

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
<b>2019 Possible Launch Date</b>									
S-649266	cefiderocol	Shionogi/ GlaxoSmithKiline	cephalosporin antibiotic	Bacterial infections	IV	Filed NDA	8/14/2019	Yes	No
Nouriastr	istradefylline	Kyowa Hakko Kogyo	A2A adenosine receptor antagonist	Parkinson's disease	PO	Filed NDA	8/27/2019	No	No
Rexista XR	oxycodone ER	IntelliPharmaCeutic	opioid agonist	Pain	PO	Filed NDA	8/28/2019	No	No
NKTR-181	NKTR-181	Nektar	opioid agonist	Pain	PO	Filed NDA	8/29/2019	No	No
tadalafil VersaFilm	tadalafil VersaFilm	IntelGenx	phosphodiesterase-5 (PDE-5) inhibitor	Erectile dysfunction	PO	Filed NDA	Mid-2019	Yes	No
fosphenytoin sodium/sulfobutylether beta-cyclodextrin sodium	fosphenytoin sodium/sulfobutylether beta-cyclodextrin sodium	Sedor	anticonvulsant	Seizures	IM/IV	Filed NDA	Mid-2019	Yes	No
XeriSol Glucagon	glucagon	Xeris	glucagon analog	Diabetes mellitus	SC	Filed NDA	9/10/2019	No	No
RDX-5791 (AZD- 1722)	tenapanor	Ardelyx	sodium-hydrogen exchanger-3 (NHE-3) inhibitor	Irritable bowel syndrome-constipation	PO	Filed NDA	9/13/2019	No	No
Imvamune; MVA- BN	Imvamune; MVA-BN	Bavarian Nordic	vaccine	Smallpox	SC	Filed BLA	9/15/2019	Yes	No
NN-9924 (OG- 217SC)	semaglutide (oral)	Novo Nordisk/ Emisphere Technologies	glucagon-like peptide-1 (GLP-1) receptor agonist	Diabetes mellitus	PO	Filed NDA	9/20/2019	Yes	No
Valtoco	diazepam	Neurelis	benzodiazepine	Seizures	Intranasal	Filed NDA	2H2019	No	Yes
Fasenra (self-administered)	benralizumab	AstraZeneca	interleukin-5 receptor (IL-5R) alpha inhibitor	Asthma	SC	Filed sNDA	2H2019	Yes	No
Scenesse	afamelanotide	Clinuvel	melanocortin receptor 1 (MC-1) agonist	Erythropoietic protoporphyria (EPP)/ Polymorphous light eruption (PLE/PMLE)/ Vitiligo	SC	Filed NDA	10/6/2019	Yes	Yes

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PF-708	teriparatide	Pfenex/ Alvogen	parathyroid hormone	Osteoporosis	SC	Filed NDA	10/7/2019	Yes	No
Vumerity	monomethyl fumarate (diroximel fumarate)	Biogen/ Alkermes	Nrf2 pathway activator	Multiple sclerosis (MS)	PO	Filed NDA	10/17/2019	Yes	No
HP-3070	asenapine maleate	Noven Hisamitsu Pharmaceutical	5-HT2a and dopamine D1/D2 antagonist	Schizophrenia	TOP	Filed NDA	10/17/2019	No	No
Xipere	triamcinolone acetonide	Clearside	corticosteroid	Macular edema	intraocular/ subretinal	Filed NDA	10/19/2019	Yes	No
synthetic ACTH depot	cosyntropin	Assertio	adrenocorticotrophic hormone (ACTH)	adrenocortical insufficiency	INJ	Filed NDA	10/19/2019	Yes	No
FMX-101 (ARK- E021)	minocycline	Foamix	tetracyclines	Acne vulgaris	TOP	Filed NDA	10/20/2019	No	No
ET-202	phenylephrine	Eton	alpha-1 adrenergic receptor agonist	Hypotension	IV	Filed NDA	10/21/2019	Yes	No
JDP-205	cetirizine	JDP Therapeutics	second generation antihistamine	Urticaria	IV	Filed NDA	10/30/2019	No	No
Zimhi	naloxone	Adamis	opioid antagonist	Opioid dependence	IM	Filed NDA	10/31/2019	No	No
RediTrex	methotrexate	Cumberland	dihydrofolate reductase (DHFR) inhibitor	Psoriasis; arthritis	SC	Filed NDA	11/1/2019	Yes	No
Talicia	rifabutin/ amoxicillin/ pantoprazole	RedHill Biopharma	RNA polymerase inhibitor/ penicillin/ proton pump inhibitor (PPI)	Bacterial infections	PO	Filed NDA	11/2/2019	No	No
Tlando	testosterone	Lipocine	androgen	Hypogonadism	PO	Filed NDA	11/9/2019	No	No
LY-573144 (COL- 144)	lasmiditan	Eli Lilly	serotonin 5-HT1F receptor agonist	Acute migraines	PO	Filed NDA	11/14/2019	No	No
RTH-258 (ESBA- 1008, DLX-1008)	brolocizumab	Novartis	anti-VEGF antibody	wet age-related (neovascular) macular degeneration (AMD)	Intravitreal	Filed BLA	11/15/2019	Yes	No
Twirla	ethinyl estradiol/ levonorgestrel	Agile Therapeutics	hormonal combination contraceptive	Pregnancy prevention	TOP	Filed NDA	11/17/2019	No	No

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YKP-3089	cenobamate	SK Biopharmaceuticals	undisclosed	Seizure	PO	Filed NDA	11/21/2019	Yes	No
AQST-117	riluzole	Aquestive Therapeutics	glutamate release inhibitor	Amyotrophic lateral sclerosis (ALS)	SL/ Transmucosal	Filed NDA	11/30/2019	No	Yes
ACE-536 (RAP- 536)	luspatercept	Celgene/ Acceleron	Modified type II activin receptor recombinant fusion protein	Anemia	SC	Filed BLA	12/4/2019	Yes	Yes
RVT-802	RVT-802	Enzyvant/Roivant	Tissue-based therapy	Congenital athymia	Implant	Filed NDA	12/2019	Yes	Yes
MK-1602 (AGN- 241689)	ubrogepant	Allergan/ Merck	calcitonin gene-related peptide (CGRP) receptor antagonist	Acute migraines	PO	Filed NDA	12/15/2019	No	No
IDP-123	IDP-123	Bausch Health	retinoid	Acne	TOP	Filed NDA	12/22/2019	No	No
Brinavess (Kynapid)	vernakalant	Correvio	potassium channel blocker	Arrhythmia	IV	Filed NDA	12/24/2019	Yes	No
E-2006	lemborexant	Eisai/ Purdue	orexin receptor antagonist	Insomnia	PO	Filed NDA	12/27/2019	No	No
ITI-007 (ITI-722)	lumateperone	Intra-Cellular Therapies	antipsychotic	Schizophrenia	PO	Filed NDA	12/27/2019	No	No
Posidur	SABER-bupivacaine CR	Novartis/ Durect	local anesthetic	Pain	SC	Filed NDA	12/27/2019	No	No
S-265744 (S/GSK- 1265744)	cabotegravir	ViiV Healthcare	HIV integrase inhibitor	Human immunodeficiency virus (HIV)	PO	Filed NDA	12/29/2019	Yes	No
TMC-278-LA	cabotegravir (long-acting)/rilpivirine (long- acting)	ViiV Healthcare	HIV integrase inhibitor/ non-nucleoside reverse transcriptase inhibitor (NNRTI)	HIV-1	IM	Filed NDA	12/29/2019	Yes	No
MitoGel	mitomycin C	UroGen	alkylating agent	Bladder cancer	Intravesical	InTrial	4Q2019	No	Yes
Xyrosa	doxycycline	Sun Pharma	tetracyclines	Rosacea	PO	Tentative Approval	4Q2019	No	No

