

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>									
AMG-5041-1	glucagon	Eli Lilly	glucagon analog	Diabetes mellitus	Intranasal	Filed NDA	5/2019	N	N
Zolgensma	onasemnogene abeparvovec	Novartis/ AveXis	gene therapy	Spinal muscular atrophy	IV	Filed BLA	5/2019	Y	Y
NKTR-181	NKTR-181	Nektar	opioid agonist	Pain	PO	Filed NDA	5/28/2019	N	N
BYL-719	alpelisib	Novartis	phosphoinositide 3- kinase CA (PIK3CA) inhibitor	Breast cancer	PO	Filed NDA	5/31/2019	Y	N
XeriSol Glucagon	glucagon	Xeris	glucagon analog	Diabetes mellitus	SC	Filed NDA	6/10/2019	N	N
GSP-301	mometasone furoate/ olopatadine HCl	Glenmark	corticosteroid/ antihistamine	Allergic rhinitis	Intranasal	Filed NDA	6/21/2019	N	N
Edsivo	celiprolol HCl	Acer Therapeutics	alpha-2/beta-1 adrenergic agent	vascular Ehlers-Danlos Syndrome	PO	Filed NDA	6/25/2019	Y	Y
Thiola	tiopronin	Retrophin	reducing agent	Cystinuria	PO	Filed NDA	6/30/2019	N	N
Ryplazim	human plasminogen	ProMetic/ Hematech	plasminogen	Plasminogen deficiency	IV	Filed BLA	Mid-2019	Y	Y
tadalafil VersaFilm	tadalafil	IntelGenx	phosphodiesterase-5 (PDE-5) inhibitor	Erectile dysfunction	PO	Filed NDA	Mid-2019	Y	N
NRL-1	diazepam	Neurelis	benzodiazepine	Seizures	Intranasal	Filed NDA	2H2019	N	Y
Fasenra (self-administered)	benralizumab	AstraZeneca	interleukin-5 (IL-5) inhibitor	Asthma	SC	Filed sNDA	2H2019	Y	N
Nucala (self-administered)	mepolizumab	GlaxoSmithKline	interleukin-5 (IL-5) inhibitor	Asthma	SC	Filed sNDA	3Q2019	Y	N

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Bronchitol	mannitol	Pharmaxis	osmotic gradient enhancer; mucus clearance enhancer	Cystic fibrosis	INH	Filed NDA	3Q2019	N	Y
KPT-330	selinexor	Karyopharm Therapeutics	selective inhibitor of nuclear export	Multiple myeloma	PO	Filed NDA	7/6/2019	Y	Y
Scenesse	afamelanotide	Clinuvel	melanocortin receptor 1 agonist	Erythropoietic protoporphyria	SC	Filed NDA	7/8/2019	Y	Y
MK-7655	relebactam/ imipenem/ cilastatin	Merck	beta-lactamase inhibitor/ carbapenem/ dehydropeptidase-1	Bacterial infections	IV	Filed NDA	7/16/2019	Y	N
BHV-0223	riluzole	Biohaven	glutamate release inhibitor	Amyotrophic lateral sclerosis	SL	Filed NDA	7/21/2019	N	Y
Feraccru	ferric trimaltol	Shield Therapeutics	iron replacement	Anemia	PO	Filed NDA	7/27/2019	N	N
Wakix	pitolisant	Harmony Biosciences	inverse histamine H-3 receptor antagonist	Narcolepsy	PO	Filed NDA	8/1/2019	N	N
PLX108-01	pexidartinib	Daiichi Sankyo	selective macrophage colony stimulating factor 1 receptor inhibitor	Tenosynovial giant cell tumor	PO	Filed NDA	8/3/2019	N	Y
S-649266	cefiderocol	Shionogi/ GlaxoSmithKline	cephalosporin antibiotic	Bacterial infections	IV	Filed NDA	8/14/2019	Y	N
KPI-121 0.25%	loteprednol etabonate	Kala	corticosteroid	Dry eyes	OP	Filed NDA	8/15/2019	N	N
entrectinib	entrectinib	Roche	tyrosine kinase inhibitor	Non-small cell lung cancer/ solid tumors	PO	Filed NDA	8/18/2019	N	Y
BC-3781	lefamulin	Nabriva Therapeutics	pleuromutilins	Bacterial infections	IV/PO	Filed NDA	8/19/2019	Y	N
SRP-4053	golodirsen	Sarepta	morpholino antisense oligonucleotide	Duchenne muscular dystrophy	IV	Filed NDA	8/19/2019	Y	N
anti-CD79b	polatuzumab vedotin	Genentech/ Roche	microtubule disrupting agent	Diffuse large B-cell lymphoma	IV	Filed BLA	8/19/2019	Y	Y
ABT-494	upadacitinib	AbbVie	janus associated kinase (JAK) inhibitor	Rheumatoid arthritis	PO	Filed NDA	8/20/2019	N	N
quizartinib	quizartinib	Daiichi Sankyo	FLT-3 receptor tyrosine kinase inhibitor	Acute myeloid leukemia	PO	Filed NDA	8/25/2019	Y	Y

