

OptumRx brand pipeline forecast

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
2018 Possible launch date									
IVIG	IVIG	Prometic	immune globulin	Primary immunodeficiency	IV	InTrial	2018	Y	N
esketamine	esketamine	Janssen	NMDA receptor antagonist	Major depressive disorder (MDD)	Intranasal	FastTrk/ Breakthru	2018	N	N
SHP-621	budesonide	Shire	corticosteroid	Eosinophilic esophagitis	PO	FastTrk/ Breakthru	2018 - 2019	Y	Y
LR-769	eptacog beta	LFB SA	recombinant human Factor VIIa	Hemophilia	IV	Filed BLA	1Q2018	Y	N
Dextenza	dexamethasone sustained-release	Ocular Therapeutix	corticosteroid	Pain/ Allergic conjunctivitis	OP	CRL	1Q2018	N	N
Hydexor	promethazine/ hydrocodone/ acetaminophen	Charleston Laboratories	anti-emetic/ opioid/ analgesic	Nausea/ Vomiting/ Pain	PO	Filed NDA	1Q2018	N	N
Evosyal	botulinum toxin A	Alphaeon	botulinum toxins	Glabellar lines/ Spasticity	IM	Filed BLA	1Q2018	Y	N
RemoSynch	treprostinil	United Therapeutics	prostacyclin analog	Pulmonary arterial hypertension (PAH)	IV/SC	Filed NDA	1H2018	Y	Y
Remune	HIV-1 vaccine	Immune Response BioPharma	vaccine	HIV	IM	Filed BLA	1H2018	Y	Y
Dexycu	dexamethasone controlled-release	Icon Bioscience	corticosteroid	Ocular inflammation	Intraocular	Filed NDA	2/12/2018	N/A	N

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GS-9883/F/TAF	bictegravir/ emtricitabine/ tenofovir alafenamide	Gilead	HIV integrase inhibitors/ nucleoside reverse transcriptase inhibitors (NRTI)/ NRTI	Human immunodeficiency virus (HIV)	PO	Filed NDA	2/12/2018	Y	N
Plenvu	NER-1006	Norgine	polyethylene glycol-based preparation	Bowel preparation	PO	Filed NDA	2/13/2018	N	N
Makena	hydroxyprogesterone caproate	Lumara Health	progestin	Preterm labor	SC	Filed sNDA	2/14/2018	Y	Y
RayVa (Vitaros)	alprostadil	Actavis/ Apricus	prostaglandin (PG) receptor agonist	Erectile dysfunction	TOP	Filed NDA	2/17/2018	N	N
TBD	angiotensin II (synthetic human)	La Jolla Pharmaceutical	renin-angiotensin peptide agonist	Hypotension	IV	Filed NDA	2/28/2018	Y	N
ivacaftor/ tezacaftor	ivacaftor/ tezacaftor	Vertex	corrector ion channel modulator	Cystic fibrosis	PO	Filed NDA	2/28/2018	Y	Y
ZTlido	lidocaine	Scilex	sodium channel blocker	Postherpetic neuralgia (PHN)	TOP	Filed NDA	2/28/2018	N	N
Yonsa	abiraterone acetate	Churchill/ Iroko	tyrosine kinase inhibitor	Prostate cancer	PO	Filed NDA	3/19/2018	Y	N
Jatenzo	testosterone	Clarus Therapeutics	androgen	Hypogonadism	PO	Filed NDA	3/26/2018	N	N
tildrakizumab	tildrakizumab	Sun/ Almirall Prodesfarma/ Merck	interleukin-23 (IL-23) inhibitor	Psoriasis	SC	Filed BLA	2Q2018	Y	N
Zoptrex	zoptarelin doxorubicin	Aeterna Zentaris	anthracycline derivative	Endometrial cancer	IV	InTrial	2Q2018	Y	N
Iomab-B	iodine I 131 monoclonal antibody BC8	Actinium	anti-CD45 monoclonal antibody	Acute myeloid leukemia (AML)/ Myelodysplastic syndrome (MDS)	IV	InTrial	2Q2018	Y	Y
CCP-07	CCP-07	Vernalis/ Tris Pharma	undisclosed	Cough and cold	PO	CRL	2Q2018	N	N
CCP-08	CCP-08	Vernalis/ Tris Pharma	undisclosed	Viral rhinitis	PO	CRL	2Q2018	Y	N

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Protectan CBLB-502	entolimod	Cleveland BioLabs	TLR5 receptor modulator	Radiation poisoning/ Colorectal cancer	SC	FastTrk/ Breakthru	2Q2018	Y	Y
NBI-56418	elagolix	AbbVie/ Neurocrine Biosciences	gonadotropin-releasing hormone (GnRH) receptor antagonist	Endometriosis/ Menstrual bleeding	PO	Filed NDA	2Q2018	Y	N
JNJ-56021927	apalutamide	Janssen	androgen receptor antagonist	Prostate cancer	PO	Filed NDA	2Q2018	N	N
VersaFilm	rizatriptan	IntelGenx / Red Hill Biopharma	triptans	Acute migraines	PO	Filed NDA	2Q2018	N	N
Akynzeo	netupitant/ palonosetron	Helsinn Group/ Eisai	selective NK1 receptor antagonist/ 5-HT3 receptor antagonist	Nausea and vomiting (N/V)	IV	Filed sNDA	2Q2018	N	N
Ella	ulipristal acetate	Actavis (Allergan)	selective progesterone receptor modulator (SPRM)	Uterine bleeding	PO	Filed NDA	2Q2018	N	N
lofexidine	lofexidine	US WorldMeds/ STADA Arzneimittel	alpha-2 receptor agonist	Opioid dependence	PO	Filed NDA	2Q2018	N	N
TEV-48125	fremanezumab	Teva/ Otsuka	calcitonin gene-related peptide (CGRP) antagonist	Migaine prevention	SC	Filed BLA	2Q2018	Y	N
TNX-355	ibalizumab	Theratechnologies/ Biogen/ Roche/ TaiMed	viral entry inhibitor	Human immunodeficiency virus (HIV)	IM/IV/SC	Filed sBLA	4/3/2018	Y	Y
Ryplazim	human plasminogen	ProMetic/ Hematech	plasminogen	Plasminogen deficiency	IV	Filed BLA	4/14/2018	Y	Y
Tavalisse	fostamatinib	Rigel	oral SYK inhibitor	Immune thrombocytopenia	PO	Filed NDA	4/17/2018	Y	Y
KRN-23	burosumab	Ultragenyx/ Kyowa Hakko Kirin	fibroblast growth factor	Hypophosphatemia	IV/SC	Filed BLA	4/17/2018	Y	Y
lubiprostone	lubiprostone	Takeda/ Sucampo	chloride channel activator	Constipation	PO	Filed NDA	4/28/2018	N	N