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OMS-721	narsoplimab	Omeros	anti-MASP-2 monoclonal antibody	Hemolytic uremic syndrome (HUS)/ Renal diseases	IV/SC	In Trial	2020	Yes	Yes
CCP-08	CCP-08	Tris Pharma	undisclosed	Viral rhinitis	PO	CRL	2020	Yes	No
tamsulosin DRS	tamsulosin delayed-release	Veru	alpha-adrenergic antagonist	Benign prostatic hyperplasia (BPH)	PO	In Trial	2020	No	No
Zalviso	sufentanil, ARX- 01	AcelRx	opioid analgesic	Pain	SL	CRL	2020	Yes	No
ELI-200	oxycodone/ naltrexone	Elite	opioid agonist	Pain	PO	CRL	2020	No	No
APL-130277	apomorphine	Sumitomo Dainippon/ MonoSol Rx/ Sunovion	non-ergoline dopamine agonist	Parkinson's disease	SL	CRL	2020	No	No
Entyvio (SC formulation)	vedolizumab	Takeda	integrin receptor antagonist	Ulcerative colitis (UC)/ Crohn's disease (CD)	SC	Filed sBLA	1/1/2020	Yes	No
AR-101	AR-101	Aimmune/ Regeneron/ Sanofi	peanut protein capsule	Peanut allergy	PO	Filed BLA	1/2020	No	No
SEG-101	crizanlizumab	Novartis	P-selectin antagonist	Sickle cell disease	IV	Filed BLA	1/15/2020	Yes	Yes
E-7438 (EPZ-6438)	tazemetostat	Epizyme/ Eisai	methyltransferase EZH2 inhibitor	Sarcoma	PO	Filed NDA	1/23/2020	Yes	Yes
Rykindo	risperidone ER	Luye	atypical antipsychotic	Schizophrenia/ Schizoaffective disorder	IM	Filed NDA	1/28/2020	Yes	No
FP-001 (LMIS)	leuprolide mesylate	Foresee	gonadotropin-releasing hormone (GnRH) analog	Prostate cancer	SC	Filed NDA	1/29/2020	Yes	No
ALN-AS1	givosiran	Alnylam	RNAi therapeutic agent	Porphyria	SC	Filed NDA	2/4/2020	Yes	Yes
BLU-285	avapritinib	Blueprint Medicines	selective KIT and PDGFRa inhibitor	Gastrointestinal stromal tumors (GIST)	PO	Filed NDA	2/14/2020	Yes	Yes

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BMS-927711 (BHV-3000)	rimegepant sulfate	Portage Biotech/ Biohaven/ Bristol- Myers Squibb	calcitonin gene-related peptide (CGRP) receptor antagonist	Acute migraines	PO	Filed NDA	2/20/2020	Yes	No
ETC-1002	bempedoic acid	Esperion Therapeutics	ATP citrate (pro-S)-lyase and stimulating AMP- activated protein kinase (AMPK)	Hypercholesterolemia	PO	Filed NDA	2/21/2020	No	No
ALD-403	eptinezumab	Alder	calcitonin gene-related peptide (CGRP) receptor antagonist	Migraine prevention	IV/SC	Filed BLA	2/22/2020	No	No
ETC-1002/ ezetimibe	bempedoic acid/ ezetimibe	Esperion Therapeutics	ATP citrate (pro-S)-lyase and stimulating AMP- activated protein kinase (AMPK)/ cholesterol absorption inhibitor	Hypercholesterolemia	PO	Filed NDA	2/26/2020	No	No
CD-5789	trifarotene	Galderma	retinoid receptor agonist	Acne	TOP	Filed NDA	2/28/2020	No	No
RV-001 (Roche-1, R-1507)	teprotumumab	Horizon/ Chugai/ Roche/ Genmab	insulin-like growth factor 1 (IGF-1) receptor antagonist	Thyroid eye disease	IV	Filed BLA	3/6/2020	Yes	Yes
naloxone nasal spray	naloxone	Insys Therapeutics	opioid antagonist	Opioid dependence	Intranasal	Filed NDA	3/15/2020	No	No
ASG-22M6E (ASG- 22CE, ASG-22ME)	enfortumab vedotin	Astellas/ Seattle Genetics	nectin-4 antagonist	Bladder cancer	IV	Filed BLA	3/16/2020	Yes	No
ET-105	lamotrigine	Eton	anticonvulsant	Epilepsy	PO	Filed NDA	3/17/2020	No	No
VX-445	elexacaftor	Vertex	cystic fibrosis transmembrane conductance regulator (CFTR) corrector	Cystic fibrosis (CF)	PO	Filed NDA	3/20/2020	Yes	No
ozanimod	ozanimod	Celgene	sphingosine 1- phosphate 1 (S1PR1) and 5 (S1PR5) receptor modulator	Multiple sclerosis/ Ulcerative colitis (UC)	PO	Filed NDA	3/25/2020	Yes	No
Corplex	donepezil transdermal system	Corium International	anticholinergic	Alzheimer's disease	TOP	InTrial	1Q2020	No	No

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ITCA-650 (sustained release exenatide)	exenatide sustained-release	Intarcia/ Quintiles/ Servier	glucagon-like peptide-1 (GLP-1) receptor agonist	Diabetes mellitus	SC implant	CRL	1Q2020	Yes	No
PPP-002	PPP-002	Tetra Bio-Pharma	botanical drug	Pain	Undisclosed	InTrial	1Q2020	No	No
Barhemsys	amisulpride	Acacia	dopamine receptor antagonist	Nausea/ Vomiting	IV	CRL	1Q2020	No	No
Bronchitol	mannitol	Pharmaxis	osmotic gradient enhancer; mucus clearance enhancer	Asthma/ Cystic fibrosis	INH	CRL	1Q2020	No	Yes
Prochymal	remestemcel-L	Mesoblast/ JCR/ Mallinckrodt/ Osiris Therapeutics	mesenchymal stem cells	Graft vs. Host disease (GvHD)/ Crohn's disease/ Gastrointestinal injury post radiation exposure/ Heart failure (HF)	IV	InTrial	1Q2020	Yes	Yes
LCI-699	osilodrostat	Novartis	aldosterone synthase inhibitor	Cushing's syndrome	PO	Filed NDA	1Q2020	No	Yes
TG-1303	ublituximab/ TGR-1202	TG Therapeutics	CD-20 monoclonal antibody/ phosphoinositide-3 kinase (PI3K) delta inhibitor	Chronic lymphocytic leukemia (CLL)/ Diffuse large B-cell lymphoma (DLBCL)/ Non-Hodgkin lymphoma (NHL)	IV/PO	InTrial	1Q2020	Yes	Yes
empagliflozin, linagliptin, metformin XR	empagliflozin, linagliptin, metformin XR	Eli Lilly/ Boehringer Ingelheim	sodium glucose co-transporter-2 (SGLT-2) inhibitor, dipeptidyl peptidase 4 (DPP4) inhibitor, biguanide	Diabetes mellitus	PO	Filed NDA	1Q2020	No	No
Taclantis	paclitaxel injection concentrate for suspension	Sun Pharma Advanced Research Company (SPARC)	taxane	Breast Cancer; Lung Cancer; Pancreatic Cancer	IV	Filed NDA	1Q2020	No	No
bimatoprost sustained release	bimatoprost sustained release	Allergan	prostaglandin agonist	Glaucoma	Implant	Filed NDA	4/1/2020	N/A	No
UX-007	triheptanoin	Ultragenyx/ Baylor Research Institute/ Uniquist	medium chain fatty acid	Glucose transport type 1 deficiency syndrome (G1DS)	PO	Filed NDA	4/1/2020	Yes	Yes

