyclo™ hydroxy propyl betadex	Cyclo Therapeutics Alachua, FL	Alzheimer's disease	Phase I www.cyclotherapeutics.com
troriluzole (BHV-4157) (glutamate modulator)	Biohaven Pharmaceuticals New Haven, CT	Alzheimer's disease	Phase II www.biohavenpharma.com
TRx0237 (tau protein aggregation inhibitor/ TDP-43 aggregation inhibitor)	TauRx Pharmaceuticals Singapore	mild to moderate Alzheimer's disease	Phase III www.taurx.com
Tysarbi® natalizumab (subcutaneous formulation)	Biogen Cambridge, MA	relapsing multiple sclerosis	application submitted www.biogen.com
UB-311 (anti-amyloid endobody vaccine)	Vaxxinity Dallas, TX	Alzheimer's disease	Phase II www.vaxxinity.com
ublituximab (rituximab biobetter)	TG Therapeutics New York, NY	relapsing multiple sclerosis	application submitted www.tgtherapeutics.com
UE-2343 (Xanamem™) (11β-HSD1 inhibitor)	Actinogen Medical Sydney, Australia	dementia in Alzheimer's disease	Phase II completed www.actinogen.com

Neurologic Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
vafidemstat (ORY-2001) (LSD1/MAOB inhibitor)	Oryzon Genomics Cambridge, MA	Alzheimer's disease	Phase II completed www.oryzon.com
XC101 (serotonin receptor agonist)	Xoc Pharmaceuticals Los Gatos, CA	migraine prevention	Phase I www.xocpharma.com
XPro1595 (TNF inhibitor)	INmune Bio La Jolla, CA	mild Alzheimer's disease	Phase I www.inmunebio.com
zavegepant (CGRP receptor antagonist)	Biohaven Pharmaceuticals New Haven, CT	migraine prevention and treatment	Phase III www.biohavenpharma.com

Obstetrics/Gynecology

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ABI-2280 (virus replication inhibitor)	Antiva Biosciences Brisbane, CA	cervical intraepithelial neoplasia	Phase I www.antivabio.com
AG200-15 (SmP) (levonorgestrel and ethinyl estradiol transdermal system)	Agile Therapeutics Princeton, NJ	contraception	Phase I www.agiletherapeutics.com
AG200-ER (levonorgestrel and ethinyl estradiol)	Agile Therapeutics Princeton, NJ	contraception	Phase I www.agiletherapeutics.com

Obstetrics/Gynecology

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AG200-ER (SmP) (levonorgestrel and ethinyl estradiol lower-dose patch)	Agile Therapeutics Princeton, NJ	contraception	Phase I www.agiletherapeutics.com
AG890 (levonorgestrel transdermal patch)	Agile Therapeutics Princeton, NJ	contraception	Phase II www.agiletherapeutics.com
AMY109 (engineered antibody)	Chugai Pharma Berkeley Heights, NJ	endometriosis	Phase I www.chugai-pharm.com
artesanate vaginal insert	Frantz Viral Therapeutics Mentor, OH	cervical intraepithelial neoplasia	Phase II www.frantzviraltheraeputics.com
BAY1817080 (eliapixant) (P2X3 antagonist)	Bayer Pharmaceuticals Whippany, NJ	endometriosis	Phase II www.bayer.com
BAY2328065 (AKR1C3 inhibitor)	Bayer Pharmaceuticals Whippany, NJ	endometriosis	Phase I www.bayer.com
BAY3427080 (elinzanetant) (neurokinin-1,3 receptor antagonist)	Bayer Pharmaceuticals Whippany, NJ	vasomotor symptoms	Phase III www.bayer.com
DARE-FRT1 (sustained release progesterone)	Dare Bioscience San Diego, CA	pregnancy maintenance	Phase I www.darebioscience.com