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EB-178	solifenacin/ mirabegron	Astellas	muscarinic antagonist/ beta-3 adrenergic receptor agonist	Overactive bladder	PO	Filed sNDA	4/28/2018	N	N
Azedra (Ultratrace MIBG)	iobenguane (I-131)	Progenics	radiopharmaceuticals	Neuroendocrine tumors (NET)	IV	Filed NDA	4/30/2018	Y	Y
AndexXa	andexanet alfa	Portola/ Pfizer/ Bristol-Myers Squibb	recombinant Factor Xa inhibitor antidote	Reversal agent	IV	Filed NDA	5/4/2018	Y	N
Tlando	testosterone	Lipocine	androgen	Hypogonadism	PO	Filed NDA	5/8/2018	N	N
Aimovig	erenumab	Amgen	calcitonin gene-related peptide (CGRP) antagonist	Migraine prevention	SC	Filed BLA	5/17/2018	Y	N
Astagraf XL	tacrolimus (extended- release)	Astellas	immunosuppressant	Organ transplantation	PO	Filed sNDA	5/18/2018	Y	N
AKR-501	avatrombopag	Astellas/ Dova	thrombopoietin receptor agonist	Thrombocytopenia/ Immune thrombocytopenic purpura (ITP)	PO	Filed NDA	5/21/2018	Y	N
LuMeBlue	methylene blue	Cosmo	imaging dye	Colonoscopy	PO	Filed NDA	5/21/2018	N	N
N-1539	meloxicam	Recro Pharma/ Alkermes	nonsteroidal anti- inflammatory drug (NSAID)	Pain	IV	Filed NDA	5/26/2018	Y	N
Peg-Pal	pegvaliase	BioMarin	enzyme replacement	Phenylketonuria (PKU)	SC	Filed BLA	5/28/2018	Y	Y
TX-004HR, TX-12- 004HR	estradiol	TherapeuticsMD	estrogen receptor agonist	Vaginal atrophy	VG	Filed NDA	5/29/2018	N	N
Consensi	celecoxib/ amlodipine	Kitov	nonsteroidal anti- inflammatory drug (NSAID)/ calcium channel blocker (CCB)	Hypertension/ Osteoarthritis	PO	Filed NDA	5/31/2018	N	N
Tbria	salmon calcitonin (TAR01-201)	Tarsa/ Unigene Laboratories	osteoclast inhibitor	Osteoporosis	PO	Filed NDA	Mid-2018	N	N

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Multikine	Leukocyte Interleukin (CS-001P3)	CEL-SCI	immunomodulator	Head and Neck cancer/ Squamous cell carcinoma	SC	InTrial	Mid-2018	Y	Y
Evenity	romosozumab	Amgen	anti-sclerostin monoclonal antibody	Osteoporosis	SC	CRL	Mid-2018	Y	N
AGB-101	levetiracetam	AgeneBio	synaptic vesicle protein modulator	Alzheimer's disease	PO	InTrial	Mid-2018	N	N
S-649266	cefiderocol	Shionogi/ GlaxoSmithKiline	cephalosporin antibiotic	Bacterial infections	IV	InTrial	Mid-2018	Y	N
XaraColl	bupivacaine implant	Innocoll	sodium channel blocker	Pain	Implant	CRL	Mid-2018	Y	N
Xelpros	latanoprost	Sun Pharma Advanced Research Company (SPARC)	prostaglandin agonist	Glaucoma/ Ocular hypertension	OP	CRL	Mid-2018	N	N
Primatene HFA	epinephrine	Amphastar	catecholamine	Asthma	INH	CRL	Mid-2018	N	N
MDL	moxidectin	Medicines Development for Global Health	chloride channel agonist	Parasitic infections	PO	Filed NDA	Mid-2018	N	N
Olumiant	baricitinib	Eli Lilly/ Incyte	janus associated kinase 1/2 (JAK1/2) inhibitor	Rheumatoid arthritis/ Psoriasis/ Diabetic nephropathy	PO	Filed NDA	Mid-2018	Y	N
ITCA-650 (sustained release exenatide)	exenatide sustained-release	Intarcia/ Quintiles/ Servier	glucagon-like peptide-1 (GLP-1) receptor agonist	Diabetes mellitus	SC implant	CRL	2H2018	Y	N
Semprana	dihydroergotamine mesylate (DHE)	MAP Pharmaceuticals/ Allergan	dihydroergotamine	Acute migraines	INH	InTrial	2H2018	N	N
Proellex	telapristone acetate (CBD4124)	Repros/ Gedeon Richter	progesterone receptor antagonist	Uterine fibroids/ Endometriosis	PO	InTrial	2H2018	N	N
cadazolid	cadazolid	Actelion	quinolonyl-oxazolidinone	Clostridium difficile infection (CDI)	PO	FastTrk/ Breakthru	2H2018	N	Y