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CNS-7056 (ONO-2745)	remimazolam	Cosmo/ Hana/ Paion/ Pharmascience/ R- Pharm/ Yichang Humanwell	benzodiazepine	Procedural sedation	IV	Filed NDA	4/3/2020	Yes	No
Viaskin Peanut	Viaskin Peanut	DBV Technologies	Immunotherapy	Peanut allergy	TOP	Filed BLA	4/7/2020	No	No
Men Quad TT	meningococcal polysaccharide (serogroups A, C, Y, and W135) tetanus toxoid conjugate vaccine	Sanofi	antibacterial	meninococcus/ tetanus	IM	Filed BLA	4/25/2020	No	No
Ongentys	opicapone	Neurocrine Biosciences/ Bial/ Ono	catechol-O-methyltransferase (COMT) inhibitor	Parkinson disease	PO	Filed NDA	4/26/2020	No	No
Trevyent	treprostinil	SteadyMed	prostacyclin analog	Pulmonary arterial hypertension (PAH)	SC	Filed NDA	4/27/2020	Yes	Yes
isatuximab	isatuximab	Sanofi/ ImmunoGen	CD38 antagonist	Multiple myeloma/ Acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL)	IV	Filed BLA	4/30/2020	Yes	Yes
SEP-225289 (DSP- 225289, SEP-289)	dasotraline	Sumitomo Dainippon/ Sunovion	triple reuptake inhibitor	Attention deficit hyperactivity disorder (ADHD)/ Eating disorders	PO	Filed NDA	5/14/2020	No	No
FMX-103	minocycline	Foamix	tetracyclines	Rosacea	TOP	InTrial	6/5/2020	No	No
Bafiertam	monomethyl fumarate	Banner Life Sciences	prodrug	Multiple sclerosis	PO	Tentative Approval	6/20/2020	Yes	No
V-114	pneumococcal conjugate vaccine	Merck	vaccine	Bacterial infection	IM	InTrial	2Q2020	Yes	No
KP-415	D-threo- methylphenidate controlled- release	KemPharm	CNS stimulant	Attention deficit hyperactivity disorder (ADHD)	PO	InTrial	2Q2020	No	No
Gimoti	metoclopramide	Evoke Pharma	antidopaminergics	Diabetic gastroparesis	Intranasal	CRL	2Q2020	No	No

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PEGPH-20	pegvorhyaluroni dase alfa	Halozyme/ Nektar	hyaluronic acid	Pancreatic cancer/ Non-small cell lung cancer (NSCLC)	IV	InTrial	1H2020	Yes	Yes
ZEBOV	VS-EBOV (rVSV- EBOV; rVSV- ZEBOV-GP)	Merck/ NewLink Genetics	vaccine	Ebola	IM	Filed BLA	1H2020	Yes	No
Lenti-D	elivaldogene tavalentec	Bluebird Bio	gene therapy	Adrenomyeloneuropat hy	Undisclosed	InTrial	1H2020	Yes	Yes
IMMU-132	sacituzumab govitecan	Immunomedics/ Royalty Pharma	RS7-SN-38 antibody- drug conjugate	Breast cancer/ Pancreatic cancer/ Pancreatic cancer/ Small cell lung cancer (SCLC)/ Non-small cell lung cancer (NSCLC)/ Colorectal cancer/ Esophageal cancer/ Urinary bladder cancer	IV	CRL	1H2020	Yes	Yes
FT-218	sodium oxybate extended-release	Avadel	dopamine receptor agonist	Narcolepsy	PO	InTrial	1H2020	Yes	No
Apealea (Paclical)	paclitaxel	Oasmia	taxane	Ovarian cancer	IV	InTrial	1H2020	Yes	Yes
Traumakine	interferon-beta - 1a	Faron/ Maruishi	interferon	Acute respiratory distress syndrome (ARDS)	IV	InTrial	1H2020	Yes	No
ropeginterferon alfa-2b	ropeginterferon alfa-2b	PharmaEssentia/ AOP Orphan	interferon	Polycythemia vera (PV)/ Myelofibrosis (MF)/ Essential thrombocythemia (ET)	SC	InTrial	1H2020	Yes	Yes
Rizaport (VersaFilm)	rizatriptan	IntelGenx / Red Hill Biopharma	triptans	Acute migraines	PO	CRL	1H2020	No	No
Zynteglo (LentiGlobin)	lentiviral beta- globin gene transfer	Bluebird Bio	gene therapy	Sickle cell disease/ Beta thalassemia	IV	InTrial	1H2020	Yes	Yes
MC2-01 (MC-201)	calcipotriene/ betamethasone	MC2 Therapeutics	vitamin D analog/ corticosteroid	Psoriasis	TOP	InTrial	1H2020	No	No
R-667 (RG-667)	palovarotene	Clementia/ Roche	selective retinoic acid receptor agonist (RAR-gamma)	Fibrodysplasia ossificans progressiva (FOP)	PO	InTrial	1H2020	Yes	Yes



