

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
2019 Possible Launch Date									
RVT-802	RVT-802	Enzyvant/Roivant	Tissue-based therapy	Congenital athymia	Implant	Filed NDA	12/2019	Yes	Yes
Zimhi	naloxone	Adamis	opioid antagonist	Opioid dependence	IM	Filed NDA	12/2019	No	No
MK-1602 (AGN-241689)	ubrogepant	Allergan/ Merck	calcitonin gene-related peptide (CGRP) receptor antagonist	Acute migraines	PO	Filed NDA	12/2019	No	No
IDP-123	IDP-123	Bausch Health	retinoid	Acne	TOP	Filed NDA	12/22/2019	No	No
Brinavess	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	lumateperone	Intra-Cellular Therapies	antipsychotic	Schizophrenia	PO	Filed NDA	12/27/2019	No	No
TMC-278-LA	cabotegravir (long-acting)/rilpivirine (long-acting)	ViiV Healthcare	HIV integrase inhibitor/non-nucleoside reverse transcriptase inhibitor (NNRTI)	HIV	IM	Filed NDA	12/29/2019	Yes	No
S-265744 (S/GSK- 1265744)	cabotegravir	ViiV Healthcare	HIV integrase inhibitor	HIV	PO	Filed NDA	12/29/2019	Yes	No
NRL-1	diazepam	Neurelis	benzodiazepine	Seizures	Intranasal	Filed NDA	2H2019	No	Yes
2020 Possible Launch Date									
Entyvio (SC formulation)	vedolizumab	Takeda	integrin receptor antagonist	Ulcerative colitis	SC	Filed sBLA	12/2019 - 1/2020	Yes	No
E-7438 (EPZ- 6438)	tazemetostat	Epizyme/ Eisai	methyltransferase EZH2 inhibitor	Sarcoma	PO	Filed NDA	1/23/2020	Yes	Yes

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
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
AR-101	AR-101	Aimmune	peanut protein capsule	Peanut allergy	PO	Filed BLA	1/2020	Yes	No
BLU-285	avapritinib	Blueprint Medicines	selective KIT and PDGFRA inhibitor	Gastrointestinal stromal tumors	PO	Filed NDA	2/14/2020	Yes	Yes
Twirla	ethinyl estradiol/ levonorgestrel	Agile Therapeutics	hormonal combination contraceptive	Pregnancy prevention	TOP	Filed NDA	2/16/2020	No	No
BMS-927711 (BHV-3000)	rimegepant sulfate	Biohaven	calcitonin gene-related peptide (CGRP) receptor antagonist	Acute migraines	PO	Filed NDA	2/20/2020	No	No
ALD-403	eptinezumab	Alder	calcitonin gene-related peptide (CGRP) receptor antagonist	Migraine prevention	IV	Filed BLA	2/21/2020	No	No
ETC-1002	bempedoic acid	Esperion Therapeutics	ATP citrate lyase inhibitor	Hypercholesterolemia	PO	Filed NDA	2/21/2020	No	No
ETC-1002/ ezetimibe	bempedoic acid/ ezetimibe	Esperion Therapeutics	ATP citrate lyase inhibitor/ cholesterol absorption inhibitor	Hypercholesterolemia	PO	Filed NDA	2/26/2020	No	No
APD-421	amisulpride	Acacia	dopamine receptor antagonist	Nausea/ vomiting	IV	Filed NDA	2/26/2020	No	No
RV-001 (Roche- 1, R-1507)	teprotumumab	Horizon Therapeutics	insulin-like growth factor 1 (IGF-1) receptor antagonist	Thyroid eye disease	IV	Filed BLA	3/8/2020	Yes	Yes
ITCA-650 (sustained release exenatide)	exenatide sustained-release	Intarcia	glucagon-like peptide-1 (GLP-1) receptor agonist	Diabetes mellitus	SC implant	Filed NDA	3/9/2020	No	No
ZEBOV	VS-EBOV (rVSV- EBOV; rVSV ZEBOV-GP)	Merck/ NewLink Genetics	vaccine	Ebola	IM	Filed BLA	3/14/2020	Yes	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
naloxone	naloxone	Insys Therapeutics	opioid antagonist	Opioid dependence	Intranasal	Filed NDA	3/15/2020	No	No
ASG-22M6E	enfortumab vedotin	Astellas/ Seattle Genetics	nectin-4 antagonist	Bladder cancer	IV	Filed BLA	3/15/2020	Yes	No
ET-105	lamotrigine	Eton	anticonvulsant	Epilepsy	PO	Filed NDA	3/17/2020	No	No
ozanimod	ozanimod	Celgene	sphingosine 1-phosphate 1 (S1PR1) and 5 (S1PR5) receptor modulator	Multiple sclerosis	PO	Filed NDA	3/25/2020	Yes	No
obeticholic acid	obeticholic acid	Intercept Pharmaceuticals	farnesoid X receptor (FXR) agonist	Nonalcoholic steatohepatitis	PO	Filed NDA	3/26/2020	Yes	No
Rizaport (VersaFilm)	rizatriptan	IntelGenx / Red Hill Biopharma	triptans	Acute migraines	PO	Filed NDA	3/26/2020	No	No
HTX-011	bupivacaine/ meloxicam	Heron Therapeutics	anesthetic/ Nonsteroidal Anti-inflammatory Drug (NSAID)	Pain	Instillation	Filed NDA	3/26/2020	No	No
SPARC-1028	paclitaxel injection concentrate for suspension	Sun Pharma Advanced Research Company (SPARC)	taxane	Breast Cancer; Lung Cancer; Pancreatic Cancer	IV	Filed NDA	1Q2020	No	No
Posidur	SABER-bupivacaine CR	Novartis/ Durect	local anesthetic	Pain	SC	Filed NDA	1Q2020	No	No
LCI-699	osilodrostat	Novartis	aldosterone synthase inhibitor	Cushing's syndrome	PO	Filed NDA	1Q2020	No	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