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Nouriast	istradefylline	Kyowa Hakko Kogyo	A2A adenosine receptor antagonist	Parkinson's disease	PO	Filed NDA	8/27/2019	N	N
Rexista XR	oxycodone ER	IntelliPharmaCeutics	opioid agonist	Pain	PO	Filed NDA	8/28/2019	N	N
PA-824	pretomanid	TB Alliance	nitroimidazole	Tuberculosis	PO	Filed NDA	9/1/2019	Y	Y
TG-101348	fedratinib	Impact Biomedicines	janus kinase 2 (JAK-2) inhibitor	Myelofibrosis	PO	Filed NDA	9/3/2019	Y	N
RDX-5791	tenapanor	Ardelyx	sodium-hydrogen exchanger-3 (NHE-3)	Irritable bowel syndrome	PO	Filed NDA	9/13/2019	N	N
Imvamune	Imvamune; MVA- BN	Bavarian Nordic	vaccine	Smallpox	SC	Filed BLA	9/15/2019	Y	N
NN-9924	semaglutide (oral)	Novo Nordisk	glucagon-like peptide-1 (GLP-1) receptor agonist	Diabetes mellitus	PO	Filed NDA	9/20/2019	Y	N
ITI-007	lumateperone	Intra-Cellular Therapies	antipsychotic	Schizophrenia	PO	Filed NDA	9/27/2019	N	N
Posidur	bupivacaine CR	Novartis/ Durect	local anesthetic	Pain	SC	CRL	4Q2019	N	N
MitoGel	mitomycin C	UroGen	alkylating agent	Bladder cancer	Intravesical	FastTrk/ Breakthru	4Q2019	N	Y
HP-3070	asenapine maleate	Noven Hisamitsu Pharmaceutical	5-HT2a and dopamine D1/D2 antagonist	Schizophrenia	TOP	Filed NDA	4Q2019	N	N
Xyrosa	doxycycline	Sun Pharma	tetracyclines	Rosacea	PO	Tentative Approval	4Q2019	N	N
PF-708	teriparatide	Pfenex/ Alvogen	parathyroid hormone	Osteoporosis	SC	Filed NDA	10/7/2019	Y	N
ALKS-8700 (RDC-1559)	monomethyl fumarate (diroximel fumarate)	Biogen/ Alkermes	prodrug	Multiple sclerosis	PO	Filed NDA	10/17/2019	Y	N
CLS-1001	triamcinolone acetonide	Clearside Biomedical	corticosteroid	Macular edema	Intraocular/ subretinal	Filed NDA	10/19/2019	Y	N
synthetic ACTH depot	cosyntropin	Assertio	adrenocorticotrophic hormone (ACTH)	adrenocortical insufficiency	INJ	Filed NDA	10/19/2019	Y	N
FMX-101	minocycline	Foamix	tetracyclines	Acne vulgaris	TOP	Filed NDA	10/20/2019	N	N
ODM-201	darolutamide	Bayer/ Orion	androgen receptor agonist	Prostate cancer	PO	Filed NDA	10/27/2019	Y	N
JDP-205	cetirizine	JDP Therapeutics	second generation antihistamine	Urticaria	IV	Filed NDA	10/30/2019	N	N
Naloxone Symject	naloxone	Adamis	opioid antagonist	Opioid dependence	IM	Filed NDA	10/31/2019	N	N
RediTrex	methotrexate	Cumberland	dihydrofolate reductase inhibitor	Psoriasis; arthritis	SC	Filed NDA	11/1/2019	Y	N
LY-573144	lasmiditan	Eli Lilly	serotonin 5-HT1F receptor agonist	Acute migraines	PO	Filed NDA	11/14/2019	Y	N

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RTH-258	brolocizumab	Novartis	anti-VEGF antibody	Neovascular age- related macular degeneration	Intravitreal	Filed BLA	11/15/2019	Y	N
YKP-3089	cenobamate	SK Biopharmaceuticals	undisclosed	Seizure	PO	Filed NDA	11/21/2019	Y	N
AQST-117	riluzole	Aquestive Therapeutics	glutamate release inhibitor	Amyotrophic lateral sclerosis	SL	Filed NDA	11/30/2019	N	Y
MK-1602 (AGN- 241689)	ubrogepant	Allergan	calcitonin gene-related peptide (CGRP) receptor antagonist	Acute migraines	PO	Filed NDA	12/15/2019	Y	N
EM-100	ketotifen	Eton	undisclosed	Allergic conjunctivitis	OP	Filed NDA	12/19/2019	N	N
E-2006	lemborexant	Eisai/ Purdue	orexin receptor antagonist	Insomnia	PO	Filed NDA	12/27/2019	N	N
TRV-130	oliceridine	Trevena	opioid receptor agonist	Pain	IV	CRL	Late 2019	N	N
Twirla	ethinyl estradiol/ levonorgestrel	Agile Therapeutics	hormonal combination contraceptive	Pregnancy prevention	TOP	CRL	Late 2019	N	N
Zalviso	sufentanil	AcelRx	opioid analgesic	Pain	SL	CRL	Late 2019	Y	N
IMMU-132	sacituzumab govitecan	Immunomedics	RS7-SN-38 antibody- drug conjugate	Breast cancer	IV	CRL	Late 2019	Y	Y
Tlando	testosterone	Lipocine	androgen	Hypogonadism	PO	CRL	Late 2019	N	N
aldoxorubicin	aldoxorubicin	CytRx	anthracycline derivative	Soft tissue sarcoma	IV	InTrial	Late 2019	Y	Y
Talicia	rifabutin/ amoxicillin/ pantoprazole	RedHill Biopharma	RNA polymerase inhibitor/ penicillin/ proton pump inhibitor (PPI)	Bacterial infections	PO	FastTrk/ Breakthru	Late 2019	N	N
PRO-140	leronlimab	CytoDyn	C-C chemokine receptor 5 (CCR5) antagonist	HIV/ Graft vs. host disease	IV/SC	FastTrk/ Breakthru	Late 2019	Y	Y

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ELI-200	oxycodone/ naltrexone	Elite	opioid agonist	Pain	PO	CRL	Late 2019	N	N
APL-130277	apomorphine	Sumitomo Dainippon/ MonoSol Rx/ Sunovion	non-ergoline dopamine agonist	Parkinson's disease	SL	CRL	Late 2019	N	N
AP-1007	alicaforsen	Atlantic Healthcare/ Ionis	intercellular adhesion molecule-1 (ICAM-1) inhibitor	Ulcerative colitis	IV/Rectal	Filed NDA	Late 2019	Y	Y
OMS-721	narsoplimab	Omeros	anti-MASP-2 monoclonal antibody	Hemolytic uremic syndrome/Renal diseases	IV/SC	FastTrk/ Breakthru	Late 2019	Y	Y
tamsulosin DRS	tamsulosin delayed-release	Veru	alpha-adrenergic antagonist	Benign prostatic hyperplasia	PO	InTrial	Late 2019	N	N
CCP-08	CCP-08	Tris Pharma	undisclosed	Viral rhinitis	PO	CRL	Late 2019	Y	N
Betalutin	<sup>177</sup> Lu-tetraxetan-tetulumab	Nordic Nanovector	anti-CD37 antibody radionuclide	Non-Hodgkin lymphoma	IV	FastTrk/ Breakthru	Late 2019	Y	Y
<b>2020 Possible launch date</b>									
AR-101	AR-101	Aimmune/ Regeneron/ Sanofi	peanut protein capsule	Peanut allergy	PO	Filed BLA	1/2020	N	N
Rykindo	risperidone ER	Luye	atypical antipsychotic	Schizophrenia/ Schizoaffective disorder	IM	Filed NDA	1/28/2020	Y	N
FP-001 (LMIS)	leuprolide mesylate	Foresee	gonadotropin-releasing hormone (GnRH) analog	Prostate cancer	SC	Filed NDA	1/29/2020	Y	N
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	4Q2019	Y	Y
ETC-1002	bempedoic acid	Esperion Therapeutics	ATP citrate (pro-S)- lyase and stimulating AMP-activated protein kinase (AMPK)	Hypercholesterolemia	PO	Filed NDA	2/20/2020	N	N
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	2/20/2020	N	N