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DS-8201	[fam-] trastuzumab deruxtecan	Daiichi Sankyo	HER2-targeting antibody-drug conjugate	Breast cancer	IV	InTrial	1H2020	Yes	No
SA-237 (RG-6168)	satralizumab	Roche/ Chugai	interleukin-6 (IL-6) monoclonal antibody	Neuromyelitis optica (NMO)	SC	InTrial	1H2020	Yes	Yes
FG-4592 (ASP- 1517)	roxadustat	FibroGen/ Astellas/ AstraZeneca	hypoxia-inducible factor prolyl hydroxylase (HIF-PHI)	Anemia	PO	InTrial	1H2020	Yes	No
RT-002	daxibotulinumto xinA	Revance Therapeutics	botulinum toxins	Cosmetic/ Cervical dystonia/ Plantar fasciitis	IM	InTrial	1H2020	Yes	Yes
Ryplazim	human plasminogen	ProMetic/ Hematech	plasminogen	Plasminogen deficiency	IV	InTrial	1H2020	Yes	Yes
JCAR-017	lisocabtagene maraleucel	Juno/ Celgene	chimeric antigen receptor (CAR) T cell therapy	Diffuse large B-cell lymphoma (DLBCL)/ Acute lymphocytic leukemia (ALL)/ Follicular lymphoma/ Mantle cell lymphoma	IV	InTrial	Mid-2020	Yes	Yes
Sarasar	lonafarnib	Eiger Biopharmaceuticals	prenylation inhibitor	Hepatitis D (HDV); Hutchinson-Gilford Progeria Syndrome (HGPS or progeria) and progeroid laminopathies	PO	InTrial	Mid-2020	Yes	Yes
GSK-2857916	GSK-2857916	GlaxoSmithKline/ Seattle Genetics	anti-BCMA antibody- drug conjugate	Multiple myeloma	SC	InTrial	Mid-2020	Yes	Yes
Ryaltris	mometasone furoate/ olopatadine HCl	Glenmark	corticosteroid/ antihistamine	Allergic rhinitis	NA	CRL	Mid-2020	No	No
QVM-149	indacaterol/ glycopyrronium bromide/mometasone furoate	Novartis/ Sosei	long-acting beta 2 adrenergic receptor agonist (LABA)/ long-acting muscarinic receptor antagonist (LAMA)/ corticosteroid	Asthma	INH	InTrial	Mid-2020	No	No
RG-7916 (RO- 7034067)	Risdiplam	Roche/ PTC Therapeutics	SMN2 splicing modifier	Spinal muscular atrophy	PO	InTrial	Mid-2020	Yes	Yes

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SRP-4045	casimersen	Sarepta	morpholino antisense oligonucleotide	Duchenne muscular dystrophy (DMD)	IV	InTrial	Mid-2020	Yes	Yes
idebenone	idebenone	Santhera	co-enzyme Q-10 analog	Duchenne muscular dystrophy	PO	CRL	Mid-2020	Yes	Yes
Amphora	Amphora	Neothetics	spermicidal agent	Pregnancy prevention/ Bacterial infections	VG	CRL	Mid-2020	No	No
GBT-440 (GTx- 011)	voxelotor	Global Blood Therapeutics	hemoglobin modulator	Sickle cell anemia	PO	InTrial	Mid-2020	Yes	Yes
TGR-1202	umbralisib	TG Therapeutics/ Rhizen	phosphoinositide-3 kinase (PI3K) delta inhibitor	Diffuse large B-cell lymphoma (DLBCL)/ Chronic lymphocytic leukemia (CLL)	PO	InTrial	Mid-2020	Yes	Yes
3-F8 (Hu-3F8)	naxitamab	Y-mAbs Therapeutics	GD2 antagonist	Neuroblastoma	IV	InTrial	Mid-2020	Yes	Yes
Winlevi/ Breezula	cortexolone 17alpha-propionate (CB- 03-01)	Intrepid	androgen antagonist	Acne vulgaris/ alopecia	TOP	InTrial	Mid-2020	No	No
Darzalex	daratumumab (with recombinant human hyaluronidase)	Johnson & Johnson / Genmab	humanized anti-CD38 monoclonal antibody	Multiple myeloma/ Amyloidosis	SC	Filed BLA	7/10/2020	Yes	Yes
BMN-270	valoctocogene roxaparvovec	BioMarin	gene therapy	Hemophilia	IV	InTrial	3Q2020	Yes	Yes
TBR-652 (TAK- 652, CVC)	cenicriviroc	Tobira Therapeutics/ Takeda	C-C chemokine receptor 5 (CCR5) and receptor 2 antagonist	HIV/ Non-alcoholic steatohepatitis (NASH)	PO	InTrial	3Q2020	Yes	No
BCX-7353	BCX-7353	BioCryst	kallikrein inhibitor	Hereditary angioedema (HAE)	PO	InTrial	3Q2020	Yes	Yes
PPP-001	delta-9- tetrahydrocannabinol/ cannabidiol	PhytoPain Pharma	cannabinoid product	Pain	INH	InTrial	3Q2020	Yes	Yes
TRC-101	TRC-101	Tricida	carrier protein modulator	Chronic kidney disease (CKD)	PO	InTrial	3Q2020	Yes	No
Brixadi	buprenorphine	Camurus/ Braeburn	opioid receptor agonist (partial)	Opioid dependence/ Pain	SC	Tentative Approval	11/1/2020	Yes	No

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IdeS (immunoglobulin G-degrading enzyme of Streptococcus pyogenes)	imlifidase	Hansa Medical	bacterial enzyme	Kidney transplant/Thrombotic thrombocytopenic purpura (TTP)/Goodpasture's disease	IV	InTrial	2H2020	Yes	Yes
INCB-54828	pemigatinib	Incyte	selective FGFR1/2/3 inhibitor	Biliary tract cancer	PO	InTrial	2H2020	Yes	Yes
BMS-663068 (BMS-626529 prodrug)	fostemsavir (temsavir prodrug)	Bristol-Myers Squibb	HIV attachment inhibitor	Human immunodeficiency virus (HIV)	PO	InTrial	2H2020	Yes	No
LIQ-861	treprostinil	Liquidia Technologies	prostacyclin analog	Pulmonary arterial hypertension (PAH)	INH	InTrial	2H2020	Yes	No
Olinvo	oliceridine	Trevena	opioid receptor agonist	Pain	IV	CRL	2H2020	No	No
INP-104	POD-dihydroergotami ne mesylate (POD-DHE)	Impel/ 3M	ergot derivative	Acute migraines	NA	InTrial	2H2020	No	No
BGB-3111	zanubrutinib	BeiGene	selective inhibitor of Bruton tyrosine kinase (BTK)	Waldenström's Macroglobulinemia (WM)/Chronic lymphocytic leukemia (CLL)	PO	InTrial	2H2020	Yes	Yes
EGP-437	dexamethasone phosphate (iontophoretic)	EyeGate	corticosteroid	Uveitis	OP	InTrial	2H2020	Yes	No
Libervant	diazepam	Aquestive Therapeutics	benzodiazepine	Seizures	SL/ Transmucosal	InTrial	2H2020	No	Yes
EM-100	ketotifen	Eton	antihistamine	Allergic conjunctivitis/ Dry eyes	OP	CRL	2H2020	No	No
MAGH-22	margetuximab	MacroGenics/ Green Cross	HER2 oncoprotein antagonist	Breast cancer	IV	InTrial	2H2020	Yes	No
Sci-B-Vac	hepatitis B vaccine	VBI Vaccines	vaccine	Hepatitis B (HBV)	IM	InTrial	2H2020	No	No
sulopenem	sulopenem	Iterum	carbapenem	Bacterial infection	IV/PO	InTrial	2H2020	No	No