bimatoprost sustained release	bimatoprost sustained release	Allergan	prostaglandin agonist	Glaucoma	Implant	Filed NDA	4/1/2020	No	No
CNS-7056	remimazolam	Cosmo	benzodiazepine	Procedural sedation	IV	Filed NDA	4/3/2020	Yes	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
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's disease	PO	Filed NDA	4/26/2020	No	No
Trevyent	treprostinil	SteadyMed	prostacyclin analog	Pulmonary arterial hypertension	SC	Filed NDA	4/27/2020	Yes	Yes
DS-8201	trastuzumab deruxtecan	Daiichi Sankyo	HER2-targeting antibody-drug conjugate	Breast cancer	IV	Filed BLA	4/29/2020	Yes	No
isatuximab	isatuximab	Sanofi/ ImmunoGen	CD38 antagonist	Multiple myeloma/ Acute lymphoblastic leukemia or lymphoblastic lymphoma	IV	Filed BLA	4/30/2020	Yes	Yes
selumetinib	selumetinib	AstraZeneca/ Merck	selective MEK kinase inhibitor	Neurofibromatosis	PO	Filed NDA	4/2020 – 5/2020	Yes	Yes
SEP-225289 (DSP-225289, SEP-289)	dasotraline	Sumitomo Dainippon/ Sunovion	triple reuptake inhibitor	Eating disorders	PO	Filed NDA	5/14/2020	No	No
INCB-54828	pemigatinib	Incyte	selective FGFR1/2/3 inhibitor	Biliary tract cancer	PO	Filed NDA	5/2020	Yes	Yes
FMX-103	minocycline	Foamix	tetracyclines	Rosacea	TOP	Filed NDA	6/2/2020	No	No
NS-065	viltolarsen	Nippon Shinyaku	morpholino antisense oligonucleotide	Duchenne muscular dystrophy	IV	Filed BLA	6/2/2020	Yes	Yes
Bafiertam	monomethyl fumarate	Banner Life Sciences	Nrf2 pathway activator	Multiple sclerosis	PO	Tentative Approval	6/20/2020	Yes	No
abicipar pegol	abicipar pegol	Allergan	VEGF-A inhibitor	Age-related macular degeneration	Intravitreal	Filed BLA	6/2020 – 7/2020	Yes	No
MEDI-551	inebilizumab	Viela Bio	CD-19 antagonist	Neuromyelitis optica spectrum disorder	IV	Filed BLA	6/13/2020 - 7/13/2020	Yes	Yes

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
EVK-001	metoclopramide	Evoke Pharma	antidopaminergics	Diabetic gastroparesis	Intranasal	CRL	2Q2020	No	No
Bronchitol	mannitol	Pharmaxis	osmotic gradient enhancer; mucus clearance enhancer	Cystic fibrosis	INH	CRL	2Q2020	No	Yes
Rexista XR	oxycodone ER	IntelliPharmaCeutics	opioid agonist	Pain	PO	Not Approved	1H2020	No	No
insulin glargine	insulin glargine	Mylan/ Biocon	Long-acting insulin	Diabetes mellitus	SC	CRL	1H2020	No	No
IMMU-132	sacituzumab govitecan	Immunomedics	RS7-SN-38 antibody-drug conjugate	Breast cancer	IV	CRL	1H2020	Yes	No
NKTR-181	NKTR-181	Nektar	opioid agonist	Pain	PO	Not Approved	1H2020	No	No
SRP-4045	casimersen	Sarepta	morpholino antisense oligonucleotide	Duchenne muscular dystrophy	IV	InTrial	Mid-2020	Yes	Yes
Contepo	fosfomycin	Nabriva Therapeutics	cell wall inhibitor	Bacterial infections	IV	CRL	Mid-2020	Yes	No
RG-7916	risdiplam	Roche/ PTC Therapeutics	SMN2 splicing modifier	Spinal muscular atrophy	PO	InTrial	Mid-2020	Yes	Yes
Apealea (Paclical)	paclitaxel	Oasmia	taxane	Ovarian cancer	IV	InTrial	Mid-2020	Yes	Yes
TGR-1202	umbralisib	TG Therapeutics/ Rhizen	phosphoinositide-3 kinase (PI3K) delta inhibitor	Diffuse large B-cell lymphoma/ Chronic lymphocytic leukemia	PO	InTrial	Mid-2020	Yes	Yes
Prochymal	remestemcel-L	Mesoblast/ JCR/ Mallinckrodt/ Osiris Therapeutics	mesenchymal stem cells	Graft vs. Host disease	IV	InTrial	Mid-2020	Yes	Yes
MOR-208 (MOR-00208, XmAB-5574)	tafasitamab	MorphoSys/ Xencor	CD-19 antagonist	Diffuse large B-cell lymphoma	IV	InTrial	Mid-2020	Yes	Yes

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
LOXO-292	selpercatinib	Eli Lilly/ Loxo Oncology	RET inhibitor	Solid tumors; non- small cell lung cancer; thyroid cancer	PO	InTrial	Mid-2020	Yes	No
Amphora	Amphora	Evoform Biosciences	spermicidal agent	Pregnancy prevention	VG	CRL	Mid-2020	No	No
PRO-140	leronlimab	CytoDyn	C-C chemokine receptor 5 (CCR5) antagonist	HIV; Graft vs. host disease	SC	InTrial	Mid-2020	Yes	Yes
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
JCAR-017	lisocabtagene maraleucel	Juno/ Celgene	chimeric antigen receptor (CAR) T cell therapy	Diffuse large B-cell lymphoma	IV	InTrial	Mid-2020	Yes	Yes
GSP-301	mometasone furoate/ olopatadine HCl	Glenmark	corticosteroid/ antihistamine	Allergic rhinitis	Intranasal	CRL	Mid-2020	No	No
Zepsyre	lurbinectidin (lurbinectedin)	PharmaMar/ Myriad Genetics	alkylating agent	Small cell lung cancer	IV	InTrial	Mid-2020	Yes	Yes
MitoGel	mitomycin C	UroGen	alkylating agent	Bladder cancer	Intravesical	InTrial	Mid-2020	No	Yes
3-F8 (Hu-3F8)	naxitamab	Y-mAbs Therapeutics	GD2 antagonist	Neuroblastoma	IV	InTrial	Mid-2020	Yes	Yes