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ALD-403	eptinezumab	Alder	calcitonin gene-related peptide (CGRP) receptor antagonist	Migraine prevention	IV/SC	Filed BLA	2/22/2020	N	N
CD-5789	trifarotene	Galderma	retinoid receptor agonist	Acne	TOP	Filed NDA	2/28/2020	N	N
ozanimod	ozanimod	Celgene	sphingosine 1-phosphate 1 (S1PR1) and 5 (S1PR5) receptor modulator	Multiple sclerosis/ Ulcerative colitis	PO	Filed NDA	3/25/2020	Y	N
RVT-802	RVT-802	Enzyvant	tissue-based therapy	DiGeorge syndrome	Undisclosed	Filed BLA	1Q2020	Y	Y
Prochymal	remestemcel-L	Mesoblast/ Osiris Therapeutics	mesenchymal stem cells	Graft vs. Host disease	IV	InTrial	1Q2020	Y	Y
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	Y	N
Trevyent	trevyent	SteadyMed	prostacyclin analog	Pulmonary arterial hypertension	SC	CRL	1Q2020	Y	Y
Corplex	donepezil transdermal system	Corium International	anticholinergic	Alzheimer's disease	TOP	InTrial	1Q2020	N	N
SEG-101	crizanlizumab	Novartis	P-selectin antagonist	Sickle cell disease	IV	FastTrk/ Breakthru	1Q2020	Y	Y
TG-1303	ublituximab/ 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	1Q2020	Y	Y
BMS-927711 (BHV-3000)	rimegepant sulfate	Portage Biotech/ Biohaven/ Bristol- Myers Squibb	calcitonin gene-related peptide (CGRP) receptor antagonist	Acute migraines	PO	InTrial	1Q2020	Y	N
ASG-22M6E (ASG-22CE, ASG-22ME)	enfortumab vedotin	Astellas/ Seattle Genetics	nectin-4 antagonist	Bladder cancer	IV	FastTrk/ Breakthru	1Q2020	Y	N
VX-445	VX-445	Vertex	cystic fibrosis transmembrane conductance regulator (CFTR) corrector	Cystic fibrosis	PO	FastTrk/ Breakthru	1Q2020	Y	N
PPP-002	PPP-002	Tetra Bio-Pharma	botanical drug	Pain	Undisclosed	InTrial	1Q2020	N	N
BLU-285	avapritinib	Blueprint Medicines	selective KIT and PDGFRA inhibitor	Gastrointestinal stromal tumors	PO	FastTrk/ Breakthru	1Q2020	Y	Y
ALN-AS1	givosiran	Alnylam	RNAi therapeutic agent	Porphyria	SC	FastTrk/ Breakthru	1Q2020	Y	Y
ACE-536 (RAP- 536)	luspatercept	Celgene	modified type II activin receptor recombinant fusion protein	Anemia	SC	Filed BLA	4/3/2020	Y	Y

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CNS-7056 (ONO-2745)	remimazolam	Cosmo/ Ono/ Paion/ Aries	benzodiazepine	Procedural sedation	IV	Filed NDA	4/5/2020	Y	N
TMC-278-LA	cabotegravir (long- acting)/ rilpivirine (long-acting)	ViiV Healthcare	HIV integrase inhibitor/ non-nucleoside reverse transcriptase inhibitor (NNRTI)	HIV	IM/SC	Filed NDA	4/28/2020	Y	N
Rizaport	rizatriptan	IntelGenx / Red Hill Biopharma	triptans	Acute migraines	PO	CRL	1H2020	N	N
Amphora	Amphora	Neothetics	spermicidal agent	Pregnancy prevention/ Bacterial infections	VG	CRL	1H2020	N	N
Apealea (Paclical)	paclitaxel	Oasmia	taxane	Ovarian cancer	IV	InTrial	1H2020	Y	Y
Brinavess (Kynapid)	vernakalant	Correvio	potassium channel blocker	Arrhythmia	IV	InTrial	1H2020	Y	N
IdeS	imlifidase	Hansa Medical	bacterial enzyme	Kidney transplant/ Thrombotic thrombocytopenic purpura/Goodpasture's disease	IV	FastTrk/ Breakthru	1H2020	Y	Y
Anti-VEGF DARPIn	abicipar pegol	Allergan	VEGF-A inhibitor	Age-related macular degeneration	Intravitreal	InTrial	1H2020	Y	N
ZEBOV	VS-EBOV (rVSV- EBOV; rVSV- ZEBOV-GP)	Merck/ NewLink Genetics	vaccine	Ebola	IM	Filed BLA	1H2020	Y	N
APD-421	amisulpride	Acacia	dopamine receptor antagonist	Nausea/ Vomiting	IV	CRL	1H2020	N	N
COR-003	levoketoconazole	Strongbridge Biopharma	azole antifungal	Cushing's syndrome	PO	InTrial	1H2020	N	Y
Traumakine	interferon-beta -1a	Faron/ Maruishi	interferon	Acute respiratory distress syndrome	IV	FastTrk/ Breakthru	1H2020	Y	N
Viaskin Peanut	Viaskin Peanut	DBV Technologies	immunotherapy	Peanut allergy	TOP	CRL	1H2020	N	N
PEGPH-20	pegvorhyaluronidas e alfa	Halozyme/ Nektar	hyaluronic acid	Pancreatic cancer/ Non-small cell lung cancer	IV	FastTrk/ Breakthru	1H2020	Y	Y
S-265744 LAP (S/GSK-1265744 LAP; GSK-744 LA)	cabotegravir (long- acting)	GlaxoSmithKline/ Pfizer/ Shionogi	HIV integrase inhibitor	HIV	SC	InTrial	1H2020	Y	N
PRX-102	alpha galactosidase (pegunigalsidase alfa)	Protalix	enzyme replacement	Fabry disease	IV	FastTrk/ Breakthru	1H2020	Y	N
Lenti-D	elivaldogene tavalentec	Bluebird Bio	gene therapy	Adrenomyeloneuropath y	Undisclosed	FastTrk/ Breakthru	1H2020	Y	Y
FT-218	sodium oxybate extended-release	Avadel	dopamine receptor agonist	Narcolepsy	PO	InTrial	1H2020	Y	N
ropeginterferon alfa-2b	ropeginterferon alfa-2b	PharmaEssentia/ AOP Orphan	interferon	Polycythemia vera/ Myelofibrosis/ Essential thrombocythemia	SC	InTrial	1H2020	Y	Y
Lentiglobin	lentiviral beta- globin gene transfer	Bluebird Bio	gene therapy	Sickle cell disease/ Beta thalassemia	IV	FastTrk/ Breakthru	1H2020	Y	Y