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quizartinib	quizartinib	Daiichi Sankyo	FLT-3 receptor tyrosine kinase inhibitor	Acute myeloid leukemia (AML)	PO	CRL	2H2020	Yes	Yes
VP-102	VP-102	Verrica	antiviral	Molluscum/ Verruca vulgaris	TOP	InTrial	2H2020	No	No
GLPG-0634	filgotinib	Galapagos NV/ Gilead	janus associated kinase- 1 (JAK) inhibitor	Rheumatoid arthritis/ Crohn's disease/ Ulcerative colitis (UC)/ Sjogren's syndrome/ Ankylosing spondylitis/ Psoriatic arthritis	PO	InTrial	2H2020	Yes	No
NX-1207 (NYM- 4805, REC 0482)	fexapotide trifluate	Nymox	pro-apoptotic	Benign prostatic hyperplasia (BPH)/ Prostate cancer	Intratumoral	InTrial	2H2020	Yes	No
AKB-6548	vadadustat	Akebia Therapeutics	hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor	Anemia	PO	InTrial	2H2020	Yes	No
NexoBrid	bromelain	MediWound/ BL&H/ CrystalGenomics/ Kaken	peptide hydrolase replacement agent	Burns/ Skin injury	TOP	InTrial	2H2020	No	Yes
LOXO-292	LOXO-292	Loxo Oncology/ Eli Lilly	RET inhibitor	Solid tumors; non- small cell lung cancer (NSCLC); thyroid cancer	PO	InTrial	2H2020	Yes	No
NPI-2358	plinabulin	BeyondSpring	tumor vascular disrupting agent (tVDA)	Neutropenia/ Non- small cell lung cancer (NSCLC)	IV	InTrial	2H2020	Yes	No
PXT-3003	baclofen/ naltrexone/ sorbitol	Pharnext	gamma-aminobutyric acid (GABA)-ergic agonist/ opioid receptor antagonist/ sorbitol combination	Charcot-Marie Tooth disease	PO	InTrial	2H2020	No	Yes
ZP-4207 (ZP-GA-1)	dasiglucagon	Zealand Pharma	glucagon analog	Diabetes mellitus	SC	InTrial	2H2020	No	Yes
Zeftera	ceftobiprole	Basilea	cephalosporin antibiotic	Bacterial infections	IV	InTrial	2H2020	Yes	No
Vicinium (VB-4- 845)	oportuzumab monatox	Eleven Biotherapeutics	anti-ECAM exotoxin A fusion protein	Bladder cancer	Intravesical	InTrial	2H2020	Yes	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
LJPC-0118	LJPC-0118	La Jolla Pharmaceutical	protozoacide	Malaria	Undisclosed	InTrial	2H2020	No	No
selumetinib	selumetinib	AstraZeneca/ Array BioPharma/ Cancer Research UK	selective MEK kinase inhibitor	Uveal melanoma/ Thyroid cancer	PO	InTrial	2H2020	Yes	Yes
Mycapssa (Octreolin)	octreotide	Chiasma	somatostatin analog	Acromegaly	PO	CRL	2H2020	Yes	Yes
Doria	risperidone	Laboratorios Farmacéuticos Rovi	atypical antipsychotic	Schizophrenia	IM	InTrial	2H2020	Yes	No
Iomab-B	iodine I 131 monoclonal antibody BC8	Actinium	anti-CD45 monoclonal antibody	Acute myeloid leukemia (AML)/ Myelodysplastic syndrome (MDS)	IV	InTrial	2H2020	Yes	Yes
SPN-812	SPN-812	Supernus	selective norepinephrine reuptake inhibitor	Attention deficit hyperactivity disorder (ADHD)	PO	InTrial	2H2020	No	No
PRX-102	alpha galactosidase (pegunigalsidase alfa)	Protalix	enzyme replacement	Fabry disease	IV	InTrial	2H2020	Yes	No
ASTX-727	decitabine and E- 7727	Otsuka/ Astex Pharmaceuticals	nucleoside metabolic inhibitor	Myelodysplastic syndrome (MDS)	PO	InTrial	2H2020	Yes	No
arimoclomol	arimoclomol	Orphazyme	cytoprotectives	Niemann-Pick Disease (NPD)/ Sporadic Inclusion Body Myositis (IBM)/ Amyotrophic lateral sclerosis (ALS)	PO	InTrial	2H2020	Yes	Yes
PRT-201	vonapanitase	Proteon Therapeutics	human elastase (recombinant)	End stage renal diease (ESRD)/Peripheral artery disease (PAD)/ Vascular access in hemodialysis	TOP	InTrial	2H2020	Yes	Yes
bb-2121	idecabtagene viciuecel	Celgene/ Bluebird Bio	chimeric antigen receptor (CAR) T cell therapy	Multiple myeloma/ Brain cancer	IV	InTrial	2H2020	Yes	Yes
KPI-121 0.25%	loteprednol etabonate	Kala	corticosteroid	Dry eyes	OP	CRL	2H2020	No	No
Anti-VEGF DARPIn	abicipar pegol	Allergan	VEGF-A inhibitor	Age-related macular degeneration (AMD)	Intravitreal	InTrial	2H2020	Yes	No
AmnioFix	dehydrated human amnion/chorion membrane (dHACM)	MiMedx	amniotic tissue membrane	Plantar fasciitis/ Achilles tendonitis/ Osteoarthritis	INJ	InTrial	4Q2020	Yes	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
tramadol	tramadol	Avenue Therapeutics	opioid receptor agonist	Pain	IV	InTrial	4Q2020	No	No
Estelle	estetrol/ drospirenone	Mithra/ Fuji/ Zhejiang Xianju	estrogen receptor agonist	Pregnancy prevention	PO/SL/ Transmucosal	InTrial	4Q2020	No	No
Infacort	hydrocortisone	Diurnal Group	corticosteroid	Adrenal insufficiency	PO	InTrial	4Q2020	No	Yes
MOR-208 (MOR- 00208, XmAB-5574)	tafasitamab	MorphoSys/ Xencor	CD-19 antagonist	Diffuse large B-cell lymphoma (DLBCL)/ Acute lymphocytic leukemia (ALL)/ Chronic lymphocytic leukemia (CLL)	IV	InTrial	4Q2020	Yes	Yes
Melflufen (Ygalo)	melphalan- flufenamide	Oncopeptides AB	alkylating agent/ DNA synthesis inhibitor	Multiple myeloma/ Non-small cell lung cancer (NSCLC)/ Ovarian cancer	IV	InTrial	4Q2020	No	Yes
BLU-667	BLU-667	Blueprint Medicines	RET inhibitor	Non-Small Cell Lung Cancer (NSCLC)	PO	InTrial	4Q2020	Yes	Yes
Qtrypta	zolmitriptan	Zosano	triptans	Acute migraines	TOP	InTrial	4Q2020	No	No
Qarziba (Isqette)	dinutuximab beta	EUSA/ Aperion/ Endo/ Gen Ilac/ Medison	disialoganglioside	Neuroblastoma	SC	InTrial	2020	Yes	Yes
Multikine	Leukocyte Interleukin (CS-001P3)	CEL-SCI	immunomodulator	Head and Neck cancer/ Squamous cell carcinoma	SC	InTrial	2020	Yes	Yes
HTX-011	bupivacaine/ meloxicam	Heron Therapeutics	anesthetic/ Nonsteroidal Anti- inflammatory Drug (NSAID)	Pain	Instillation	CRL	2020	No	No
ublrituximab (LFB- R603, TG20, TGTX-1101, TG-1101, Utuxin)	ublrituximab	TG Therapeutics	CD-20 monoclonal antibody	Chronic lymphocytic leukemia (CLL)/ Small cell lymphocytic lymphoma (SLL)/ Mantle cell lymphoma (MCL)/ Multiple sclerosis	IV	InTrial	2020	Yes	Yes
INCB-028060	capmatinib	Novartis/ Incyte	cMET inhibitor	Non-small cell lung cancer (NSCLC)	PO	InTrial	2020	Yes	No
Oralair Mites	dust mite peptide	Stallergenes/ Shionogi	vaccine	Dust mite allergic rhinitis	SL	InTrial	2020	Yes	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
Deltyba	delamanid	Otsuka	mycolic acid biosynthesis inhibitor	Tuberculosis	PO	InTrial	2020	No	No
JNJ-872 (VX-787)	JNJ-872 (VX-787)	Johnson & Johnson/ Vertex	viral protein inhibitor	Influenza	PO	InTrial	2020	No	No
Zynquista	sotagliflozin	Sanofi/ Lexicon	sodium-dependent glucose transporter 1 (SGLT-1) and SGLT-2 inhibitor	Diabetes mellitus	PO	CRL	2020	No	No
NeoCart	autologous chondrocyte tissue implant	Histogenics/ Purpose	autologous chondrocyte tissue implant	Joint repair	Undisclosed	InTrial	2020	Yes	No
NNC-0195-0092 (NN-8640)	somapacitan	Novo Nordisk	recombinant human growth hormone (rhGH)	Short stature/ Growth hormone deficiency	SC	InTrial	2020	Yes	No
Sativex	nabiximols	GW Pharmaceuticals/ Otsuka	cannabinoid product	Multiple sclerosis (MS)/ Pain	SL/ SPR	InTrial	2020	No	No
Contepo	fosfomycin	Nabriva Therapeutics	cell wall inhibitor	Bacterial infections	IV	CRL	2020	Yes	No
VivaGel	astodimer sodium (SPL-7013)	Starpharma	viral attachment inhibitor	Bacterial infections	VG	CRL	2020	No	No
CM-AT	CM-AT	Curemark	protein absorption enhancer	Autism	PO	InTrial	2020	Yes	No
MLN-4924 (TAK- 92)	pevonedistat	Takeda	Nedd 8 Activating Enzyme (NAE) antagonist	Acute myeloid leukemia (AML)/ Chronic myelogenous leukemia (CML)/ Myelodysplastic syndrome (MDS)	PO	InTrial	2020	Yes	No
N-1539	meloxicam	Recro Pharma/ Alkermes	nonsteroidal anti-inflammatory drug (NSAID)	Pain	IV	CRL	2020	Yes	No
ND-0612H	levodopa/ carbidopa	NeuroDerm	dopamine precursor/ dopa-decarboxylase inhibitor	Parkinson's disease (PD)	SC	InTrial	2020	Yes	No
Pedmark (STS)	sodium thiosulfate	Fennec	reducing agent	Hearing loss	IV	InTrial	2020	Yes	Yes
ursodeoxycholic acid	ursodeoxycholic acid	Retrophin/ Asklepion	bile acid derivative	Primary biliary cirrhosis/cholangitits	PO	InTrial	2020	Yes	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
Travivo	gepirone ER	GSK/Fabre-Kramer	5-HT-1A receptor agonist	Major depressive disorder (MDD)	PO	CRL	2020	No	No
Dexasite	dexamethasone	InSite Vision	corticosteroid	Blepharitis/ Ocular inflammation	TOP	InTrial	2020	No	No
APC-8000	tadalafil	Adamis	phosphodiesterase-5 (PDE-5) inhibitor	Erectile dysfunction	PO	CRL	2020	Yes	No
ND-0612L	levodopa/ carbidopa	NeuroDerm	dopamine precursor/ dopa-decarboxylase inhibitor	Parkinson's disease (PD)	SC	InTrial	2020	Yes	No
BGF-MDI (PT-010)	budesonide/ glycopyrronium/ formoterol	AstraZeneca	corticosteroid/ long- acting muscarinic receptor antagonist (LAMA)/ long-acting beta 2 adrenergic receptor agonist (LABA)	Chronic obstructive pulmonary diseaser (COPD)/ Asthma	INH	InTrial	2020	No	No
Tivopath (AV-951, KRN-951, ASP- 4130)	tivozanib	Aveo/ Astellas/ Kyowa Hakko Kirin	VEGF inhibitor	Renal cell cancer	PO	InTrial	2020	Yes	No
DS-200	DS-200	Eton	undisclosed	Ophthalmological disease	SC	InTrial	2020	unknown	No
QMF-149	indacaterol maleate/ mometasone furoate	Novartis/ Merck	long-acting beta 2 agonist/ corticosteroid	Asthma	INH	InTrial	2020	No	No
BHV-0223	riluzole	Biohaven	glutamate release inhibitor	Amyotrophic lateral sclerosis (ALS)	SL/ Transmucosal	CRL	2020	No	Yes
MNK-812	oxycodone	Mallinckrodt	opioid agonist	Pain	PO	CRL	2020	No	No
CPP-1X/ sulindac (DFMO)	eflornithine/ sulindac	Cancer Prevention Pharma/ Zeria	ornithine decarboxylase inhibitor/ non-steroidal anti-inflammatory drug (NSAID)	Familial adenomatous polyposis (FAP)/ Colorectal cancer	PO	InTrial	2020	Yes	Yes
GZ-402666 (NeoGAA)	neo-recombinant human acid alpha glucosidase	Sanofi	enzyme therapy	Pompe disease	IV	InTrial	2020	Yes	No
Numbrino	cocaine HCl	Lannett	anesthetic	Anesthesia	TOP	CRL	2020	No	No
cannabidiol	cannabidiol	Insys Therapeutics	cannabinoid product	Seizures/ Prader-Willi	PO	InTrial	Late 2020	Yes	No



Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
skQ1	visomitin	Mitotech	plastoquinone derivative	Dry eyes	OP	InTrial	Late 2020	Yes	No
tanezumab	tanezumab	Pfizer/ Eli Lilly	neurotrophic tyrosine kinase receptor type 1 (TrkA) antagonist (monoclonal antibody)	Osteoarthritis/ Pain	IV/SC	InTrial	Late 2020	Yes	No
BMN-111	vosoritide (vasoritide)	BioMarin/ Chugai	C-type natriuretic peptide (CNP) analog	Achondroplasia	SC	InTrial	Late 2020	Yes	Yes
NS-2 (ALDX-1E1, ALDX-1E2, ADX- 102)	reproxalap	Aldeyra Therapeutics	aldehyde antagonist	Uveitis/ Allergic conjunctivitis/ Dry eyes	OP	InTrial	Late 2020	No	No
azacitidine	azacitidine	Celgene	DNA methylation inhibitor	Acute myeloid leukemia (AML)/ Myelodysplastic syndromes	PO	InTrial	Late 2020	Yes	Yes
MVA-MUC1-IL2	TG-4010	Transgene	vaccine	Non-small cell lung cancer (NSCLC)	SC	InTrial	Late 2020	No	No
QAW-039 (NVP- QAW-039)	fevipirant	Novartis	chemoattractant receptor-homologous molecule (CRTH2) antagonist	Asthma/ Atopic dermatitis	PO	InTrial	Late 2020	Yes	No
Molgradex	molgramostim	Savara	granulocyte macrophage-colony stimulating factor	Pulmonary alveolar proteinosis (PAP)	INH	InTrial	Late 2020	Yes	Yes
Translarna	ataluren	PTC Therapeutics	gene transcription modulator	Duchenne muscular dystrophy/ Mucopolysaccharidosis (MPS)	PO	CRL	Late 2020	Yes	Yes
BIVV-009 (TNT- 009)	sutimlimab	Sanofi	complement C1s subcomponent inhibitor	Cold agglutnin disease	IV	InTrial	Late 2020	Yes	Yes
RG-3477 (ACT- 128800)	ponesimod	Johnson & Johnson	sphingosine 1 phosphate receptor agonists	Multiple sclerosis	PO	InTrial	Late 2020	Yes	No
Lucassin	terlipressin	Orphan Therapeutics/ Ikaria	V-1 (vasopressin) agonist	Hepato-renal syndrome (HRS)	IV	CRL	Late 2020	Yes	Yes
HuMax-TF ADC	tisotumab vedotin	Genmab/ Seattle Genetics	tissue factor antibody	Solid tumors	Undisclosed	InTrial	Late 2020	Yes	No
RE-024	fosmetpantotena te	Retrophin	phosphopantothenate replacement therapy	Neurodegeneration	IV	InTrial	Late 2020	Yes	Yes