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LMTX	methylthioninum	Roche	apoptosis inhibitor	Alzheimer's disease/ Dementia	PO	InTrial	2H2018	N	Y
Dexasite	dexamethasone	InSite Vision	corticosteroid	Blepharitis/ Ocular inflammation	TOP	InTrial	2H2018	N	N
HyperAcute Lung	tergenpantucel-L (turgempumatucel-L, tergenpumatucel-L)	NewLink Genetics	immunotherapy	Non-small cell lung cancer (NSCLC)	IV	InTrial	2H2018	Y	N
NX-1207 (NYM-4805, REC 0482)	fexapotide triflutate	Nymox	pro-apoptotic	Benign prostatic hyperplasia (BPH)/ Prostate cancer	Intratumoral	InTrial	2H2018	Y	N
Zeftera	ceftobiprole	Basilea	cephalosporin antibiotic	Bacterial infections	IV	FastTrk/ Breakthru	2H2018	Y	N
Simdax	levosimendan	Tenax Therapeutics	calcium sensitizing phosphodiesterase inhibitor	Septic shock/ Heart failure/ Pulmonary arterial hypertension (PAH)/ Low cardiac output syndrome (LCOS)	IV	FastTrk/ Breakthru	2H2018	Y	N
COR-003	levoketoconazole	Cortendo	azole antifungal	Cushing's syndrome	PO	InTrial	2H2018	N	Y
tremelimumab	tremelimumab	AstraZeneca	cytotoxic T lymphocyte- associated antigen 4 (CTLA4) inhibitor	Head and neck cancer/ Solid tumors/ Mesothelioma/ Non-small cell lung cancer (NSCLC)	IV	InTrial	2H2018	Y	Y
CardiaPill	aspirin/ lisinopril/ simvastatin	CardioPharma	aspirin/ angiotensin converting enzyme inhibitor/ HMG Co-A reductase inhibitor	Cardiovascular disease	PO	InTrial	2H2018	N	N
DS-5565	mirogabalin	Daiichi Sankyo	gamma-aminobutyric acid (GABA)-ergic analog	Fibromyalgia/ Diabetic neuropathic pain (DNP)	PO	InTrial	2H2018	N	N
Cevira	hexaminolevulinate (hexyl aminolevulinate)	Photocure/ Ipsen/ Juno	heme precursor	Cervical cancer/ Bladder cancer (imaging)	Intravesical	InTrial	2H2018	Y	N

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IVIG-SN	human normal immunoglobulin G	Green Cross	immune globulin (IVIG)	Primary immunodeficiency	IV	CRL	2H2018	Y	N
TV-46763	hydrocodone bitartrate/ acetaminophen	Teva	opioid receptor agonist/ analgesic	Pain	PO	InTrial	2H2018	N	N
ZP-triptan	zolmitriptan	Zosano	triptans	Acute migraines	TOP	InTrial	2H2018	N	N
naloxone	naloxone	Amphastar	opioid antagonist	Opioid dependence	Intranasal	CRL	2H2018	N	N
tafenoquine	tafenoquine	GSK/MMV	apoptosis modulator	Malaria	PO	Filed NDA	2H2018	N	Y
PF-06463922	lorlatinib	Pfizer	tyrosine kinase inhibitor	Non-small cell lung cancer (NSCLC)	PO	Filed NDA	2H2018	Y	N
Nuplazid	pimavanserin	Acadia	5-HT-2A receptor agonist	Parkinson's disease (PD) psychosis	PO	InTrial	2H2018	Y	N
LX-4211	sotagliflozin	Sanofi/ Lexicon	sodium-dependent glucose transporter 1 (SGLT-1) and SGLT-2 inhibitor	Diabetes mellitus	PO	InTrial	2H2018	N	N
AMG-761 (KW-0761, KM-8761)	mogamulizumab	Kyowa Hakko Kirin	CCR-4 chemokine receptor antibody	Cutaneous T-cell lymphoma (CTCL)/ Adult T-cell leukemia-lymphoma (ATCL)	IV	Filed BLA	6/4/2018	Y	Y
IDP-118	tazarotene/ halobetasol	Valeant	retinoid/ corticosteroid	Psoriasis	TOP	Filed NDA	6/18/2018	N	N
Furoscix	furosemide	scPharmaceuticals	diuretic	Heart failure	SC	Filed NDA	6/23/2018	Y	N
plazomicin	plazomicin	Achaogen/ Ionis	next-generation aminoglycoside	Bacterial infections	IV	Filed NDA	6/25/2018	Y	N
Epidiolex	cannabidiol	GW Pharmaceuticals	cannabinoid product	Seizures	PO	Filed NDA	6/27/2018	Y	Y

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MEK-162	binimetinib	Array BioPharma/ Novartis	MEK inhibitor	Melanoma/ Fallopian tube cancer/ Ovarian cancer/ Peritoneal cancer/ Colorectal cancer	PO	Filed NDA	6/30/2018	Y	N
LGX-818	encorafenib	Array BioPharma/ Pierre Fabre Medicament	rapidly accelerated fibrosarcoma (RAF) inhibitor	Melanoma	PO	Filed NDA	6/30/2018	Y	Y
DRM-04B	glycopyrronium tosylate	Dermira	anticholinergic	Hyperhidrosis	TOP	Filed NDA	6/30/2018	N	N
ALNCD	aripiprazole lauroxil NanoCrystal Dispersion	Alkermes	antipsychotic	Schizophrenia	IV	Filed NDA	6/30/2018	Y	N
RBP-7000	risperidone	Indivior/ Reckitt Benckiser	atypical antipsychotic	Schizophrenia	SC	Filed NDA	3Q2018	Y	N
BAX-817	BAX-817	Baxter	factor VIIa stimulant	Hemophilia	IV	InTrial	3Q2018	Y	N
TPOXX	tecovirimat	SIGA Technologies/ PharmAthene	antiviral	Smallpox	IV/PO	Filed NDA	3Q2018	Y	Y
ALN-TTR02 (GENZ438027, SAR438027)	patisiran	Alnylam/ Ionis/ Sanofi/ Tekmira	RNAi therapeutic	Polyneuropathy	IV	Filed NDA	3Q2018	Y	Y
Galafold (Amigal, HGT-3310, AT-1001)	migalastat	Amicus/ GSK	alpha-galactosidase A enhancer	Fabry disease	PO	Filed NDA	3Q2018	Y	Y
AQST-120	clobazam	Aquestive Therapeutics	benzodiazepine	Seizures	PO	Filed NDA	3Q2018	N	N
AG-120 (AGI-5198)	ivosidenib	Agios/ Celgene	isocitrate dehydrogenase-1 (IDH-1) inhibitor	Acute myeloid leukemia (AML)/ Biliary tract cancer	PO	Filed NDA	3Q2018	Y	Y
SEP-225289 (DSP-225289, SEP-289)	dasotraline	Sumitomo Dainippon/ Sunovion	triple reuptake inhibitor	Attention deficit hyperactivity disorder (ADHD)/ Eating disorders	PO	Filed NDA	3Q2018	N	N
CLS-1003 (CLS-TA)	triamcinolone acetonide/ aflibercept	Clearside	corticosteroid	Uveitis	intraocular/ subretinal	InTrial	3Q2018	Y	N