Obstetrics/Gynecology

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
DARE-HRT1 (estradiol/progesterone intravaginal ring)	Dare Bioscience San Diego, CA	menopausal syndrome (hormone therapy)	Phase I www.darebioscience.com
DARE-VVA1 (tamoxifen vaginal)	Dare Bioscience San Diego, CA	vulvar and vaginal atrophy	Phase I www.darebioscience.com
fezolinetant (NK3 receptor antagonist)	Astellas Pharma US Northbrook, IL	menopausal vasomotor symptoms	Phase III www.astellas.com
FE-202767 (merotocin) (oxytocin receptor agonist)	Ferring Pharmaceuticals Parsippany, NJ	lactation failure	Phase II www.ferringusa.com
FE-999049 (follitropin delta)	Ferring Pharmaceuticals Parsippany, NJ	female infertility	Phase III www.ferringusa.com
HMI-115 (PRL receptor mAb)	Hope Medicine Nanjing, China	endometriosis-related pain	Phase II
IW-3300 (GC-C agonist)	Ironwood Pharmaceuticals Boston, MA	endometriosis-related pain	Phase I www.ironwoodpharma.com
LACTIN-V (live biotherapeutic)	Osel Mountain View, CA	in vitro fertilization	Phase II www.oselinc.com

Obstetrics/Gynecology

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
linzagolix (GnRH receptor antagonist)	ObsEva Geneva, Switzerland	uterine fibroids	application submitted www.obseva.com
		endometriosis	Phase III www.obseva.com
LPCN 1107 (progesterone receptor agonist) ORPHAN DRUG	Lipocine Salt Lake City, UT	prevention of recurrent preterm labor	Phase II www.lipocine.com
LPRI-424 (dienogest/ethinylestradiol)	Exeltis (Insud Pharma) Florham Park, NJ	contraception	Phase III www.exeltis.com
MT-2990 (IL33 mAb)	Mitsubishi Tanabe Pharma Jersey City, NJ	pain associated with endometriosis	Phase II www.mt-pharma.co.jp
MT-8554 (TRPM8 protein inhibitor)	Mitsubishi Tanabe Pharma Jersey City, NJ	menopausal vasomotor symptoms	Phase II www.mt-pharma.co.jp
MVT-602 (KISS1R protein agonist)	Myovant Sciences Brisbane, CA	female infertility as part of assisted reproduction	Phase II www.myovant.com

Obstetrics/Gynecology

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Myfembree® relugolix, estradiol, norethisterone	Myovant Sciences Brisbane, CA	pain associated with endometriosis	application submitted www.myovant.com
		pregnancy prevention in women with endometriosis or uterine fibroids	Phase III www.myovant.com
nipocalimab (Fc receptor antagonist)	Janssen Research & Development Raritan, NJ	prevention of fetal/neonatal alloimmune thrombocytopenia (Fast Track)	Phase II www.janssen.com
Ovaprene® hormone free intravaginal drug-device	Dare Bioscience San Diego, CA Bayer Pharmaceuticals Whippany, NJ	monthly contraception	Phase III www.darebioscience.com
P2X4 antagonist	Bayer Pharmaceuticals Whippany, NJ	endometriosis	Phase I www.bayer.com
quinagolide (dopamine D2 receptor agonist)	Ferring Pharmaceuticals Parsippany, NJ	endometriosis-related pain	Phase II www.ferringusa.com
RLYB211 (polyclonal HPA-1a antibody) ORPHAN DRUG	Rallybio New Haven, CT	prevention of fetal/neonatal alloimmune thrombocytopenia	Phase I www.rallybio.com

Obstetrics/Gynecology

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
RLYB212 (monoclonal HPA-1a antibody) ORPHAN DRUG	Rallybio New Haven, CT	prevention of fetal/neonatal alloimmune thrombocytopenia	Phase I www.rallybio.com
ZB-06 (vaginal film)	ZabBio San Diego, CA	contraception	Phase I www.zabbio.com

Respiratory Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ADL-018 (biosimilar)	Kashiv BioSciences Piscataway, NJ	asthma	Phase I www.kashivbiosciences.com
ADX-629 (Aldehyde inhibitor)	Aldeyra Therapeutics Lexington, MA	allergic asthma	Phase II www.aldeyra.com
AMG 104 (AZD8630) (TSLP inhibitor)	Amgen Thousand Oaks, CA AstraZeneca Wilmington, DE	asthma	Phase I www.amgen.com www.astrazeneca.com
astegolimab (RG6149) (anti-ST2)	Roche/Genentech South San Francisco, CA	chronic obstructive pulmonary disease (COPD)	Phase II www.roche.com