Zynteglo (LentiGlobin)	lentiviral beta- globin gene transfer	Bluebird Bio	gene therapy	Beta-thalassemia	IV	InTrial	Mid-2020	Yes	Yes

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
EBP-994 (rEBP- 994)	lonafarnib	Eiger Biopharmaceuticals	prenylation inhibitor	Hutchinson-Gilford Progeria Syndrome (HGPS or progeria) and progeroid laminopathies; Hepatitis D (HDV)	PO	InTrial	Mid-2020	Yes	Yes
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
Fintepla	fenfluramine	Zogenix	serotonin receptor agonist	Dravet syndrome	PO	Filed NDA	7/24/2020	Yes	Yes
MC2-01	calcipotriene/ betamethasone	MC2 Therapeutics	vitamin D analog/ corticosteroid	Psoriasis	TOP	Filed NDA	7/24/2020	No	No
UX-007	triheptanoin	Ultragenyx/ Baylor Research Institute/ Uniquist	medium chain fatty acid	Glucose transport type 1 deficiency syndrome	PO	Filed NDA	7/31/2020	Yes	Yes
Viaskin Peanut	Viaskin Peanut	DBV Technologies	Immunotherapy	Peanut allergy	TOP	Filed BLA	8/5/2020	No	No
TRC-101	veverimer	Tricida	carrier protein modulator	Chronic kidney disease	PO	Filed NDA	8/22/2020	Yes	No
Winlevi	clascoterone	Cassiopea	androgen antagonist	Acne vulgaris	TOP	Filed NDA	8/27/2020	No	No
SA-237 (RG- 6168)	satralizumab	Roche/ Chugai	interleukin-6 (IL-6) monoclonal antibody	Neuromyelitis optica	SC	Filed BLA	8/2020 – 9/2020	Yes	Yes
collagenase clostridium histolyticum	collagenase clostridium histolyticum	Endo	protease enzyme	Cellulite	SC	Filed BLA	9/6/2020	Yes	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
VP-102	VP-102	Verrica	antiviral	Molluscum	TOP	Filed NDA	9/16/2020	No	No
NNC-0195- 0092 (NN-8640)	somapacitan	Novo Nordisk	recombinant human growth hormone (rhGH)	Growth hormone deficiency	SC	Filed BLA	9/21/2020	Yes	No
LY-900014 (URLi)	insulin lispro	Eli Lilly	insulins	Diabetes mellitus	SC	Filed BLA	3Q2020	No	No
BMN-270	valoctocogene roxaparvovec	BioMarin	gene therapy	Hemophilia	IV	InTrial	3Q2020	Yes	Yes
efavirenz	efavirenz	Micro Labs	non-nucleoside reverse transcriptase inhibitor (NNRTI)	HIV	PO	Tentative Approval	3Q2020	Yes	No
GSK-2857916	belantamab mafodotin	GlaxoSmithKline/ Seattle Genetics	anti-BCMA antibody-drug conjugate	Multiple myeloma	SC	InTrial	3Q2020	Yes	Yes
PPP-001	delta-9- tetrahydrocannabinol/ cannabidiol	PhytoPain Pharma	cannabinoid product	Pain	INH	InTrial	3Q2020	Yes	Yes
BCX-7353	BCX-7353	BioCryst	kallikrein inhibitor	Hereditary angioedema	PO	InTrial	3Q2020	Yes	Yes
SPI-2012	eflapegrastim	Spectrum/ Hanmi	granulocyte colony-stimulating factor (GCSF)	Neutropenia	SC	Filed BLA	10/25/2020	Yes	No
CAM-2038	buprenorphine	Camurus/ Braeburn	opioid receptor agonist (partial)	Opioid use disorder/ Pain	SC	Tentative Approval	11/1/2020	Yes	No
SPN-812	SPN-812	Supernus	selective norepinephrine reuptake inhibitor	Attention deficit hyperactivity disorder	PO	Filed NDA	11/11/2020	No	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
Melflufen (Ygalo)	melphalan- flufenamide	Oncopeptides AB	alkylating agent/ DNA synthesis inhibitor	Multiple myeloma/ Non-small cell lung cancer/ Ovarian cancer	IV	InTrial	4Q2020	No	Yes
DCC-2618	ripretinib	Deciphera	PDGFR-alpha kinase inhibitor	Gastrointestinal stromal tumors	PO	InTrial	4Q2020	Yes	Yes
ALN-PCSSc (PCSK9si)	inclisiran	The Medicines Company/ Alnylam	proprotein convertase subtilisin/kexin 9 (PCSK-9) inhibitor	Hyperlipidemia	SC	InTrial	4Q2020	Yes	Yes
ARRY-380 (ONT-380)	tucatinib	Seattle Genetics/ Array BioPharma	ErbB-2 (Her-2/neu) inhibitor	Breast cancer	PO	InTrial	4Q2020	Yes	Yes
BLU-667	pralsetinib	Blueprint Medicines	RET inhibitor	Non-small cell lung cancer	PO	InTrial	4Q2020	Yes	Yes
GLPG-0634	filgotinib	Gilead/ Galapagos	janus associated kinase-1 (JAK) inhibitor	Rheumatoid arthritis	PO	InTrial	4Q2020	Yes	No
LIQ-861	treprostinil	Liquidia Technologies	prostacyclin analog	Pulmonary arterial hypertension	INH	InTrial	4Q2020	Yes	No
ofatumumab (OMB-157)	ofatumumab	Novartis	CD20 monoclonal antibody	Multiple sclerosis	SC	InTrial	4Q2020	Yes	No
Infacort	hydrocortisone	Diurnal Group	corticosteroid	Adrenal insufficiency	PO	InTrial	4Q2020	No	Yes
TAK-385	TAK-385	Myovant Sciences/ Roivant Sciences/ Takeda	gonadotropin-releasing hormone (GnRH) receptor antagonist	Uterine fibroids/ Endometriosis	PO	InTrial	4Q2020	Yes	No
tramadol	tramadol	Avenue Therapeutics	opioid receptor agonist	Pain	IV	InTrial	4Q2020	No	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