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Stanate	stansporfin	InfaCare	heme oxygenase inhibitor	Hyperbilirubemia	IM	Filed NDA	3Q2018	Y	N
Symtuza	darunavir/ emtricitabine/ cobicistat/ tenofovir alafenamide	Janssen	protease inhibitor/ NRTI/ boosting agent/ NRTI	Human immunodeficiency virus (HIV)	PO	Filed NDA	3Q2018	Y	N
ALKS-5461	buprenorphine/ samidorphan	Alkermes	opioid receptor agonist (partial)/ opioid receptor antagonist	Major depressive disorder (MDD)	PO	Filed NDA	3Q2018	N	N
LY-2951742	galcanezumab	Eli Lilly/ Arteaus	calcitonin gene-related peptide (CGRP) antagonist	Migraine prevention/ Cluster headache prevention	SC	Filed BLA	3Q2018	Y	N
IONIS-TTRx (ISIS- TTRRx, ISIS-420915; GSK-2998728)	inotersen	Ionis	antisense RNA modulator	Transthyretin (TTR) amyloidosis/ Transthyretin (TTR) cardiomyopathy	SC	Filed NDA	7/6/2018	Y	Y
Numbrino	cocaine HCl	Lannett	anesthetic	Anesthesia	TOP	Filed NDA	7/21/2018	N	N
buprenorphine	buprenorphine	Insys Therapeutics	opioid receptor agonist (partial)	Pain	SL/ Transmucosal	Filed NDA	7/28/2018	N	N
Zenavod	doxycycline	Dr. Reddy's Laboratories	tetracyclines	Rosacea	PO	Tentative Approval	8/7/2018	N	N
Inveltys	loteprednol etabonate MPP	Kala	corticosteroid	Dry eyes/ Ocular inflammation	TOP	Filed NDA	8/24/2018	N	N
IDP-121	tretinoin	Valeant	retinoid	Acne vulgaris	TOP	Filed NDA	8/27/2018	N	N
ISIS 304801 (ISIS- APOCIII Rx)	volanesorsen	Ionis	antisense drug	Familial chylomicronemia syndrome (FCS)/ Lipodystrophy	SC	Filed NDA	8/30/2018	Y	Y
BAY94-9027	damoctocog alfa pegol	Bayer	anithemophilic factor	Hemophilia	IV	Filed BLA	8/31/2018	Y	N
ARQ-197	tivantinib	ArQule/ Daiichi Sankyo	c-Met receptor tyrosine kinase inhibitor	Hepatic cancer	PO	InTrial	4Q2018	Y	N

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Zemcolo (Aemcolo)	rifamycin	Cosmo/ Dr. Falk	DNA-dependent RNA polymerase inhibitor	Traveler's diarrhea	PO	FastTrk/ Breakthru	4Q2018	N	N
Remoxy	oxycodone	Pain Therapeutics	mu-opioid receptor agonist	Pain	PO	CRL	4Q2018	N	N
Zalviso	sufentanil, ARX-01	AcelRx	opioid analgesic	Pain	SL	CRL	4Q2018	Y	N
masitinib	masitinib	AB Science	protein tyrosine kinase inhibitor	Asthma/ GST/ Mastocytosis/ Multiple myeloma/ Prostate cancer/ Crohn's disease/ Multiple sclerosis/ Rheumatoid arthritis/ Pancreatic cancer/ Amyotrophic lateral sclerosis (ALS)	PO	InTrial	4Q2018	N	Y
ARX-04	sufentanil	AcelRx	opioid analgesic	Pain	SL	CRL	4Q2018	Y	N
VRS-317 (hGH-XTEN)	somavaratan	Versartis/ Amunix	growth hormone analog	Short stature/ Growth hormone deficiency	SC	InTrial	4Q2018	Y	Y
CAM-2038	buprenorphine	Camurus/ Braeburn	opioid receptor agonist (partial)	Opioid dependence/ Pain	SC	CRL	4Q2018	Y	N
AP-1007 (AP-1431; AP-1450; AP-1451; ISIS-2302)	alicaforfen	Atlantic Healthcare/ Ionis	intercellular adhesion molecule-1 (ICAM-1) inhibitor	Ulcerative colitis (UC)	IV/Rectal	Filed NDA	4Q2018	Y	Y
Seysara	sarecycline	Allergan/ Paratek	tetracyclines	Acne vulgaris	PO	Filed NDA	4Q2018	N	N
FMX-102 (FXFM-244)	minocycline	Foamix	tetracyclines	Impetigo	TOP	InTrial	4Q2018	N	N
FMX-101 (ARK-E021)	minocycline	Foamix	tetracyclines	Acne vulgaris/ Rosacea	TOP	InTrial	4Q2018	N	N
tadalafil VersaFilm	tadalafil VersaFilm	IntelGenx	phosphodiesterase-5 (PDE-5) inhibitor	Erectile dysfunction	PO	InTrial	4Q2018	Y	N