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RT-002	daxibotulinumtoxin A	Revance Therapeutics	botulinum toxins	Cosmetic/ Cervical dystonia/ Plantar fasciitis	IM	InTrial	1H2020	Y	Y
UX-007	triheptanoin	Ultragenyx/ Baylor Research Institute/ Uniquist	medium chain fatty acid	Glucose transport type 1 deficiency syndrome	PO	FastTrk/ Breakthru	1H2020	Y	Y
R-667 (RG-667)	palovarotene	Clementia/ Roche	selective retinoic acid receptor agonist (RAR-gamma)	Fibrodysplasia ossificans progressiva	PO	FastTrk/ Breakthru	1H2020	Y	Y
MC2-01 (MC- 201)	calcipotriene/ betamethasone	MC2 Therapeutics	vitamin D analog/ corticosteroid	Psoriasis	TOP	InTrial	1H2020	N	N
Winlevi/ Breezula	cortexolone 17alpha-propionate (CB-03-01)	Intrepid	androgen antagonist	Acne vulgaris/ alopecia	TOP	InTrial	1H2020	N	N
DS-8201	[fam-] trastuzumab deruxtecan	Daiichi Sankyo	HER2-targeting antibody-drug conjugate	Breast cancer	IV	FastTrk/ Breakthru	1H2020	Y	N
Darzalex	daratumumab (with recombinant human hyaluronidase)	Johnson & Johnson / Genmab	humanized anti-CD38 monoclonal antibody	Multiple myeloma/ Amyloidosis	SC	InTrial	1H2020	Y	Y
FG-4592 (ASP- 1517)	roxadustat	FibroGen/ Astellas/ AstraZeneca	hypoxia-inducible factor prolyl hydroxylase	Anemia	PO	InTrial	1H2020	Y	N
SA-237 (RG- 6168)	satralizumab	Roche/ Chugai	interleukin-6 (IL-6) monoclonal antibody	Neuromyelitis optica	SC	FastTrk/ Breakthru	1H2020	Y	Y
V-114	pneumococcal conjugate vaccine	Merck	vaccine	Bacterial infection	IM	FastTrk/ Breakthru	2Q2020	Y	N
KP-415	D-threo- methylphenidate controlled-release	KemPharm	CNS stimulant	Attention deficit hyperactivity disorder	PO	InTrial	2Q2020	N	N
BMN-270	valoctocogene roxaparvovec	BioMarin	gene therapy	Hemophilia	IV	FastTrk/ Breakthru	2Q2020	Y	Y
Bafiertam	monomethyl fumarate	Banner Life Sciences	prodrug	Multiple sclerosis	PO	Tentative Approval	6/20/2020	Y	N
ALKS-3831	olanzapine/ samidorphan	Alkermes	dopamine receptor antagonist/ opioid receptor antagonist	Schizophrenia/ Bipolar disorder	PO	InTrial	Mid-2020	N	N
EBP-994 (rEBP- 994)	lonafarnib	Eiger Biopharmaceuticals	prenylation inhibitor	Hepatitis D/ Hutchinson-Gilford Progeria Syndrome and progeroid laminopathies	PO	FastTrk/ Breakthru	Mid-2020	Y	Y
JCAR-017	lisocabtagene maraleucel	Juno/ Celgene	chimeric antigen receptor (CAR) T cell therapy	Diffuse large B-cell lymphoma/ Acute lymphocytic leukemia/ Follicular lymphoma/ Mantle cell lymphoma	IV	FastTrk/ Breakthru	Mid-2020	Y	Y



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GLPG-0634	filgotinib	Galapagos NV/ Gilead	janus associated kinase- 1 (JAK) inhibitor	Rheumatoid arthritis	PO	InTrial	Mid-2020	Y	N
idebenone	idebenone	Santhera	co-enzyme Q-10 analog	Duchenne muscular dystrophy	PO	CRL	Mid-2020	Y	Y
RV-001 (Roche- 1, R-1507)	teprotumumab	Horizon/ Chugai/ Roche/ Genmab	insulin-like growth factor 1 (IGF-1) receptor antagonist	Thyroid eye disease	IV	FastTrk/ Breakthru	Mid-2020	Y	Y
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	N	N
GBT-440 (GTx- 011)	voxelotor	Global Blood Therapeutics	hemoglobin modulator	Sickle cell anemia	PO	FastTrk/ Breakthru	Mid-2020	Y	Y
TGR-1202	umbralisib	TG Therapeutics/ Rhizen	phosphoinositide-3 kinase (PI3K) delta inhibitor	Diffuse large B-cell lymphoma/ Chronic lymphocytic leukemia	PO	FastTrk/ Breakthru	Mid-2020	Y	Y
SRP-4045	casimersen	Sarepta	morpholino antisense oligonucleotide	Duchenne muscular dystrophy	IV	InTrial	Mid-2020	Y	Y
RG-7916 (RO- 7034067)	Risdiplam	Roche/ PTC Therapeutics	SMN2 splicing modifier	Spinal muscular atrophy	PO	InTrial	Mid-2020	Y	Y
GSK-2857916	GSK-2857916	GlaxoSmithKline/ Seattle Genetics	anti-BCMA antibody- drug conjugate	Multiple myeloma	SC	FastTrk/ Breakthru	Mid-2020	Y	Y
TBR-652 (TAK- 652, CVC)	cenicriviroc	Tobira Therapeutics/ Takeda	C-C chemokine receptor 5 (CCR5) and receptor 2 antagonist	HIV/ Non-alcoholic steatohepatitis	PO	FastTrk/ Breakthru	3Q2020	Y	N
PPP-001	delta-9-tetrahydrocannabinol/ cannabidiol	PhytoPain Pharma	cannabinoid product	Pain	INH	InTrial	3Q2020	Y	Y
Libervant	diazepam	Aquestive Therapeutics	benzodiazepine	Seizures	SL	InTrial	2H2020	N	Y
BGB-3111	zanubrutinib	BeiGene	selective inhibitor of Bruton tyrosine kinase (BTK)	Waldenström's Macroglobulinemia/ Chronic lymphocytic leukemia	PO	FastTrk/ Breakthru	2H2020	Y	Y
selumetinib	selumetinib	AstraZeneca/ Array BioPharma	selective MEK kinase inhibitor	Uveal melanoma/ Thyroid cancer	PO	InTrial	2H2020	Y	Y
naloxone	naloxone	Insys Therapeutics	opioid antagonist	Opioid dependence	Intranasal	FastTrk/ Breakthru	2H2020	N	N
MEDI-546	anifrolumab	AstraZeneca/ BMS	interferon receptor antagonist	Systemic lupus erythematosus	IV	FastTrk/ Breakthru	2H2020	Y	N
NX-1207	fexapotide trifluate	Nymox	pro-apoptotic	Benign prostatic hyperplasia/ Prostate cancer	Intratumoral	InTrial	2H2020	Y	N