AmnioFix	dehydrated human amnion/chorion membrane (dHACM)	MiMedx	amniotic tissue membrane	Plantar fasciitis/ Achilles tendonitis/ Osteoarthritis	INJ	InTrial	4Q2020	Yes	No
Estelle	estetrol/ drospirenone	Mithra/ Fuji/ Zhejiang Xianju	estrogen receptor agonist	Pregnancy prevention	PO/SL	InTrial	4Q2020	No	No
Qtrypta	zolmitriptan	Zosano	triptans	Acute migraines	TOP	InTrial	4Q2020	No	No
R-667 (RG-667)	palovarotene	Clementia/ Roche	selective retinoic acid receptor agonist (RAR-gamma)	Fibrodysplasia ossificans progressiva (FOP)	PO	InTrial	4Q2020	Yes	Yes
ALKS-3831	olanzapine/ samidorphan	Alkermes	dopamine receptor antagonist/ opioid receptor antagonist	Schizophrenia/ Bipolar disorder	PO	InTrial	4Q2020	No	No
REGN-EB3	REGN-EB3	Regeneron	anti-Ebola virus	Ebola	IV	InTrial	4Q2020	Yes	Yes
FG-4592	roxadustat	FibroGen/ AstraZeneca	hypoxia-inducible factor prolyl hydroxylase (HIF-PHI)	Anemia	PO	InTrial	2H2020	Yes	No
Doria	risperidone	Laboratorios Farmacéuticos Rovi	atypical antipsychotic	Schizophrenia	IM	InTrial	2H2020	Yes	No
Traumakine	interferon-beta - 1a	Faron/ Maruishi	interferon	Acute respiratory distress syndrome	IV	InTrial	2H2020	Yes	No
NX-1207 (NYM-4805, REC 0482)	fexapotide trifluate	Nymox	pro-apoptotic	Benign prostatic hyperplasia	Intratumoral	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
bb-2121	idecabtagene vicleucel	Celgene/ Bluebird Bio	chimeric antigen receptor (CAR) T cell therapy	Multiple myeloma	IV	InTrial	2H2020	Yes	Yes
131I-8H9	omburtamab	Y-mAbs Therapeutics	B7-H3 antagonist	Brain cancer	Undisclosed	InTrial	2H2020	Yes	Yes
IdeS	imlifidase	Hansa Medical	bacterial enzyme	Kidney transplant	IV	InTrial	2H2020	Yes	Yes
ASTX-727	decitabine and E- 7727	Otsuka/ Astex Pharmaceuticals	nucleoside metabolic inhibitor	Myelodysplastic syndrome	PO	InTrial	2H2020	Yes	Yes
Sci-B-Vac	hepatitis B vaccine	VBI Vaccines	vaccine	Hepatitis B	IM	InTrial	2H2020	No	No
LJPC-0118	LJPC-0118	La Jolla Pharmaceutical	protozoacide	Malaria	Undisclosed	InTrial	2H2020	No	No
BMS-663068	fostemsavir	Bristol-Myers Squibb	HIV attachment inhibitor	HIV	PO	InTrial	2H2020	Yes	No
Zeftera	ceftobiprole	Basilea	cephalosporin antibiotic	Bacterial infections	IV	InTrial	2H2020	Yes	No
AGIL-AADC	AGIL-AADC	Agilis Biotherapeutics	gene therapy	Aromatic L-amino acid decarboxylase deficiency	Intracerebral	InTrial	2H2020	Yes	Yes
KTE-X19	KTE-X19	Gilead	chimeric antigen receptor (CAR) T cell therapy	Mantle cell lymphoma	IV	InTrial	2H2020	Yes	Yes
CLS-1001	triamcinolone acetonide	Clearside	corticosteroid	Macular edema	intraocular/ subretinal	CRL	2H2020	Yes	No
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

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
KPI-121 0.25%	loteprednol etabonate	Kala	corticosteroid	Dry eyes	OP	CRL	2H2020	No	No
ropeginterfero n alfa-2b	ropeginterferon alfa-2b	PharmaEssentia/ AOP Orphan	interferon	Polycythemia vera	SC	InTrial	2H2020	Yes	Yes
KP-415	D-threo- methylphenidate controlled-release	KemPharm	CNS stimulant	Attention deficit hyperactivity disorder	PO	InTrial	2H2020	No	No
Iomab-B	iodine I 131 monoclonal antibody BC8	Actinium	anti-CD45 monoclonal antibody	Acute myeloid leukemia/ Myelodysplastic syndrome	IV	InTrial	2H2020	Yes	Yes
quizartinib	quizartinib	Daiichi Sankyo	FLT-3 receptor tyrosine kinase inhibitor	Acute myeloid leukemia	PO	CRL	2H2020	Yes	Yes
EGP-437	dexamethasone phosphate (iontophoretic)	EyeGate	corticosteroid	Uveitis	OP	InTrial	2H2020	Yes	No
Libervant	diazepam	Aquestive Therapeutics	benzodiazepine	Seizures	SL	InTrial	2H2020	No	Yes
TRV-130	oliceridine	Trevena	opioid receptor agonist	Pain	IV	CRL	2H2020	No	No
arimoclomol	arimoclomol	Orphazyme	cytoprotectives	Niemann-Pick Disease/ Sporadic Inclusion Body Myositis/ Amyotrophic lateral sclerosis	PO	InTrial	2H2020	Yes	Yes
Mycapssa (Octreolin)	octreotide	Chiasma	somatostatin analog	Acromegaly	PO	CRL	2H2020	Yes	Yes
PRT-201	vonapanitase	Proteon Therapeutics	human elastase (recombinant)	End stage renal disease/ Peripheral artery disease/ Vascular access in hemodialysis	TOP	InTrial	2H2020	Yes	Yes
PRX-102	alpha galactosidase	Protalix	enzyme replacement	Fabry disease	IV	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
INCB-028060 (INC-280)	capmatinib	Novartis/ Incyte	cMET inhibitor	Non-small cell lung cancer	PO	InTrial	2H2020	Yes	Yes
ET-103	levothyroxine	Eton Pharmaceuticals	L-thyroxine	Hypothyroidism	PO	InTrial	2H2020	No	No
Vicinium (VB-4- 845)	oportuzumab monatox	Eleven Biotherapeutics	anti-ECAM exotoxin A fusion protein	Bladder cancer	Intravesical	InTrial	2H2020	Yes	No