Respiratory Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AVTX-002 (anti-LIGHT mAb)	Avalo Therapeutics Wayne, PA	non-eosinophilic asthma	Phase II www.avalotx.com
AZD1402 (interleukin 4 receptor antagonist)	AstraZeneca Wilmington, DE	asthma	Phase II www.astrazeneca.com
AZD4604 (JAK inhibitor)	AstraZeneca Wilmington, DE	asthma	Phase I www.astrazeneca.com
AZD5718 (5-lipoxygenase activating protein inhibitor)	AstraZeneca Wilmington, DE	asthma	Phase II www.astrazeneca.com
AZD7986 (DPP1 inhibitor)	AstraZeneca Wilmington, DE	COPD	Phase II www.astrazeneca.com
Breztri Aerosphere® budesonide/formoterol/ glycopyrrolate	AstraZeneca Wilmington, DE	asthma	Phase III www.astrazeneca.com
CBP-201 (interleukin 4 receptor antagonist)	Connect Biopharma San Diego, CA	asthma	Phase II www.connectbiopharm.com

Respiratory Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
CHF1535	Chiesi USA Cary, NC	COPD	Phase III www.chiesi.com
CHF5993	Chiesi USA Cary, NC	COPD	Phase III www.chiesi.com
		asthma	Phase II www.chiesi.com
CHF6001 (PDE4 inhibitor)	Chiesi USA Cary, NC	COPD	Phase II www.chiesi.com
CSJ117 (TSLP inhibitor)	Novartis East Hanover, NJ	asthma, COPD	Phase II www.novartis.com
depemokimab (IL5 antagonist long acting)	GlaxoSmithKline Research Triangle Park, NC	asthma	Phase III www.gsk.com
dexpramipexole (dopamine receptor agonist)	Knopp Biosciences Pittsburgh, PA	eosinophilic asthma	Phase II www.knoppbio.com

Respiratory Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Dupixent® dupilumab	Regeneron Tarrytown, NY Sanofi Bridgewater, NJ	COPD	Phase III www.regeneron.com www.sanofi.com
ensifentrine (PDE 3/4 inhibitor)	Verona Pharma Raleigh, NC	COPD	Phase III www.veronapharma.com
Fasenra® benralizumab	AstraZeneca Wilmington, DE	COPD	Phase III www.astrazeeenca.com
GSK3923868 (PI4K beta inhibitor)	GlaxoSmithKline Research Triangle Park, NC	viral COPD exacerbations	Phase I www.gsk.com
ifetroban (TPR antagonist)	Cumberland Pharmaceuticals Nashville, TN	aspirin-induced asthma	Phase II www.cumberlandpharma.com
interferon-gamma-primed mesenchymal stem cell therapy	Ossium Health San Francisco, CA	asthma	Phase I www.ossiumhealth.com
itepekimab (IL-33 antibody)	Regeneron Tarrytown, NY Sanofi Bridgewater, NJ	COPD	Phase III www.regeneron.com www.sanofi.com

Respiratory Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
KN-002 (JAK inhibitor)	Kinaset Therapeutics Boston, MA	severe asthma	Phase I www.kinasettherapeutics.com
MRx-4DP0004 (live biotherapeutic product)	4D Pharma Leeds, United Kingdom	asthma	Phase I/II www.4dpharmapl.com
navafenterol (muscarinic antagonist/beta2 agonist)	AstraZeneca Wilmington, DE	COPD	Phase II www.astrazeneca.com
Nucala [®] mepolizumab	GlaxoSmithKline Research Triangle Park, NC	COPD	Phase III www.gsk.com
PT027 (budesonide/salbutamol)	AstraZeneca Wilmington, DE	asthma	Phase III www.astrazeneca.com
PUR1800 (protein kinase inhibitor)	Pulmatrix Lexington, MA	COPD	Phase I www.pulmatrix.com
QBW251 (CFTR potentiator)	Novartis East Hanover, NJ	COPD	Phase II www.novartis.com
RG6173 (tryptase inhibitor)	Roche/Genentech South San Francisco, CA	asthma	Phase II www.roche.com