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Zeftera	ceftobiprole	Basilea	cephalosporin antibiotic	Bacterial infections	IV	FastTrk/ Breakthru	2H2020	Y	N
arimoclomol	arimoclomol	Orphazyme	cytoprotectives	Niemann-Pick Disease/ Sporadic Inclusion Body Myositis/ Amyotrophic lateral sclerosis	PO	FastTrk/ Breakthru	2H2020	Y	Y
Ongentys	opicapone	Neurocrine Biosciences/ Bial/ Ono	catechol-O- methyltransferase (COMT) inhibitor	Parkinson disease	PO	InTrial	2H2020	N	N
EGP-437	dexamethasone phosphate (iontophoretic)	EyeGate	corticosteroid	Uveitis	OP	InTrial	2H2020	Y	N
ZP-4207 (ZP- GA-1)	dasiglucagon	Zealand Pharma	glucagon analog	Diabetes mellitus	SC	InTrial	2H2020	N	Y
NexoBrid	bromelain	MediWound/ BL&H/ CrystalGenomics/ Kaken	peptide hydrolase replacement agent	Burns/ Skin injury	TOP	InTrial	2H2020	N	Y
PXT-3003	baclofen/ naltrexone/ sorbitol	Pharnext	gamma-aminobutyric acid (GABA)-ergic agonist/ opioid receptor antagonist/ sorbitol combination	Charcot-Marie Tooth disease	PO	FastTrk/ Breakthru	2H2020	N	Y
bimatoprost	bimatoprost	Allergan	prostaglandin agonist	Glaucoma	Implant	InTrial	2H2020	N/A	N
PRT-201	vonapanitase	Proteon Therapeutics	human elastase (recombinant)	End stage renal disease/ Peripheral artery disease/ Vascular access in hemodialysis	TOP	FastTrk/ Breakthru	2H2020	Y	Y
MGN-1703	lefitolimod	Mologen	Toll-like receptor 9 (TLR9) agonist	Colorectal cancer	SC	InTrial	2H2020	Y	N
Iomab-B	iodine I 131 monoclonal antibody BC8	Actinium	anti-CD45 monoclonal antibody	Acute myeloid leukemia/ Myelodysplastic syndrome	IV	InTrial	2H2020	Y	Y
AKB-6548	vadadustat	Akebia Therapeutics	hypoxia-inducible factor- prolyl hydroxylase (HIF- PH) inhibitor	Anemia	PO	InTrial	2H2020	Y	N
E-7438 (EPZ- 6438)	tazemetostat	Epizyme/ Eisai	methyltransferase EZH2 inhibitor	Solid tumors/ Diffuse large B-cell lymphoma/ Non- Hodgkin lymphoma	PO	FastTrk/ Breakthru	2H2020	Y	Y
NPI-2358	plinabulin	BeyondSpring	tumor vascular disrupting agent (tVDA)	Neutropenia/ Non-small cell lung cancer	IV	InTrial	2H2020	Y	N
Sci-B-Vac	hepatitis B vaccine	VBI Vaccines	vaccine	Hepatitis B	IM	InTrial	2H2020	N	N
INP-104	POD- dihydroergotamine mesylate	Impel/ 3M	ergot derivative	Acute migraines	Intranasal	InTrial	2H2020	N	N

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
INCB-54828	pemigatinib	Incyte	selective FGFR1/2/3 inhibitor	Biliary tract cancer	PO	InTrial	2H2020	Y	Y
FMX-103	minocycline	Foamix	tetracyclines	Rosacea	TOP	InTrial	2H2020	N	N
BMS-663068 (BMS-626529 prodrug)	fostemsavir (temsavir prodrug)	Bristol-Myers Squibb	HIV attachment inhibitor	HIV	PO	FastTrk/ Breakthru	2H2020	Y	N
BCX-7353	BCX-7353	BioCryst	kallikrein inhibitor	Hereditary angioedema	PO	FastTrk/ Breakthru	2H2020	Y	Y
IMGN-853 (M-9346A-sulfo- SPDB-DM4)	mirvetuximab soravtansine	ImmunoGen	folate receptor-1 antagonist	Ovarian cancer	IV	FastTrk/ Breakthru	2H2020	Y	Y
bb-2121	bb-2121	Celgene/ Bluebird Bio	chimeric antigen receptor (CAR) T cell therapy	Multiple myeloma/ Brain cancer	IV	InTrial	2H2020	Y	Y
LIQ-861	treprostinil	Liquidia Technologies	prostacyclin analog	Pulmonary arterial hypertension	INH	InTrial	2H2020	Y	N
Doria	risperidone	Laboratorios Farmacéuticos Rovi	atypical antipsychotic	Schizophrenia	IM	InTrial	2H2020	Y	N
LJPC-0118	LJPC-0118	La Jolla Pharmaceutical	protozoacide	Malaria	Undisclosed	FastTrk/ Breakthru	2H2020	N	N
Qtrypta	zolmitriptan	Zosano	triptans	Acute migraines	TOP	InTrial	4Q2020	N	N
MOR-208 (MOR-00208, XmAB-5574)	MOR-208 (MOR- 00208, XmAB-5574)	MorphoSys/ Xencor	CD-19 antagonist	Diffuse large B-cell lymphoma/ Acute lymphocytic leukemia/ Chronic lymphocytic leukemia	IV	FastTrk/ Breakthru	4Q2020	Y	Y
ALN-PCSSc (PCSK9si)	inclisiran	The Medicines Company/ Alnylam/ Arbutus Biopharma	proprotein convertase subtilisin/kexin 9 (PCSK-9) inhibitor	Hyperlipidemia	SC	InTrial	4Q2020	Y	Y
tramadol	tramadol	Avenue Therapeutics	opioid receptor agonist	Pain	IV	InTrial	4Q2020	N	N
AmnioFix	dehydrated human amnion/chorion membrane (dHACM)	MiMedx	amniotic tissue membrane	Plantar fasciitis/ Achilles tendonitis/ Osteoarthritis	INJ	InTrial	4Q2020	Y	N
Estelle	estetrol/ drospirenone	Mithra/ Fuji/ Zhejian Xianju	estrogen receptor agonist	Pregnancy prevention	PO/SL/ Transmucosal	InTrial	4Q2020	N	N
Infacort	hydrocortisone	Diurnal Group	corticosteroid	Adrenal insufficiency	PO	InTrial	4Q2020	N	Y
TAK-385	relugolix	Myovant Sciences/ Roivant Sciences/ Takeda	gonadotropin-releasing hormone (GnRH) receptor antagonist	Uterine fibroids/ Endometriosis/ Prostate cancer	PO	InTrial	4Q2020	Y	N
CAM-2038	buprenorphine	Camurus/ Braeburn	opioid receptor agonist (partial)	Opioid dependence/ Pain	SC	Tentative Approval	11/1/2020	Y	N
VivaGel	astodimer sodium	Starpharma	viral attachment inhibitor	Bacterial infections	VG	CRL	2020	N	N
JNJ-872 (VX- 787)	JNJ-872 (VX-787)	Johnson & Johnson/ Vertex	viral protein inhibitor	Influenza	PO	FastTrk/ Breakthru	2020	N	N
Sativex	nabiximols	GW Pharmaceuticals/ Otsuka	cannabinoid product	Multiple sclerosis/ Pain	SL/ SPR	FastTrk/ Breakthru	2020	N	N