RT-002	daxibotulinumtoxi nA	Revance Therapeutics	botulinum toxins	Glabellar lines (frown lines)	IM	InTrial	2H2020	Yes	Yes
N-1539	meloxicam	Recro Pharma/ Alkermes	nonsteroidal anti-inflammatory drug (NSAID)	Pain	IV	CRL	2020	Yes	No
QMF-149	indacaterol maleate/ mometasone furoate	Novartis/ Merck	long-acting beta 2 agonist/ corticosteroid	Asthma	INH	InTrial	2020	No	No
ND-0612L	levodopa/ carbidopa	NeuroDerm	dopamine precursor/ dopa-decarboxylase inhibitor	Parkinson's disease	SC	InTrial	2020	Yes	No
CPP-1X/ sulindac (DFMO)	eflornithine/ sulindac	Cancer Prevention Pharma/ Zeria	ornithine decarboxylase inhibitor/ non-steroidal anti-inflammatory drug (NSAID)	Familial adenomatous polyposis/ Colorectal cancer	PO	InTrial	2020	Yes	Yes
Zalviso	sufentanil, ARX-01	AcelRx	opioid analgesic	Pain	SL	CRL	2020	No	No
Delyba	delamanid	Otsuka	mycolic acid biosynthesis inhibitor	Tuberculosis	PO	InTrial	2020	No	No
Pedmark (STS)	sodium thiosulfate	Fennec	reducing agent	Hearing loss	IV	InTrial	2020	Yes	Yes
ND-0612H	levodopa/ carbidopa	NeuroDerm	dopamine precursor/ dopa-decarboxylase inhibitor	Parkinson's disease	SC	InTrial	2020	Yes	No
DS-200	DS-200	Eton	undisclosed	Ophthalmological disease	SC	InTrial	2020	No	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
ELI-200	oxycodone/ naltrexone	Elite	opioid agonist	Pain	PO	CRL	2020	No	No
VivaGel	astodimer sodium (SPL-7013)	Starpharma	viral attachment inhibitor	Bacterial infections	VG	CRL	2020	No	No
Dexasite	dexamethasone	InSite Vision	corticosteroid	Blepharitis/ Ocular inflammation	TOP	InTrial	2020	No	No
ublituximab (LFB-R603, TG20, TGTX- 1101, TG-1101, Utuxin)	ublituximab	TG Therapeutics	CD-20 monoclonal antibody	Chronic lymphocytic leukemia/ Small cell lymphocytic lymphoma/ Mantle cell lymphoma/ Multiple sclerosis	IV	InTrial	2020	Yes	Yes
CCP-08	CCP-08	Tris Pharma	undisclosed	Viral rhinitis	PO	CRL	2020	No	No
NeoCart	autologous chondrocyte tissue implant	Histogenics/ Purpose	autologous chondrocyte tissue implant	Joint repair	Undisclosed	InTrial	2020	Yes	No
APN-311	dinutuximab beta	EUSA Pharma	disialoganglioside	Neuroblastoma	SC	InTrial	2020	Yes	Yes
tamsulosin DRS	tamsulosin delayed-release	Veru	alpha-adrenergic antagonist	Benign prostatic hyperplasia	PO	InTrial	2020	No	No
Oralair Mites (Actair)	dust mite peptide	Stallergenes/ Shionogi	vaccine	Dust mite allergic rhinitis	SL	InTrial	2020	Yes	No
Travivo	gepirone ER	GSK/Fabre-Kramer	5-HT-1A receptor agonist	Major depressive disorder	PO	CRL	2020	No	No
MNK-812	oxycodone	Mallinckrodt	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
tadalafil VersaFilm	tadalafil VersaFilm	IntelGenx	phosphodiesterase-5 (PDE-5) inhibitor	Erectile dysfunction	PO	Filed NDA	2020	Yes	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
Multikine	Leukocyte Interleukin (CS-001P3)	CEL-SCI	immunomodulator	Head and Neck cancer/ Squamous cell carcinoma	SC	InTrial	2020	Yes	Yes
APC-8000	tadalafil	Adamis	phosphodiesterase-5 (PDE-5) inhibitor	Erectile dysfunction	PO	CRL	2020	Yes	No
Corplex donepezil	donepezil	Corium International	anticholinergic	Alzheimer's disease	TOP	InTrial	Late 2020	No	No
CC-486	azacitidine	Celgene	DNA methylation inhibitor	Acute myeloid leukemia/ Myelodysplastic syndromes	PO	InTrial	Late 2020	Yes	Yes
Linhaliq	ciprofloxacin	Aradigm/ Grifols	fluoroquinolone	Non-cystic fibrosis bronchiectasis/ Cystic fibrosis	INH	CRL	Late 2020	Yes	Yes
MLN-4924 (TAK-92)	pevonedistat	Takeda	Nedd 8 Activating Enzyme (NAE) antagonist	Acute myeloid leukemia/ Chronic myelogenous leukemia/ Myelodysplastic syndrome	PO	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
BIVV-009 (TNT- 009)	sutimlimab	Sanofi	complement C1s subcomponent inhibitor	Cold agglutinin disease	IV	InTrial	Late 2020	Yes	Yes
Lucassin	terlipressin	Orphan Therapeutics/ Ikaria	V-1 (vasopressin) agonist	Hepato-renal syndrome	IV	CRL	Late 2020	Yes	Yes
iclaprim	iclaprim	Motif Bio	tetrahydrofolate dehydrogenase inhibitor	Bacterial infections	IV	CRL	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
SRP-4053	golodirsen	Sarepta	morpholino antisense oligonucleotide	Duchenne muscular dystrophy	IV	CRL	Late 2020	Yes	Yes
NS-2 (ALDX- 1E1, ALDX-1E2, ADX-102)	reproxalap	Aldeyra Therapeutics	aldehyde antagonist	Allergic conjunctivitis/ Dry eyes	OP	InTrial	Late 2020	No	No
Ryplazim	human plasminogen	ProMetic/ Hematech	plasminogen	Plasminogen deficiency	IV	CRL	Late 2020	Yes	Yes