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Nestorone/ ethinyl estradiol	Nestorone/ ethinyl estradiol	Allergan	progestin/ estrogen receptor agonist	Pregnancy prevention	VG	Filed NDA	4Q2018	N	N
Inbrija	levodopa	Acorda	antiparkinson	Parkinson's disease	INH	Filed NDA	4Q2018	N	N
IDP-122	halobetasol propionate	Valeant	corticosteroid	Psoriasis	TOP	Filed NDA	4Q2018	N	N
tafenoquine	tafenoquine	60 degrees	apoptosis modulator	Malaria	PO	Filed NDA	4Q2018	N	N
Seciera (OTX-101)	cyclosporine	Auven Therapeutics	immunosuppressant	Dry eyes	TOP	Filed NDA	4Q2018	Y	N
TX-001HR (TX-12-001HR)	estradiol/ progesterone	TherapeuticsMD	estrogen receptor agonist/progesterone receptor agonist	Menopause	PO	Filed NDA	4Q2018	N	N
Sollpura	liprotamase (amylase/lipase/ protease) (ALTU-135)	Eli Lilly/ Anthera	pancreatic enzyme replacement therapy (PERT)	Exocrine pancreatic insufficiency (EPI)/ Low digestive enzymes	PO	CRL	4Q2018	N	Y
KPT-330	selinexor	Karyopharm Therapeutics	selective inhibitor of nuclear export (SINE)	Sarcoma/ Diffuse large B-cell lymphoma (DLBCL)/ Acute myeloid leukemia (AML)/ Multiple myeloma	PO	InTrial	4Q2018	Y	Y
APD-421	amisulpride	Acacia	dopamine receptor antagonist	Nausea/ Vomiting	IV	Filed NDA	10/5/2018	N	N
MK-1439A	doravirine/ lamivudine/ tenofovir disoproxil fumarate	Merck	non-nucleoside reverse transcriptase inhibitor (NNRTI)/ Nucleoside reverse transcriptase inhibitor (NRTI)/ NRTI	Human immunodeficiency virus (HIV)	PO	Filed NDA	10/23/2018	Y	N
MK-1439	doravirine	Merck	non-nucleoside reverse transcriptase inhibitor (NNRTI)	Human immunodeficiency virus (HIV)	PO	Filed NDA	10/23/2018	Y	N
TRV-130	oliceridine	Trevena	opioid receptor agonist	Pain	IV	Filed NDA	11/2/2018	N	N

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TD-4208 (GSK-1160724)	revefenacin	Theravance Biopharma/ Mylan	long-acting muscarinic antagonist (LAMA)	Chronic obstructive pulmonary disease (COPD)	INH	Filed NDA	11/13/2018	N	N
DX-2930	lanadelumab	Dyax	kallikrein inhibitor	Hereditary angioedema (HAE)	SC	FastTrk/ Breakthru	Late 2018	Y	Y
Scenesse	afamelanotide	Clinuvel	melanocortin receptor 1 (MC-1) agonist	Erythropoietic protoporphyria (EPP)/ Polymorphous light eruption (PLE/PMLE)/ Vitiligo	SC implant	Filed NDA	Late 2018	Y	Y
Ampion	aspartyl-alanyl diketopiperazine (DA-DKP)	Ampio Pharmaceuticals	immunomodulator	Osteoarthritis	Intra-articular	InTrial	Late 2018	Y	N
human plasminogen	human plasminogen	Kedrion	plasminogen	Plasminogen deficiency	TOP	InTrial	Late 2018	Y	Y
Durasert	fluocinolone acetonide	Alimera/ pSivida	corticosteroid	Posterior uveitis	INJ	Filed NDA	Late 2018	Y	N
BMN-673	talazoparib	Pfizer/ BioMarin	poly (ADP-ribose) polymerase (PARP) inhibitor	Breast cancer	PO	InTrial	Late 2018	Y	N
selumetinib	selumetinib	AstraZeneca/ Array BioPharma/ Cancer Research UK	selective MEK kinase inhibitor	Thyroid cancer/ Uveal melanoma	PO	InTrial	Late 2018	Y	Y
PF-00299804	dacomitinib	Pfizer	pan-HER inhibitor	Non-small cell lung cancer (NSCLC)	PO	InTrial	Late 2018	Y	N
sapacitabine	sapacitabine	Cyclacel / Daiichi Sankyo	antimetabolite	Acute myeloid leukemia (AML)/ Non-small cell lung cancer (NSCLC)	PO	InTrial	Late 2018	Y	Y
Adlumiz	anamorelin	Helsinn / Novo Nordisk	growth hormone secretagogue receptor (GHSR) agonist	Anorexia/ Cachexia (cancer-related)	PO	FastTrk/ Breakthru	Late 2018	Y	N