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
USL-261	midazolam	UCB	benzodiazepine	Seizures	Intranasal	CRL	2020	N	Y
CM-AT	CM-AT	Curemark	protein absorption enhancer	Autism	PO	FastTrk/ Breakthru	2020	Y	N
Dexasite	dexamethasone	InSite Vision	corticosteroid	Blepharitis/ Ocular inflammation	TOP	InTrial	2020	N	N
EVK-001	metoclopramide	Evoke Pharma	antidopaminergics	Diabetic gastroparesis	Intranasal	CRL	2020	N	Y
Entyvio (SC formulation)	vedolizumab	Takeda	integrin receptor antagonist	Ulcerative colitis/ Crohn's disease	SC	InTrial	2020	Y	N
Multikine	Leukocyte Interleukin (CS-001P3)	CEL-SCI	immunomodulator	Head and Neck cancer/ Squamous cell carcinoma	SC	InTrial	2020	Y	Y
iclaprim	iclaprim	Motif Bio	tetrahydrofolate dehydrogenase inhibitor	Bacterial infections	IV	CRL	2020	Y	Y
tanezumab	tanezumab	Pfizer/ Eli Lilly	neurotrophic tyrosine kinase receptor type 1 (TrkA) antagonist (monoclonal antibody)	Osteoarthritis/ Pain	IV/SC	FastTrk/ Breakthru	2020	Y	N
ublrituximab (LFB-R603, TG20, TGTX- 1101, TG-1101, Utuxin)	ublrituximab	TG Therapeutics	CD-20 monoclonal antibody	Chronic lymphocytic leukemia/ Small cell lymphocytic lymphoma/ Mantle cell lymphoma/ Multiple sclerosis	IV	InTrial	2020	Y	Y
Fintepla	fenfluramine	Zogenix	serotonin receptor agonist	Dravet syndrome/ Lennox-Gastaut syndrome	PO	CRL	2020	Y	Y
Zynquista	sotagliflozin	Sanofi/ Lexicon	sodium-dependent glucose transporter 1 (SGLT-1) and SGLT-2 inhibitor	Diabetes mellitus	PO	CRL	2020	N	N
Deltyba	delamanid	Otsuka	mycolic acid biosynthesis inhibitor	Tuberculosis	PO	InTrial	2020	N	N
ND-0612L	levodopa/ carbidopa	NeuroDerm	dopamine precursor/ dopa-decarboxylase inhibitor	Parkinson's disease	SC	InTrial	2020	Y	N
ND-0612H	levodopa/ carbidopa	NeuroDerm	dopamine precursor/ dopa-decarboxylase inhibitor	Parkinson's disease	SC	InTrial	2020	Y	N
Pedmark (STS)	sodium thiosulfate	Fennec	reducing agent	Hearing loss	IV	FastTrk/ Breakthru	2020	Y	Y
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/ Asthma	INH	InTrial	2020	N	N

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
Tivopath (AV- 951, KRN-951, ASP-4130)	tivozanib	Aveo/ Astellas/ Kyowa Hakko Kirin	VEGF inhibitor	Renal cell cancer	PO	InTrial	2020	Y	N
LCI-699	osilodrostat	Novartis	aldosterone synthase inhibitor	Cushing's syndrome	PO	InTrial	2020	N	Y
Vicinium (VB-4- 845)	oportuzumab monatox	Eleven Biotherapeutics	anti-ECAM exotoxin A fusion protein	Bladder cancer	Intravesical	FastTrk/ Breakthru	2020	Y	N
N-1539	meloxicam	Recro Pharma/ Alkermes	nonsteroidal anti-inflammatory drug (NSAID)	Pain	IV	CRL	2020	Y	N
Contepo	fosfomycin	Nabriva Therapeutics	cell wall inhibitor	Bacterial infections	IV	CRL	2020	Y	N
GZ-402666 (NeoGAA)	neo-recombinant human acid alpha glucosidase	Sanofi	enzyme therapy	Pompe disease	IV	InTrial	2020	Y	N
ursodeoxycholic acid	ursodeoxycholic acid	Retrophin/ Asklepion	bile acid derivative	Primary biliary cirrhosis/cholangitits	PO	InTrial	2020	Y	N
HTX-011	bupivacaine/ meloxicam	Heron Therapeutics	anesthetic/ nonsteroidal anti-inflammatory Drug (NSAID)	Pain	Instillation	CRL	2020	N	N
APN-311	dinutuximab beta	EUSA/ Aperion/ Gen Ilac/ Medison/ Paladin	disialoganglioside	Neuroblastoma	SC	InTrial	2020	Y	Y
isatuximab	isatuximab	Sanofi/ ImmunoGen	CD38 antagonist	Multiple myeloma/ Acute lymphoblastic leukemia or lymphoblastic lymphoma	IV	InTrial	2020	Y	Y
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	FastTrk/ Breakthru	2020	Y	Y
QMF-149	indacaterol maleate/ mometasone furoate	Novartis/ Merck	long-acting beta 2 agonist/ corticosteroid	Asthma	INH	InTrial	2020	N	N
DS-200	DS-200	Eton	undisclosed	Ophthalmological disease	SC	InTrial	2020	unknown	N
DS-100	DS-100	Eton	undisclosed	Ophthalmological disease	SC	InTrial	2020	unknown	N
NNC-0195-0092 (NN-8640)	somapacitan	Novo Nordisk	recombinant human growth hormone (rhGH)	Short stature/ Growth hormone deficiency	SC	InTrial	2020	Y	N
MLN-4924 (TAK-92)	pevonedistat	Takeda	Nedd 8 Activating Enzyme (NAE) antagonist	Acute myeloid leukemia/ Chronic myelogenous leukemia/ Myelodysplastic syndrome	PO	InTrial	2020	Y	N
INCB-028060	capmatinib	Novartis/ Incyte	cMET inhibitor	Non-small cell lung cancer	PO	InTrial	2020	Y	N
MNK-812	oxycodone	Mallinckrodt	opioid agonist	Pain	PO	CRL	2020	N	N
APC-8000	tadalafil	Adamis	phosphodiesterase-5 (PDE-5) inhibitor	Erectile dysfunction	PO	CRL	2020	Y	N