OMS-721	narsoplimab	Omeros	anti-MASP-2 monoclonal antibody	Hematopoietic stem cell transplant- associated thrombotic microangiopathy	IV/SC	InTrial	Late 2020	Yes	Yes
Lenti-D	elivaldogene tavalentivec	Bluebird Bio	gene therapy	Cerebral adreno-myeloneuropathy	IV	InTrial	Late 2020	Yes	Yes
TG-1303	ublrituximab/ TGR- 1202	TG Therapeutics	CD-20 monoclonal antibody/ phosphoinositide-3 kinase (PI3K) delta inhibitor	Chronic lymphocytic leukemia/ Diffuse large B-cell lymphoma/ Non-Hodgkin lymphoma	IV/PO	InTrial	Late 2020	Yes	Yes
MVA-MUC1- IL2	TG-4010	Transgene	vaccine	Non-small cell lung cancer	SC	InTrial	Late 2020	No	No
SHP-621	budesonide	Shire	corticosteroid	Eosinophilic esophagitis	PO	InTrial	Late 2020	Yes	Yes
HuMax-TF ADC	tisotumab vedotin	Genmab/ Seattle Genetics	tissue factor antibody	Solid tumors	Undisclosed	InTrial	Late 2020	Yes	No
BMN-111	vosoritide (vasoritide)	BioMarin/ Chugai	C-type natriuretic peptide (CNP) analog	Achondroplasia	SC	InTrial	Late 2020	Yes	Yes
TSR-042	dostarlimab	AnaptysBio	PD-1 checkpoint inhibitor	Endometrial cancer	IV	InTrial	Late 2020	Yes	No
JZP-258	sodium oxybate extended-release	Jazz	dopamine receptor agonist	Narcolepsy	PO	InTrial	Late 2020	Yes	No
Translarna	ataluren	PTC Therapeutics	gene transcription modulator	Duchenne muscular dystrophy	PO	CRL	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
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 disease	INH	CRL	Late 2020	No	No
Oraxol	HM-30181A/ paclitaxel	Athenex	P-glycoprotein pump inhibitor/ taxane	Breast cancer	PO	InTrial	Late 2020	Yes	Yes
BIM-22493 (RM-493)	setmelanotide	Rhythm/ Camurus/ Ipsen	melanocortin 4 receptor (MC4R) agonist	Rare genetic disorders of obesity	SC	InTrial	Late 2020	Yes	Yes
RG-3477 (ACT- 128800)	ponesimod	Johnson & Johnson	sphingosine 1 phosphate receptor agonist	Multiple sclerosis	PO	InTrial	Late 2020	Yes	No
2021 Possible Launch Date									
ALNG-01 (ALN- G-01)	lumasiran	Alnylam	glycolate oxidase antagonist	Hyperoxaluria	Intranasal	InTrial	1Q2021	Yes	Yes
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
BIIB-037	aducanumab	Biogen Idec/ Eisai	amyloid beta-protein inhibitor	Alzheimer's disease	IV	InTrial	1Q2021	Yes	No
KX-01 (KX2- 391)	tirbanibulin	Athenex	Src kinase and tubulin inhibitor	Actinic keratosis	PO	InTrial	1Q2021	Yes	No
ZP-4207 (ZP- GA-1)	dasiglucagon	Zealand Pharma	glucagon analog	Diabetes mellitus	SC	InTrial	1Q2021	No	Yes
Furoscix	furosemide	scPharmaceuticals	diuretic	Heart failure	SC	CRL	1Q2021	Yes	No
SDP-037, SDN- 037	SDP-037, SDN-037	Sun Pharma Advanced Research Company (SPARC)	Corticosteroid	Ocular inflammation/pain	OP	InTrial	2Q2021	No	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
SCY-078	ibrexafungerp	Scynexis	glucan synthase inhibitors	Fungal infections	IV/PO	InTrial	1H2021	No	Yes
ACP-001	TransCon Growth Hormone	Ascendis	growth hormone prodrug	Short stature/ growth hormone deficiency	SC	InTrial	1H2021	Yes	No
RGN-259 (GBT- 201; RGN-352)	thymosin beta 4	RegeneRx	actin regulating peptide	Neurotrophic keratitis/ Dry eyes	OP	InTrial	1H2021	No	Yes
CM-AT	CM-AT	Curemark	protein absorption enhancer	Autism	PO	InTrial	1H2021	Yes	No
GFT-505	elafibranor	Genfit	selective peroxisome proliferator-activated receptor (PPAR) modulator	Non-alcoholic steatohepatitis/ Primary biliary cirrhosis	PO	InTrial	1H2021	Yes	No
NexoBrid	bromelain	MediWound/ BL&H/ CrystalGenomics/ Kaken	peptide hydrolase replacement agent	Burns/ Skin injury	TOP	InTrial	1H2021	No	Yes
PDR-001	PDR-001	Novartis	PD-1 checkpoint inhibitor	Melanoma	IV	InTrial	1H2021	Yes	No
CCX-168	avacopan	ChemoCentryx/ Galencia	C5a receptor (C5aR) antagonist	Vasculitis	PO	InTrial	1H2021	Yes	Yes
StrataGraft Skin Tissue	StrataGraft Skin Tissue	Mallinckrodt	autologous skin tissue	Burn injury	TOP	InTrial	1H2021	Yes	Yes
NPI-2358	plinabulin	BeyondSpring	tumor vascular disrupting agent	Neutropenia	IV	InTrial	1H2021	Yes	No
GZ-402665	olipudase alfa	Sanofi	sphingomyelinase	Niemann-Pick disease type B	IV	InTrial	Mid-2021	Yes	Yes
AT-132 (AAV8- MTM1)	AT-132 (AAV8- MTM1)	Audentes Therapeutics	gene therapy	X-linked myotubular myopathy	IV	InTrial	Mid-2021	Yes	Yes
GZ-402666 (NeoGAA)	avalglucosidase alfa	Sanofi	enzyme therapy	Pompe disease	IV	InTrial	Mid-2021	Yes	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
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 infection	IM	InTrial	Mid-2021	Yes	No