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
MK-0594 (VPD- 737)	serlopitant	Menlo	NK-1 receptor antagonist	Atopic dermatitis/ Cough	PO	InTrial	Late 2020	Yes	No
Linhaliq	ciprofloxacin	Aradigm/ Grifols	fluoroquinolone	Non-cystic fibrosis bronchiectasis/ Cystic fibrosis	INH	CRL	Late 2020	Yes	Yes
MEDI-551	inebilizumab	AstraZeneca	CD-19 antagonist	Neuromyelitis optica (NMO)	IV	InTrial	Late 2020	Yes	Yes
TSR-042	dostarlimab	AnaptysBio	PD-1 checkpoint inhibitor	Endometrial cancer	IV	InTrial	Late 2020	Yes	No
LY-900014 (URLi)	LY-900014	Eli Lilly	insulins	Diabetes mellitus	SC	InTrial	Late 2020	No	No
SHP-621	budesonide	Shire	corticosteroid	Eosinophilic esophagitis	PO	InTrial	Late 2020	Yes	Yes
iclaprim	iclaprim	Motif Bio	tetrahydrofolate dehydrogenase inhibitor	Bacterial infections	IV	CRL	Late 2020	Yes	Yes
GFT-505	elafibranor	Genfit	selective peroxisome proliferator-activated receptor (PPAR) modulator	Non-alcoholic steatohepatitis (NASH)/ Primary biliary cirrhosis	PO	InTrial	Late 2020	No	No
BIM-22493 (RM- 493)	setmelanotide	Rhythm/ Camurus/ Ipsen	melanocortin 4 receptor (MC4R) agonist	Obesity/ Bardet-Biedl syndrome	SC	InTrial	Late 2020	Yes	Yes
SCY-078 (MK- 3118)	ibrexafungerp	Scynexis/ R-Pharm JSC/ Merck	glucan synthase inhibitors	Fungal infections	IV/PO	InTrial	Late 2020	No	Yes
<b>2021 Possible Launch Date</b>									
Furoscix	furosemide	scPharmaceuticals	diuretic	Heart failure	SC	CRL	1Q2021	Yes	No
MK-4618 (KRP- 114V, RVT-901)	vibegron	Roivant Sciences/ Urovant/ Kissei/ Kyorin/ Merck	selective beta 3 adrenergic receptor agonist	Overactive bladder	PO	InTrial	1Q2021	No	No
ALNG-01 (ALN-G- 01)	lumasiran	Alnylam	glycolate oxidase antagonist	Hyperoxaluria	Intranasal	InTrial	1Q2021	Yes	Yes