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	PO	CRL	2020	N	N
Oralair Mites	dust mite peptide	Stallergenes/ Shionogi	vaccine	Dust mite allergic rhinitis	SL	InTrial	2020	Y	N
azacitidine	azacitidine	Celgene	DNA methylation inhibitor	Acute myeloid leukemia/ Myelodysplastic syndromes	PO	FastTrk/ Breakthru	Late 2020	Y	Y
Translarna	ataluren	PTC Therapeutics	gene transcription modulator	Duchenne muscular dystrophy	PO	CRL	Late 2020	Y	Y
GFT-505	elafibranor	Genfit	selective peroxisome proliferator-activated receptor (PPAR) modulator	Non-alcoholic steatohepatitis/ Primary biliary cirrhosis	PO	FastTrk/ Breakthru	Late 2020	N	N
MVA-MUC1-IL2	TG-4010	Transgene	vaccine	Non-small cell lung cancer	SC	FastTrk/ Breakthru	Late 2020	N	N
GRN-163L	imetelstat	Geron/ Johnson & Johnson	telomerase inhibitor	Myelofibrosis/ Myelodysplastic syndrome/ Acute myelogenous leukemia	IV	FastTrk/ Breakthru	Late 2020	Y	Y
Mycapssa (Octreolin)	octreotide	Chiasma	somatostatin analog	Acromegaly	PO	CRL	Late 2020	Y	Y
NS-2 (ALDX- 1E1, ALDX-1E2, ADX-102)	reproxalap	Aldeyra Therapeutics	aldehyde antagonist	Uveitis/ Allergic conjunctivitis/ Dry eyes	OP	InTrial	Late 2020	N	N
Linhaliq	ciprofloxacin	Grifols	fluoroquinolone	Non-cystic fibrosis bronchiectasis	INH	CRL	Late 2020	Y	Y
Lucassin	terlipressin	Orphan Therapeutics/ Ikaria	V-1 (vasopressin) agonist	Hepato-renal syndrome	IV	CRL	Late 2020	Y	Y
RSV-F (ResVax)	respiratory syncytial virus vaccine	Novavax	vaccine	Respiratory syncytial virus infection	IM	FastTrk/ Breakthru	Late 2020	Y	N
QAW-039 (NVP-QAW- 039)	fevipiprant	Novartis	chemoattractant receptor-homologous molecule (CRTH2) antagonist	Asthma/ Atopic dermatitis	PO	InTrial	Late 2020	Y	N
Molgradex	molgramostim	Savara	granulocyte macrophage-colony stimulating factor	Pulmonary alveolar proteinosis	INH	InTrial	Late 2020	Y	Y
SHP-621	budesonide	Shire	corticosteroid	Eosinophilic esophagitis	PO	FastTrk/ Breakthru	Late 2020	Y	Y
cannabidiol	cannabidiol	Insys Therapeutics	cannabinoid product	Seizures/ Prader-Willi	PO	FastTrk/ Breakthru	Late 2020	Y	N
skQ1	visomitin	Mitotech	plastoquinone derivative	Dry eyes	OP	InTrial	Late 2020	Y	N
SCY-078 (MK- 3118)	ibrexafungerp	Scynexis/ R-Pharm JSC/ Merck	glucan synthase inhibitors	Fungal infections	IV/PO	FastTrk/ Breakthru	Late 2020	N	Y
BIM-22493 (RM-493)	setmelanotide	Rhythm/ Camurus/ Ipsen	melanocortin 4 receptor (MC4R) agonist	Obesity/ Bardet-Biedl syndrome/ Prader-Willi syndrome	SC	FastTrk/ Breakthru	Late 2020	Y	Y
GSK-2696274 (OTL-200)	GSK-2696274 (OTL-200)	GlaxoSmithKline	gene therapy	Leukodystrophy	IV	InTrial	Late 2020	Y	Y

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
RE-024	fosmetpantotate	Retrophin	phosphopantothenate replacement therapy	Neurodegeneration	IV	FastTrk/ Breakthru	Late 2020	Y	Y
BMN-111	vosoritide (vasoritide)	BioMarin/ Chugai	C-type natriuretic peptide (CNP) analog	Achondroplasia	SC	InTrial	Late 2020	Y	Y
Furoscix	furosemide	scPharmaceuticals	diuretic	Heart failure	SC	CRL	Late 2020	Y	N
HuMax-TF ADC	tisotumab vedotin	Genmab/ Seattle Genetics	tissue factor antibody	Solid tumors	Undisclosed	InTrial	Late 2020	Y	N
MK-0594	serlopitant	Menlo	NK-1 receptor antagonist	Atopic dermatitis/ Cough	PO	FastTrk/ Breakthru	Late 2020	Y	N
LY-900014	LY-900014	Eli Lilly	insulins	Diabetes mellitus	SC	InTrial	Late 2020	N	N
<b>2021 Possible launch date</b>									
MK-4618 (KRP- 114V, RVT-901)	vibegron	Roivant Sciences/ Urovant/ Kissei/ Kyorin/ Merck	selective beta 3 adrenergic receptor agonist	Overactive bladder	PO	InTrial	1Q2021	N	N
ALNG-01 (ALN- G-01)	lumasiran	Alnylam	glycolate oxidase antagonist	Hyperoxaluria	Intranasal	InTrial	1Q2021	Y	Y
PDP-716	brimonidine	Sun Pharma Advanced Research Company (SPARC)	alpha-2 agonist	Glaucoma	OP	InTrial	1Q2021	N	N
RGN-259 (GBT- 201; RGN-352)	thymosin beta 4	Regenerx	actin regulating peptide	Neurotrophic keratitis/ Dry eyes	OP	InTrial	1H2021	N	Y
UCB-4940 (CDP-4940)	bimekizumab	UCB	interleukin-17 (IL-17) receptor inhibitor	Psoriasis/ Psoriatic arthritis/ Ankylosing spondylitis/ Rheumatoid arthritis	IV	InTrial	1H2021	Y	N
ACP-001	TransCon Growth Hormone	Ascendis	growth hormone prodrug	Short stature/ Growth hormone deficiency	SC	InTrial	1H2021	Y	N
CCX-168	avacopan	ChemoCentryx/ Galencia	C5a receptor (C5aR) antagonist	Vasculitis/ Glomerulopathy	PO	InTrial	1H2021	Y	Y
GSK-2894512 (WBI-1001)	tapinarof	GSK/ Celestial/ Roivant Sciences/ Welichem Biotech	therapeutic aryl hydrocarbon receptor modulating agent	Atopic dermatitis/ Psoriasis	TOP	InTrial	1H2021	Y	Y
SDP-037, SDN- 037	SDP-037, SDN-037	Sun Pharma	Corticosteroid	Ocular inflammation/pain	OP	InTrial	2Q2021	N	Y
BAY-1021189 (MK-1242)	vericiguat	Merck/ Bayer	guanylate cyclase stimulator	Heart failure	PO	InTrial	Mid-2021	Y	N
SPN-810	molindone	Supernus	atypical antipsychotic	Attention deficit hyperactivity disorder	PO	FastTrk/ Breakthru	2H2021	N	Y
GS-010	GS-010	GenSight Biologics	gene therapy	Optic neuropathy	Intraocular	InTrial	2H2021	Y	N
Otividex	dexamethasone sustained-release	Otonomy	corticosteroid	Meniere's disease	Intratympanic	InTrial	2H2021	Y	Y