entinostat	entinostat	Syndax	histone deacetylase (HDAC) inhibitor	Breast cancer	PO	InTrial	Mid-2021	Yes	No
ADCT-402	loncastuximab tesirine	ADC Therapeutics	antibody drug conjugate	Diffuse large B-cell lymphoma	IV	InTrial	Mid-2021	Yes	Yes
TadFin	tadalafil and finasteride	Veru	phosphodiesterase type 5 inhibitor /5-alpha- reductase inhibitor	Benign prostatic hyperplasia	PO	InTrial	Mid-2021	No	No
AXS-07	meloxicam/rizatri ptan	Axsome Therapeutics	non-steroidal anti- inflammatory drug/triptan	Migraine	PO	InTrial	Mid-2021	No	No
ALN-APC (ALN- AT3)	fitusiran	Alnylam/ Sanofi	RNAi therapeutic	Hemophilia	SC	InTrial	Mid-2021	Yes	Yes
WVE-210201	suvodirsen	Wave Life Sciences	oligonucleotide	Duchenne muscular dystrophy	IV	InTrial	Mid-2021	Yes	Yes
PDP-716	brimonidine	Sun Pharma Advanced Research Company (SPARC)	alpha-2 agonist	Glaucoma	OP	InTrial	3Q2021	No	No
PRV-031	teplizumab	MacroGenics/ Provention Bio	CD3 antigen inhibitor	Diabetes mellitus	IV	InTrial	4Q2021	Yes	Yes
TBR-652	cenicriviroc	Tobira Therapeutics/ Takeda	C-C chemokine receptor 5 (CCR5) and receptor 2 antagonist	Non-alcoholic steatohepatitis	PO	InTrial	4Q2021	Yes	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
BXCL-501	dexmedetomidine	BioXcel Therapeutics	selective alpha 2a receptor agonist	Schizophrenia and bipolar disorder	PO	InTrial	2H2021	No	No
UCB-4940 (CDP-4940)	bimekizumab	UCB	interleukin-17 (IL-17) receptor inhibitor	Psoriasis/ Psoriatic arthritis/ Ankylosing spondylitis/ Rheumatoid arthritis	IV	InTrial	2H2021	Yes	No
¹⁷⁷ Lu-PSMA-617	Lutetium	Endocyte	Radiopharmaceutical	Prostate cancer	IV	InTrial	2H2021	Yes	No
OS-01	OC-01	Oyster Point Pharma	nicotinic acetylcholine receptor (nAChR) agonist	Dry eye disease	Intranasal	InTrial	2H2021	No	No
SHP-647	SHP-647	Shire	MAdCAM-1 antagonist	Irritable bowel disease	IV/SC	InTrial	2H2021	Yes	Yes
IDP-124	pimecrolimus	Bausch Health	calcineurin Inhibitor	Atopic dermatitis	TOP	InTrial	2H2021	No	No
glatiramer acetate depot	glatiramer acetate long-acting	Mylan/ Mapi Pharma	immunosuppressant	Multiple sclerosis	IM	InTrial	2H2021	Yes	No
KD-025	KD-025	Kadmon	ROCK2 (Rho-associated coiled-coiled kinase 2) inhibitor	Graft vs. Host disease	PO	InTrial	2H2021	No	Yes
AXS-05	dextromethorpha n/ bupropion	Axsome	N-methyl-D-aspartate (NMDA) antagonist	Treatment-resistant depression	PO	InTrial	2H2021	No	No
Otividex	dexamethasone sustained-release	Otonomy	corticosteroid	Meniere's disease	Intratympanic	InTrial	2H2021	Yes	No
MEDI-546	anifrolumab	AstraZeneca/ BMS	interferon receptor antagonist	Systemic lupus erythematosus	IV	InTrial	2H2021	Yes	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
LN-145	lifileucel	Iovance Biotherapeutics	tumor infiltrating lymphocyte	Cervical Cancer	IV	InTrial	2H2021	Yes	No
INP-104	POD-dihydroergotamine mesylate (POD-DHE)	Impel/ 3M	ergot derivative	Acute migraines	Intranasal	InTrial	2H2021	No	No
SPN-810	molindone	Supernus	atypical antipsychotic	Attention deficit hyperactivity disorder	PO	InTrial	2H2021	No	No
GS-010	GS-010	GenSight Biologics	gene therapy	Optic neuropathy	Intraocular	InTrial	2H2021	Yes	Yes
TWIN (S6G5T- 1; S6G5T-3)	benzoyl peroxide/ tretinoin	Sol-Gel Technologies	retinoid	Acne vulgaris	TOP	InTrial	2H2021	No	No
AMAG-423	digoxin immune fab (DIF)	AMAG/ Velo	digitalis-like factor antagonist	Preeclampsia	IV	InTrial	2H2021	Yes	Yes
CR-845	difelikefalin	Cara Therapeutics	opioid receptor agonist	Pruritus	IV/PO	InTrial	2H2021	No	No
pIL-12	tavokinogene tetsaplasmid	OncoSec Medical	gene therapy	Melanoma	Intratumoral	InTrial	2H2021	Yes	Yes
MD-1003	MD-1003	MedDay	biotin	Multiple sclerosis	PO	InTrial	2H2021	Yes	No
VBP-15	vamorolone	Santhera	corticosteroid	Duchenne muscular dystrophy	PO	InTrial	2H2021	Yes	Yes
ZYN-002	ZYN-002	Zynerba	cannabinoid product	Fragile X syndrome	TOP	InTrial	2H2021	Yes	Yes
PL-56	budesonide	Calliditas/ Kyowa Hakko Kirin	corticosteroid	Nephropathy	PO	InTrial	2H2021	No	No
dovitinib	dovitinib	Oncology Venture	fibroblast growth factor receptor 3 (FGFR3) inhibitor	Renal cell carcinoma	PO	InTrial	2H2021	Yes	No

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
Edsivo	celiprolol HCl	Acer Therapeutics	alpha-2/beta-1 adrenergic agent	vascular Ehlers-Danlos Syndrome	PO	CRL	2021	Yes	Yes
Tlando	testosterone	Lipocine	androgen	Hypogonadism	PO	CRL	2021	No	No
PRO-145223	etrolizumab	Genentech	IgG1 monoclonal antibody	Ulcerative colitis	SC	InTrial	2021	Yes	No