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
SDP-037, SDN-037	SDP-037, SDN- 037	Sun Pharma Advanced Research Company (SPARC)	Corticosteroid	Ocular inflammation/pain	OP	InTrial	2Q2021	No	No
UCB-4940 (CDP- 4940)	bimekizumab	UCB	interleukin-17 (IL-17) receptor inhibitor	Psoriasis(Ps)/ Psoriatic arthritis (PsA)/ Ankylosing spondylitis (AS)/ Rheumatoid arthritis (RA)	IV	InTrial	1H2021	Yes	No
RGN-259 (GBT- 201; RGN-352)	thymosin beta 4	RegeneRx	actin regulating peptide	Neurotrophic keratitis (NK)/ Dry eyes	OP	InTrial	1H2021	No	Yes
WVE-210201	WVE-210201	Wave Life Sciences	oligonucleotide	Duchenne muscular dystrophy (DMD)	IV	InTrial	1H2021	Yes	Yes
ACER-001	sodium phenylbutyrate	Acer Therapeutics	BCKDC kinase inhibitor	Maple Syrup Urine Disease	PO	InTrial	1H2021	No	Yes
AXS-05	dextromethorph an/ bupropion	Axsome	N-methyl-D-aspartate (NMDA) antagonist/ antidepressant	Treatment-resistant depression/ Alzheimer's disease	PO	InTrial	1H2021	No	No
ACP-001	TransCon Growth Hormone	Ascendis	growth hormone prodrug	Short stature/ Growth hormone deficiency	SC	InTrial	1H2021	Yes	No
CCX-168	avacopan	ChemoCentryx/ Galencia	C5a receptor (C5aR) antagonist	Vasculitis/ Glomerulopathy	PO	InTrial	1H2021	Yes	Yes
GSK-2894512 (WBI-1001)	tapinarof	GSK/ Celestial/ Roivant Sciences/ Welichem Biotech	therapeutic aryl hydrocarbon receptor modulating agent (TAMA)	Atopic dermatitis (AD)/ Psoriasis	TOP	InTrial	1H2021	Yes	No
TadFin	tadalafil and finasteride	Veru	phosphodiesterase type 5 inhibitor /5-alpha-reductase inhibitor	Benign prostatic hyperplasia (BPH)	PO	InTrial	Mid-2021	No	No
EBV-CTL (ATA- 129)	tabelecleucel	Atara Biotherapeutics/ Memorial Sloan- Kettering Cancer Center	cell therapy	Lymphoproliferative disorder	IV	InTrial	Mid-2021	Yes	Yes
RSV-F (ResVax)	respiratory syncytial virus vaccine	Novavax	vaccine	Respiratory syncytial virus (RSV) infection	IM	InTrial	Mid-2021	Yes	No
Recorlev	levoketoconazol e	Strongbridge Biopharma	azole antifungal	Cushing's syndrome	PO	InTrial	3Q2021	No	Yes
PDP-716	brimonidine	Sun Pharma Advanced Research Company (SPARC)	alpha-2 agonist	Glaucoma	OP	InTrial	3Q2021	No	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
Otividex	dexamethasone sustained-release	Otonomy	corticosteroid	Meniere's disease	Intratympanic	InTrial	2H2021	Yes	No
VBP-15	vamorolone	Santhera	corticosteroid	Duchenne muscular dystrophy (DMD)	PO	InTrial	2H2021	Yes	Yes
PL-56	budesonide	Calliditas/ Kyowa Hakko Kirin	corticosteroid	Nephropathy	PO	InTrial	2H2021	No	No
TWIN (S6G5T-1; S6G5T-3)	benzoyl peroxide/ tretinoin	Sol-Gel Technologies	retinoid	Acne vulgaris	TOP	InTrial	2H2021	No	No
177Lu-PSMA-617	Lutetium	Endocyte	Radiopharmaceutical	Prostate cancer	IV	InTrial	2H2021	Yes	No
LN-145	lifileucel	Iovance Biotherapeutics	tumor infiltrating lymphocyte	Cervical Cancer	IV	InTrial	2H2021	Yes	No
GS-010	GS-010	GenSight Biologics	gene therapy	Optic neuropathy	Intraocular	InTrial	2H2021	Yes	Yes
AMAG-423	digoxin immune fab (DIF)	AMAG/ Velo	digitalis-like factor antagonist	Preeclampsia	IV	InTrial	2H2021	Yes	Yes
SPN-810	molindone	Supernus	atypical antipsychotic	Attention deficit hyperactivity disorder (ADHD)	PO	InTrial	2H2021	No	No
R-1658 (RG-1658, JTT-705, RO- 4607381)	dalcetrapib	DalCor/ Japan Tobacco/ Roche	cholesteryl ester transfer protein inhibitor	Acute coronary syndrome (ACS)	PO	InTrial	2021	Yes	No
Korsuva	difelikefalin	Cara Therapeutics/ Vifor/ Fresenius	opioid receptor agonist	Pruritus/ Pain/ Osteoarthritis	IV/PO	InTrial	2021	No	No
OTL-101	ADA-transduced autologous stem cell therapy	Orchard Therapeutics	gene therapy	Adenosine deaminase (ADA)-deficient severe combined immunodeficiency (SCID)	Undisclosed	InTrial	2021	Yes	Yes
BMS-986089 (RG- 6206)	BMS-986089 (RG-6206)	Roche/ Bristol- Myers Squibb	anti-myostatin adnectin	Duchenne muscular dystrophy (DMD)	SC	InTrial	2021	Yes	Yes
AZD-6094 (HMPL- 504)	savolitinib (volitinib)	AstraZeneca (Hutchison MediPharma)	c-Met receptor tyrosine kinase inhibitor	Renal cell cancer (RCC)/ Non-small cell lung cancer (NSCLC)	PO	InTrial	2021	Yes	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
CT-100	corticotrophin	Eton	adrenocorticotrophic hormone (ACTH)	Rheumatoid arthritis (RA)	INJ	InTrial	2021	No	No
SHP-647 (PF- 00547659)	SHP-647 (PF- 00547659)	Shire	MAdCAM-1 antagonist	Irritable bowel disease (IBD)/ Crohn's disease (CD)/ Ulcerative colitis (UC)	IV/SC	InTrial	2021	Yes	Yes
ABL-001	asciminib	Novartis	allosteric Bcr-Abl inhibitor	Chronic myelogenous leukemia (CML)	PO	InTrial	2021	Yes	Yes
CMX-001	brincidofovir hexadecyloxypro pyl ester	Chimerix	DNA-directed DNA polymerase inhibitor	Adenovirus/ Cytomegalovirus (CMV)/ Smallpox	PO	InTrial	2021	No	Yes
S5G4T-1 (DER-45- EV)	benzoyl peroxide	Sol-Gel Technologies	benzoyl peroxide	Rosacea	TOP	InTrial	2021	No	No
POL-6326	balixafortide	Polyphor	chemokine (CXCR4) antagonist	Transplant/ Breast cancer	IV	InTrial	2021	Yes	No
DS-100	DS-100	Eton	undisclosed	Ophthalmological disease	SC	InTrial	2021	unknown	No
Qizenday	MD-1003	MedDay	biotin	Multiple sclerosis	PO	InTrial	2021	Yes	No
ATI-5923	tecarfarin	ARYx Therapeutics/ Armetheon	vitamin K epoxide reductase enzyme inhibitor	Anticoagulation	PO	InTrial	2021	No	No
RG-7314 (RO- 5285119)	balovaptan	Roche	V1A vasopressin receptor antagonist	Autism spectrum disorder	PO	InTrial	2021	Yes	No
Edsivo	celiprolol HCl	Acer Therapeutics	alpha-2/beta-1 adrenergic agent	vascular Ehlers-Danlos Syndrome (vEDS)	PO	CRL	2021	Yes	Yes
OSE-2101 (IDM- 2101, EP-2101)	tedopi	OSE Pharma/ Takeda	vaccine	Non-small cell lung cancer (NSCLC)	SC	InTrial	2021	Yes	Yes
LY-686017	tradipitant	Vanda Pharmaceuticals	neurokinin 1 receptor (NK-1R) antagonist	Motion sickness	PO	InTrial	2021	No	No
IMO-2125	tilsotolimod	Idera	toll-like receptor 9 (TLR-9) agonist	Melanoma	SC/ intratumoral	InTrial	2021	Yes	Yes
gantenerumab	gantenerumab	Roche	beta-amyloid (Abeta) inhibitor	Alzheimer's disease	SC	InTrial	Late 2021	Yes	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
Ultomiris SC	ravulizumab- cwvz	Alexion	C5 complement inhibitor	paroxysmal nocturnal hemoglobinuria (PNH); Hemolytic uremic syndrome (HUS)	SC	InTrial	Late 2021	Yes	Yes
ONS-5010	bevacizumab	Outlook Therapeutics	anti-VEGF antibody	wet age-related macular degeneration	Intravitreal	InTrial	Late 2021	Yes	No
PF-06482077	multivalent group B streptococcus vaccine	Pfizer	vaccine	Bacterial infection	IM	InTrial	Late 2021	Yes	No
CAT-1004	edasalonexent	Catabasis	NF-kB inhibitor	Duchenne muscular dystrophy (DMD)	PO	InTrial	Late 2021	Yes	Yes
Humacyl	human acellular vessel	Humacyte	cellular therapy	End-stage renal disease (ESRD)/ Peripheral artery disease (PAD)	Implant	InTrial	Late 2021	Yes	No
AMT-061	AMT-061	uniQure	gene therapy	Hemophilia B	IV	InTrial	Late 2021	Yes	No
PW-4142 (T-111)	nalbuphine ER	Trevi Therapeutics/ Endo	opioid agonist/ antagonist	Prurigo nodularis	PO	InTrial	Late 2021	No	No
NNZ-2566	trofinetide	Neuren	insulin-like growth factor 1 (IGF-1) derivative	Rett syndrome/ Fragile X syndrome/ Brain injury	IV/PO	InTrial	Late 2021	Yes	Yes
GSK-2696274 (OTL-200)	GSK-2696274 (OTL-200)	GlaxoSmithKline	gene therapy	Leukodystrophy	IV	InTrial	Late 2021	Yes	Yes

IM = intramuscular, INH = inhalation, INJ = injection, IUD = intrauterine device, IV = intravenous, OP = ophthalmic, PO = oral, SC = subcutaneous, SL = sublingual, SPR = spray, TOP = topical, VG = vaginal, NSCLC = Non-small cell lung cancer, COPD = Chronic Obstructive Pulmonary Disease