Respiratory Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
RG6341	Roche/Genentech South San Francisco, CA	asthma	Phase I www.roche.com
RPT193 (CCR4 receptor antagonist)	RAPT Therapeutics South San Francisco, CA	asthma	Phase I www.rapt.com
SelK 2 (P-selectin ligand protein inhibitor)	Tetherex Pharmaceuticals Oklahoma City, OK	asthma, COPD	Phase II completed www.tetherex.com
STMC-103H (immunomodulator)	Siolta Therapeutics San Carlos, CA	allergic asthma	Phase I www.sioltatherapeutics.com
TD-8236 (JAK inhibitor)	Theravance Biopharma South San Francisco, CA	asthma	Phase I www.theravance.com
TEV-48574 (subcutaneous biologic)	Teva Pharmaceuticals USA Parsippany, NJ	asthma	Phase II www.tevapharm.com
TEV-53275 (subcutaneous biologic)	Teva Pharmaceuticals USA Parsippany, NJ	asthma	Phase II www.tevapharm.com
Tezspire™ tezepelumab-ekko	Amgen Thousand Oaks, CA AstraZeneca Wilmington, DE	COPD	Phase II www.amgen.com www.astrazeneca.com

Respiratory Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
tozorakimab (IL33 inhibitor)	AstraZeneca Wilmington, DE	asthma, COPD	Phase II www.astrazeneca.com
TS-142 (DORA antagonist)	Taisho Pharmaceutical R&D Morristown, NJ	insomnia	Phase I www.taisho.co.jp
Zofin (nanoparticle based therapeutic)	Organicell Miami, FL	COPD	Phase I/II www.organicell.com

Other Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AMDC-USR (autologous muscle-derived cell therapy)	Cook MyoSite Pittsburgh, PA	stress urinary incontinence	Phase III www.cookmyosite.com
BAY1817080 (eliapixant) (P2X3 antagonist)	Bayer Pharmaceuticals Whippany, NJ	overactive bladder	Phase II completed www.bayer.com
blautix (live bacterial product)	4D Pharma Leeds, United Kingdom	irritable bowel syndrome	Phase II completed www.4dpharmapl.com

Other Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
CIN 103 (D2/3 antagonist)	CinRx Pharma Cincinnati, OH	irritable bowel syndrome	Phase I www.cinrx.com
CT38 (CRFR2 agonist)	Cortene Burlingame, CA	chronic fatigue syndrome	Phase II www.corteneinc.com
IMB-150 (mociceptin receptor agonist)	Imbrium Therapeutics Stamford, CT	interstitial cystitis, overactive bladder	Phase I www.imbriumthera.com
IMC-1 (celecoxib/famciclovir)	Virios Therapeutics Alpharetta, GA	chronic fatigue syndrome, irritable bowel syndrome	Phase I www.virios.com
IW-3300 (guanylate cyclase C agonist)	Ironwood Pharmaceuticals Boston, MA	interstitial cystitis	Phase I www.ironwoodpharma.com
KER-047 (ACVR1 protein inhibitor)	Keros Therapeutics Lexington, MA	iron deficiency anemia	Phase II www.kerostx.com
ORP-101 (opioid kappa receptor antagonist/ opioid mu receptor agonist)	OrphoMed San Francisco, CA	irritable bowel syndrome (Fast Track)	Phase II www.orphomed.com

Other Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
RHB-102 (once-daily ondansetron formulation)	RedHill Biopharma Raleigh, NC	irritable bowel syndrome	Phase II completed www.redhillbio.com
SI-722 (chondroitin sulfate steroid conjugate)	Seikagaku Tokyo, Japan	interstitial cystitis	Phase I completed www.seikagaku.co.jp
URO-902 (hMaxi-K gene therapy)	Urovant Sciences Irvine, CA	overactive bladder	Phase I www.urovant.com
vibegron (ADRB3 agonist)	Urovant Sciences Irvine, CA	irritable bowel syndrome	Phase II www.urovant.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 **March 18, 2022**. 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.

Definitions

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

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

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

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

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