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CMX-001	brincidofovir hexadecyloxypropyl ester	Chimerix	DNA-directed DNA polymerase inhibitor	Adenovirus/ Cytomegalovirus (CMV)	PO	FastTrk/ Breakthru	Late 2018	N	N
CEM-101	solithromycin	Cempra	macrolide	Bacterial infections	IV/PO	CRL	Late 2018	N	N
BAY-41-6551	amikacin	Nektar/ Bayer	aminoglycoside	Bacterial infections	INH	FastTrk/ Breakthru	Late 2018	Y	N
Sativex	nabiximols	GW Pharmaceuticals/ Otsuka	cannabinoid product	Multiple sclerosis (MS)/ Pain	SL/ SPR	FastTrk/ Breakthru	Late 2018	N	N
Nerventra	laquinimod	Teva	immunomodulator	Multiple sclerosis/ Huntington's disease	PO	FastTrk/ Breakthru	Late 2018	Y	N
BAF-312	siponimod	Novartis	selective sphingosine-1 phosphate receptor agonist	Multiple sclerosis	PO	InTrial	Late 2018	Y	N
midazolam (USL-261)	midazolam (USL-261)	Upsher-Smith	benzodiazepine	Seizures	Intranasal	FastTrk/ Breakthru	Late 2018	N	Y
Nourias	istradefylline	Kyowa Hakko Kogyo/ Biovail	A2A adenosine receptor antagonist	Parkinson's disease	PO	CRL	Late 2018	N	N
CM-AT	CM-AT	Curemark	protein absorption enhancer	Autism	PO	FastTrk/ Breakthru	Late 2018	Y	N
RGN-259	thymosin beta 4	RegeneRx	actin regulating peptide	Neurotrophic keratitis (NK)/ Dry eyes	TOP	InTrial	Late 2018	N	Y
Bronchitol	mannitol	Pharmaxis	osmotic gradient enhancer; mucus clearance enhancer	Asthma/ Cystic fibrosis	INH	InTrial	Late 2018	N	Y
Duaklir	aclidinium/ formoterol	AstraZeneca/ Actavis/ Circassia	long-acting muscarinic acetylcholine receptor (mAChR) antagonist/long-acting beta 2 agonist (LAMA/LABA)	Chronic obstructive pulmonary disease (COPD)	INH	InTrial	Late 2018	N	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
quizartinib	quizartinib	Ambit Biosciences	FLT-3 receptor tyrosine kinase inhibitor	Acute myeloid leukemia (AML)	PO	InTrial	Late 2018	Y	N
moxetumomab pasudotox	moxetumomab pasudotox	MedImmune	CD22 antigen inhibitor	Hairy cell leukemia	IV	InTrial	Late 2018	Y	Y
Zybrestat	combretastatin A4 phosphate (fosbretabulin tromethamine)	OXiGENE	vascular targeting agent	Neuroendocrine tumors (NET)/ Glioma	IV	FastTrk/ Breakthru	Late 2018	Y	Y
Hepacid	ADI-PEG-20	Polaris	pegylated arginine deiminase	Hepatic cancer	IM	InTrial	Late 2018	Y	Y
Reolysin	pelareorep	Oncolytics Biotech	human reovirus	Head and Neck cancer/ Ovarian cancer/ Fallopian tube cancer/ Peritoneal cancer/ Breast cancer	IV/ intratumoral	FastTrk/ Breakthru	Late 2018	Y	Y
Apealea (Paclical)	paclitaxel	Oasmia	taxane	Ovarian cancer	IV	InTrial	Late 2018	Y	Y
Collategene	bepermingene perplasmid (AMG-0001)	AnGes / Mitsubishi Tanabe	angiogenesis	Peripheral artery disease (PAD)/ Critical Limb Ischemia (CLI)	IM	FastTrk/ Breakthru	Late 2018	Y	N
Reasanz	serelaxin (RLX-030)	Novartis	recombinant human relaxin (rhRlx) agonist	Heart failure	IV	InTrial	Late 2018	Y	N
somatropin	somatropin	Opko/ Pfizer	enzyme replacement	Growth hormone deficiency/ Small for gestational age (SGA)	SC	InTrial	Late 2018	Y	Y
DCVax-L, DCVax-Brain	glioblastoma multiforme vaccine	Northwest Biotherapeutics	vaccine	Glioblastoma	SC	InTrial	Late 2018	Y	Y
NeuVax	nelipepimut-S	Galena	vaccine	Breast cancer	intradermal	FastTrk/ Breakthru	Late 2018	Y	N
tertomotide	tertomotide	KAEL-GemVax	vaccine	Non-small cell lung cancer (NSCLC)/ Melanoma	Intradermal	InTrial	Late 2018	Y	N
aldoxorubicin	aldoxorubicin	CytRx	anthracycline derivative	Soft tissue sarcoma	IV	InTrial	Late 2018	Y	Y

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
ALIS	amikacin liposome inhalation suspension	Insmed	aminoglycoside	Bacterial infections	INH	FastTrk/ Breakthru	Late 2018	Y	Y
CAT-354	tralokinumab	AstraZeneca	interleukin-13 (IL-13) inhibitor	Asthma/ Atopic dermatitis	SC	InTrial	Late 2018	Y	N
Xeglyze	abametapir	Hatchtech	metalloprotease inhibitor	Lice	TOP	CRL	Late 2018	N	N
Fovista (E-10030; OAP-030)	pegpleranib sodium	Ophthotech/ Archemix/ Astellas/ Novartis	antiplatelet derived growth factor subunit B (PDGF-B) aptamer	Age-related macular degeneration (AMD)	Intravitreal	FastTrk/ Breakthru	Late 2018	Y	N
RI-002	RI-002	ADMA Biologics	immunoglobulin	Primary immunodeficiency/ Respiratory syncytial virus (RSV)/ Bacterial infections	IV	CRL	Late 2018	Y	N
PT-141	bremelanotide (bremelanotide)	Palatin	melanocortin type 4 receptor agonist	Female sexual disorder (FSD)	SC	InTrial	Late 2018	Y	N
BKM-120	buparlisib	Novartis	1 phosphatidylinositol 3 kinase inhibitor	Diffuse large B-cell lymphoma (DLBCL)/ Non-Hodgkin lymphoma (NHL)/ Mantle cell lymphoma (MCL)/ Breast cancer	PO	InTrial	Late 2018	Y	N
entrectinib	entrectinib	Ignyta	tyrosine kinase inhibitor	Non-small cell lung cancer (NSCLC)/ Colorectal cancer/ Solid tumors/ Neuroblastoma	PO	FastTrk/ Breakthru	Late 2018	N	Y
IPI-145	duvelisib	Verastem/ Infinity	phosphatidylinositol 3 kinase inhibitor	Chronic lymphocytic leukemia (CLL)/ Non-Hodgkin lymphoma (NHL)	PO	InTrial	Late 2018	N	Y
BI-655066 (ABBV-066)	risankizumab	Boehringer Ingelheim/ AbbVie	interleukin-23 (IL-23) inhibitor	Psoriasis/ Crohn's disease/ Ankylosing spondylitis/ Asthma	IV/SC	InTrial	Late 2018	Y	Y