Drug Name	Generic Name	Company	Drug Class	Therapeutic Use	Route of Administration	Regulatory Status	Estimated Release Date	Specialty Drug	Orphan Drug
DigiFab	digoxin immune fab	AMAG/ Velo	digitalis-like factor antagonist	Preeclampsia	IV	FastTrk/ Breakthru	2H2021	Y	Y
RG-7716 (RO- 6867461)	RG-7716 (RO- 6867461)	Roche/ Chugai	bispecific VEGF-A/ angiopoietin-2 antagonist	Macular degeneration	Intravitreal	InTrial	2H2021	Y	N
VBP-15	vamorolone	Santhera	corticosteroid	Duchenne muscular dystrophy	PO	FastTrk/ Breakthru	2H2021	Y	Y
CMX-001	brincidofovir hexadecyloxypropyl ester	Chimerix	DNA-directed DNA polymerase inhibitor	Adenovirus/ Cytomegalovirus/ Smallpox	PO	FastTrk/ Breakthru	2021	N	Y
Junovan	mifamurtide	Millenium	muramyl tripeptide phosphatidylethanolamine (MTP-PE)	Osteosarcoma	IV	InTrial	2021	Y	N
rivipansel	rivipansel	Pfizer/ GlycoMimetics	synthetic glycomimetic	Sickle cell	IV	FastTrk/ Breakthru	2021	Y	N
Luveniq	voclosporin	ILJIN	calcineurin inhibitor	Lupus nephritis/ Transplant rejection	PO	FastTrk/ Breakthru	2021	Y	Y
ATI-5923	tecarfarin	ARYx Therapeutics/ Armetheon	vitamin K epoxide reductase enzyme inhibitor	Anticoagulation	PO	InTrial	2021	N	Y
OSE-2101 (IDM-2101, EP-2101)	tedopi	OSE Pharma/ Takeda	vaccine	Non-small cell lung cancer	SC	InTrial	2021	Y	N
MD-1003	MD-1003	MedDay	biotin	Multiple sclerosis	PO	InTrial	2021	Y	Y
R-1658 (RG- 1658, JTT-705, RO-4607381)	dalcetrapib	DalCor/ Japan Tobacco/ Roche	cholesteryl ester transfer protein inhibitor	Acute coronary syndrome	PO	InTrial	2021	Y	Y
IMO-2125	tilsotolimod	Idera	toll-like receptor 9 (TLR-9) agonist	Melanoma	SC/ intratumoral	FastTrk/ Breakthru	2021	Y	N
AZD-6094 (HMPL-504)	savolitinib (volitinib)	AstraZeneca (Hutchison MediPharma)	c-Met receptor tyrosine kinase inhibitor	Renal cell cancer/ Non-small cell lung cancer	PO	InTrial	2021	Y	Y
CT-100	corticotrophin	Eton	adrenocorticotrophic hormone (ACTH)	Rheumatoid arthritis	INJ	InTrial	2021	Y	N
SHP-647 (PF- 00547659)	SHP-647 (PF- 00547659)	Shire	MAdCAM-1 antagonist	Irritable bowel disease/ Crohn's disease/ Ulcerative colitis	IV/SC	InTrial	2021	Y	Y
RG-7314 (RO- 5285119)	balovaptan	Roche	V1A vasopressin receptor antagonist	Autism spectrum disorder	PO	FastTrk/ Breakthru	2021	Y	N
ABL-001	asciminib	Novartis	allosteric Bcr-Abl inhibitor	Chronic myelogenous leukemia	PO	InTrial	2021	Y	N
POL-6326	balixafortide	Polyphor	chemokine (CXCR4) antagonist	Transplant/ Breast cancer	IV	InTrial	2021	Y	N
BMS-986089 (RG-6206)	BMS-986089 (RG- 6206)	Roche/ Bristol- Myers Squibb	anti-myostatin adnectin	Duchenne muscular dystrophy	SC	InTrial	2021	Y	N



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Luveniq	voclosporin	ILJIN	calcineurin inhibitor	Lupus nephritis/ Psoriasis/ Transplant rejection	PO	FastTrk/ Breakthru	2021	Y	Y
TWIN (S6G5T- 1; S6G5T-3)	benzoyl peroxide/ tretinoin	Sol-Gel Technologies	retinoid	Acne vulgaris	TOP	InTrial	2021	N	N
OTL-101	ADA-transduced autologous stem cell therapy	Orchard Therapeutics	gene therapy	Adenosine deaminase-deficient severe combined immunodeficiency	Undisclosed	FastTrk/ Breakthru	2021	Y	Y
gantenerumab	gantenerumab	Roche	beta-amyloid (Abeta) inhibitor	Alzheimer's disease	SC	InTrial	Late 2021	Y	N
ADXS-HPV (ADXS-11-001, Lm-LLO-E7, lovaxin C)	axalimogene filolisbac	Advaxis/ Biocon/ FusionVax/ Sorrento Therapeutics/ Taiwan Biotech	vaccine	Anal cancer/ Cervical cancer/ Head and neck cancer	IV	FastTrk/ Breakthru	Late 2021	Y	N
PW-4142 (T- 111)	nalbuphine ER	Trevi Therapeutics/ Endo	opioid agonist/ antagonist	Prurigo nodularis	PO	InTrial	Late 2021	N	N
Humacyl	human acellular vessel	Humacyte	cellular therapy	End-stage renal disease/ Peripheral artery disease	Implant	FastTrk/ Breakthru	Late 2021	Y	N
NNZ-2566	trofinetide	Neuren	insulin-like growth factor 1 (IGF-1) derivative	Rett syndrome/ Fragile X syndrome/ Brain injury	IV/PO	FastTrk/ Breakthru	Late 2021	Y	N
Chronocort	hydrocortisone modified-release	Diurnal Group	corticosteroid	Congenital adrenal hyperplasia	PO	InTrial	Late 2021	N	N
AMT-061	AMT-061	uniQure	coagulation Factor IX	Hemophilia B	IV	FastTrk/ Breakthru	Late 2021	Y	Y
PF-06482077	multivalent group B streptococcus vaccine	Pfizer	vaccine	Bacterial infection	IM	FastTrk/ Breakthru	Late 2021	Y	Y
Ultomiris SC	ravulizumab-cwvz	Alexion	C5 complement inhibitor	paroxysmal nocturnal hemoglobinuria/ Hemolytic uremic syndrome	SC	InTrial	Late 2021	Y	Y

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