POL-6326	balixafortide	Polyphor	chemokine (CXCR4) antagonist	Transplant/ Breast cancer	IV	InTrial	2021	Yes	No
idebenone	idebenone	Santhera	co-enzyme Q-10 analog	Duchenne muscular dystrophy	PO	InTrial	2021	Yes	Yes
ABL-001	asciminib	Novartis	allosteric Bcr-Abl inhibitor	Chronic myelogenous leukemia	PO	InTrial	2021	Yes	Yes
PPP-002	PPP-002	Tetra Bio-Pharma	botanical drug	Pain	Undisclosed	InTrial	2021	No	No
Zynquista	sotagliflozin	Sanofi/ Lexicon	sodium-dependent glucose transporter 1 (SGLT-1) and SGLT-2 inhibitor	Diabetes mellitus	PO	CRL	2021	No	No
JNJ-3872 (VX- 787)	pimodivir	Johnson & Johnson/ Vertex	viral protein inhibitor	Influenza	PO	InTrial	2021	No	No
RG-7314 (RO- 5285119)	balovaptan	Roche	V1A vasopressin receptor antagonist	Autism spectrum disorder	PO	InTrial	2021	Yes	No
RG-6264	trastuzumab/ pertuzumab	Roche	HER2/neu receptor antagonist	Breast cancer	SC	InTrial	2021	Yes	No
IMO-2125	tilsotolimod	Idera	toll-like receptor 9 (TLR-9) agonist	Melanoma	SC/ intratumoral	InTrial	2021	Yes	Yes

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
ATI-5923	tecarfarin	ARYx Therapeutics/ Armetheon	vitamin K epoxide reductase enzyme inhibitor	Anticoagulation	PO	InTrial	2021	No	No
RG-7388 (RO- 5503781)	idasanutlin	Roche	MDM2 antagonist	Acute myelogenous leukemia	PO	InTrial	2021	Yes	No
CMX-001	brincidofovir hexadecyloxyprop yl ester	Chimerix	DNA-directed DNA polymerase inhibitor	Adenovirus/ Cytomegalovirus/ Smallpox	PO	InTrial	2021	No	Yes
LY-686017	tradipitant	Vanda Pharmaceuticals	neurokinin 1 receptor (NK-1R) antagonist	Motion sickness	PO	InTrial	2021	No	No
RG-7440	ipatasertib	Roche	pan-Akt inhibitor	Prostate cancer; breast cancer	PO	InTrial	2021	Yes	No
EMD-1214063	tepotinib	Merck	c-Met receptor tyrosine kinase inhibitor	Non-small cell lung cancer	PO	InTrial	2021	Yes	No
RTA-408	omaveloxolone	Reata Pharmaceuticals	Nrf2 activator	Friedreich's ataxia	PO	InTrial	2021	Yes	Yes
Recentin	cediranib	AstraZeneca	vascular endothelial growth factor receptor (VEGF) antagonists	Ovarian cancer	PO	InTrial	2021	Yes	Yes
MOD-401	somatrogon	OPKO Health/ Pfizer	enzyme replacement	Growth hormone deficiency	SC	InTrial	2021	Yes	Yes
DS-100	DS-100	Eton	undisclosed	Ophthalmological disease	SC	InTrial	2021	No	No
S5G4T-1 (DER- 45-EV)	benzoyl peroxide	Sol-Gel Technologies	benzoyl peroxide	Rosacea	TOP	InTrial	2021	No	No
OTL-101	ADA-transduced autologous stem cell therapy	Orchard Therapeutics	gene therapy	Adenosine deaminase-deficient severe combined immunodeficiency	Undisclosed	InTrial	2021	Yes	Yes

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
CAT-1004	edasalonexent	Catabasis	NF-kB inhibitor	Duchenne muscular dystrophy	PO	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
REGN-1500	evinacumab	Regeneron	angiopoietin-like 3 (ANGPTL3) antagonist	Hyperlipidemia	IV/SC	InTrial	Late 2021	Yes	No
AMT-061	etranacogene dezaparvovec	uniQure	gene therapy	Hemophilia B	IV	InTrial	Late 2021	Yes	No
PDS-1.0	ranibizumab	Roche/ Genentech	Anti-VEGF (vascular endothelial growth factor)	Wet age-related macular degeneration	Intravitreal implant	InTrial	Late 2021	Yes	No
Humacyl	human acellular vessel	Humacyte	cellular therapy	End-stage renal disease/ Peripheral artery disease	Implant	InTrial	Late 2021	Yes	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
MK-0594 (VPD- 737)	serlopitant	Menlo	NK-1 receptor antagonist	Pruritus	PO	InTrial	Late 2021	Yes	No
QAW-039 (NVP-QAW- 039)	fevipirant	Novartis	chemoattractant receptor-homologous molecule (CRTH2) antagonist	Asthma	PO	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
ADV-7103	tripotassium citrate monohydrate/ potassium hydrogen carbonate	Advicenne	Undisclosed	Distal renal tubular acidosis	PO	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
GSK-2696274 (OTL-200)	GSK-2696274 (OTL-200)	GlaxoSmithKline	gene therapy	Leukodystrophy	IV	InTrial	Late 2021	Yes	Yes
Ultomiris SC	ravulizumab-cwvz	Alexion	C5 complement inhibitor	paroxysmal nocturnal hemoglobinuria; Hemolytic uremic syndrome	SC	InTrial	Late 2021	Yes	Yes
PF-04965842	abrocitinib	Pfizer	janus kinase 1 (JAK-1) inhibitor	Atopic dermatitis	PO	InTrial	Late 2021	Yes	No
COR-003	levoketoconazole	Strongbridge	azole antifungal	Cushing's syndrome	PO	InTrial	Late 2021	No	Yes
AKB-6548	vadadustat	Akebia Therapeutics	hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor	Anemia	PO	InTrial	Late 2021	Yes	No

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