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
MVA-MUC1-IL2	TG-4010	Transgene	vaccine	Non-small cell lung cancer (NSCLC)	SC	FastTrk/ Breakthru	Late 2018	N	N
SB-204 (NVN-1000)	SB-204 (NVN-1000)	Novan Therapeutics	nitric oxide-releasing compound	Acne vulgaris	TOP	InTrial	Late 2018	N	N
SAGE-547	allopregnanolone (brexanolone)	SAGE/ Ligand	gamma aminobutyric acid-A (GABA-A) receptor allosteric modulator	Seizures/ Postpartum depression	IV	FastTrk/ Breakthru	Late 2018	Y	Y
BC-3781	lefamulin	Nabriva Therapeutics	pleuromutilins	Bacterial infections	IV/PO	FastTrk/ Breakthru	Late 2018	Y	N
Delyba	delamanid	Otsuka	mycolic acid biosynthesis inhibitor	Tuberculosis	PO	InTrial	Late 2018	N	N
STS	sodium thiosulfate	Fennec	reducing agent	Hearing loss	IV	InTrial	Late 2018	Y	Y
GRN-163L	imetelstat	Geron/ Johnson & Johnson	telomerase inhibitor	Myelofibrosis (MF)/ Myelodysplastic syndrome (MDS)/ Acute myelogenous leukemia (AML)	IV	FastTrk/ Breakthru	Late 2018	Y	Y
Otividex	dexamethasone sustained-release	Otonomy	corticosteroid	Meniere's disease	Intratympanic	InTrial	Late 2018	Y	N
LCI-699	osilodrostat	Novartis	aldosterone synthase inhibitor	Cushing's syndrome	PO	InTrial	Late 2018	N	Y
ELI-200	oxycodone/ naltrexone	Elite	opioid agonist	Pain	PO	CRL	Late 2018	N	N
ELI-202	opioid (undisclosed)	Elite	opioid agonist	Pain	PO	InTrial	Late 2018	N	N
PTK-0796	omadacycline	Paratek	aminomethylcyclines	Bacterial infections	IV/PO	FastTrk/ Breakthru	Late 2018	N	N
Pollinex Quattro Grass	birch pollen allergen extract	Allergy Therapeutics/ Endo/ GSK/ Teva	vaccine	Allergic rhinitis	SC	InTrial	Late 2018	Y	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
PLX108-01 (PLX-3397)	pexidartinib	Daiichi Sankyo	selective macrophage colony stimulating factor 1 receptor inhibitor	Pigmented Villonodular Synovitis (PVNS)	PO	FastTrk/ Breakthru	Late 2018	N	Y
APL-130277	apomorphine	Sumitomo Dainippon/ MonoSol Rx/ Sunovion	non-ergoline dopamine agonist	Parkinson's disease	PO/SL	FastTrk/ Breakthru	Late 2018	N	N
PRX-102	alpha galactosidase (pegunigalsidase alfa)	Protalix	enzyme replacement	Fabry disease	IV	FastTrk/ Breakthru	Late 2018	Y	N
Zolyd	fosfomycin	Zavante Therapeutics	cell wall inhibitor	Bacterial infections	IV	FastTrk/ Breakthru	Late 2018	Y	N
ALX-0081	caplacizumab	Ablynx NV	anti-von Willebrand factor (vWF) nanobody	Thrombotic thrombocytopenic purpura (TTP)	IV/SC	FastTrk/ Breakthru	Late 2018	Y	Y
EZN-2285	calaspargase pegol	Shire	enzyme therapy	Acute lymphocytic leukemia (ALL)	IM/IV	InTrial	Late 2018	Y	N
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	Late 2018	N	N
GDC-0032	taselisib	Roche/ Chugai	PI3 Kinase Inhibitor	Breast cancer	PO	InTrial	Late 2018+	Y	N
FMX-103	minocycline	Foamix	tetracyclines	Rosacea	TOP	InTrial	Late 2018	N	N
ursodeoxycholic acid	ursodeoxycholic acid	Retrophin/ Asklepion	bile acid derivative	Primary biliary cirrhosis/cholangitits	PO	InTrial	Late 2018	Y	N
DFN-02 (DFP-02)	DFN-02 (DFP-02)	Dr. Reddy's Laboratories	triptans	Acute migraines	Intranasal	InTrial	Late 2018	N	N
tamsulosin DRS	tamsulosin DRS	Female Health/ Aspen	alpha-adrenergic antagonist	Benign prostatic hyperplasia (BPH)	PO	InTrial	Late 2018	N	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
AM-111 (D-JNK1-1, XG-102)	brimapitide	Xigen/ Auris Medical	JNK stress kinase inhibitor	Hearing loss/ Ocular inflammation	Intratympanic/ Intraocular	FastTrk/ Breakthru	Late 2018	Y	Y
ropeginterferon alfa-2b	ropeginterferon alfa-2b	PharmaEssentia/ AOP Orphan	interferon	Polycythemia vera (PV)/ Myelofibrosis (MF)/ Essential thrombocythemia (ET)	SC	InTrial	Late 2018	Y	Y
BYL-719	alpelisib	Novartis	phosphoinositide 3-kinase CA (PIK3CA) inhibitor	Breast cancer/ Head and neck cancer	PO	InTrial	Late 2018	Y	N
LOXO-101	larotrectinib	Loxo Oncology	tyrosine kinase inhibitor	Solid tumors/ Sarcoma	PO	FastTrk/ Breakthru	Late 2018	Y	Y
Rova-T	rovalpituzumab tesirine	AbbVie	anti-DLL3 monoclonal antibody	Small cell lung cancer (SCLC)	IV	InTrial	Late 2018	Y	Y
TGR-1202	TGR-1202	TG Therapeutics/ Rhizen	phosphoinositide-3 kinase (PI3K) delta inhibitor	Diffuse large B-cell lymphoma (DLBCL)/ Chronic lymphocytic leukemia (CLL)	PO	InTrial	Late 2018	Y	Y
SRP-4053	golodirsen	Sarepta	morpholino antisense oligonucleotide	Duchenne muscular dystrophy (DMD)	IV	InTrial	Late 2018	Y	N
S-888711	lusutrombopag	Shionogi	thrombopoietin receptor agonist	Thrombocytopenia	PO	Filed NDA	Late 2018	Y	N
GSP-301	mometasone furoate/ olopatadine HCl	Glenmark	corticosteroid/ antihistamine	Allergic rhinitis	NA	InTrial	Late 2018	N	N
BHV-4157	trigriluzole	Portage Biotech	glutamate release inhibitor	Spinocerebellar ataxia/ Obsessive-compulsive disorder (OCD)	PO	FastTrk/ Breakthru	Late 2018	Y	Y
RVT-802	RVT-802	Enzyvant	tissue-based therapy	DiGeorge syndrome	Undisclosed	FastTrk/ Breakthru	Late 2018	Y	Y
SEG-101	crizanlizumab	Novartis	P-selectin antagonist	Sickle cell disease	IV	InTrial	Late 2018	Y	Y
Oxervate	cengermin	Dompe	recombinant human nerve growth factor	Neurotrophic keratitis/ Dry eyes	Intraocular	Filed BLA	Late 2018	Y	Y

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
SC-411	docosahexaenoic acid	Sancilio	essential fatty acid conjugate	Sickle cell disease	PO	InTrial	Late 2018	Y	Y
Entyvio	vedolizumab	Takeda	integrin receptor antagonist	Ulcerative colitis (UC)/ Crohn's disease (CD)	SC	InTrial	Late 2018	Y	N
REGN-2810	cemiplimab	Regeneron/ Sanofi	programmed death ligand-1 (PD-L1) inhibitor	Non-small cell lung cancer (NSCLC)/ Cutaneous squamous cell carcinoma/ Basal cell carcinoma	IV	FastTrk/ Breakthru	Late 2018	Y	N
B-244	B-244	AOBiome	antibacterial	Acne	TOP	InTrial	Late 2018	Y	N
Wakix	tiprolisant (pitolisant)	Harmony Biosciences/ BioProject/ Grupo Ferrer	inverse histamine H-3 receptor antagonist	Narcolepsy/ Excessive daytime sleepiness/ Schizophrenia	PO	InTrial	Late 2018	N	N
EM-100	EM-100	Eton	undisclosed	Ophthalmological disease	SC	InTrial	Late 2018	Y	N
EN-3342	risperidone	Apple Tree/ Endo	atypical antipsychotic	Schizophrenia	SC	InTrial	Late 2018	Y	N
Otezla	apremilast	Celgene	phosphodiesterase-4 inhibitor	Psoriasis	PO	Filed sNDA	Late 2018	Y	N
lopinavir/ritonavir	lopinavir/ritonavir	Cipla	HIV-1 protease inhibitor/ CYP3A4 inhibitor	Human immunodeficiency virus (HIV)	PO	Tentative Approval	Late 2018	Y	N
ADX-N05	solriamfetol	Jazz Pharmaceuticals/ Aerial BioPharma	phenylalanine derivative	Narcolepsy/ Sleep apnea	PO	Filed NDA	Late 2018	N	Y
VivaGel	astodrimer sodium	Starpharma	viral attachment inhibitor	Bacterial infections	VG	Filed NDA	Late 2018	N	N
RPC-1063	ozanimod	Celgene	sphingosine 1-phosphate 1 (S1PR1) and 5 (S1PR5) receptor modulator	Multiple sclerosis/ Ulcerative colitis (UC)	PO	Filed NDA	Late 2018	Y	N
tenofovir disoproxyl fumarate/ lamivudine/ efavirenz	tenofovir disoproxyl fumarate/ lamivudine/ efavirenz	Hetero Labs	nucleoside reverse transcriptase inhibitor (NRTI)/ NRTI/ non-nucleoside reverse transcriptase inhibitor	Human immunodeficiency virus (HIV)	PO	Tentative Approval	Late 2018	Y	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
			(NNRTI)						
tenofovir disoproxyl fumarate/ lamivudine/ efavirenz	tenofovir disoproxyl fumarate/ lamivudine/ efavirenz	Matrix Labs	nucleoside reverse transcriptase inhibitor (NRTI)/ NRTI/ non-nucleoside reverse transcriptase inhibitor (NNRTI)	Human immunodeficiency virus (HIV)	PO	Tentative Approval	Late 2018	Y	N
tenofovir disoproxyl fumarate/ lamivudine/ efavirenz	tenofovir disoproxyl fumarate/ lamivudine/ efavirenz	Aurobindo	nucleoside reverse transcriptase inhibitor (NRTI)/ NRTI/ non-nucleoside reverse transcriptase inhibitor (NNRTI)	Human immunodeficiency virus (HIV)	PO	Tentative Approval	Late 2018	Y	N
tenofovir disoproxyl fumarate/ lamivudine/ efavirenz	tenofovir disoproxyl fumarate/ lamivudine/ efavirenz	Cipla	nucleoside reverse transcriptase inhibitor (NRTI)/ NRTI/ non-nucleoside reverse transcriptase inhibitor (NNRTI)	Human immunodeficiency virus (HIV)	PO	Tentative Approval	Late 2018	Y	N
tenofovir disoproxyl fumarate/ lamivudine/ efavirenz	tenofovir disoproxyl fumarate/ lamivudine/ efavirenz	Macleods	nucleoside reverse transcriptase inhibitor (NRTI)/ NRTI/ non-nucleoside reverse transcriptase inhibitor (NNRTI)	Human immunodeficiency virus (HIV)	PO	Tentative Approval	Late 2018	Y	N
2019 Possible launch date									
azacitidine	azacitidine	Celgene	DNA methylation inhibitor	Acute myeloid leukemia (AML)/ Myelodysplastic syndromes	PO	FastTrk/ Breakthru	2019	Y	Y
ALS-8176	lumicitabine	Johnson & Johnson	RSV polymerase inhibitor	Respiratory syncytial virus (RSV)	PO	InTrial	2019	N	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
JNJ-42756493 (JNJ-493)	erdafitinib	Johnson & Johnson/ Otsuka	pan-fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitor	Urothelial cancer	PO	InTrial	2019	Y	N
eravacycline	eravacycline	Tetraphase Pharmaceuticals	fully synthetic tetracycline antibiotic	Bacterial infections	IV/PO	Filed NDA	1Q2019	Y	N
EVK-001	metoclopramide	Evoke Pharma	antidopaminergics	Diabetic gastroparesis	Intranasal	InTrial	1Q2019	N	Y
Tonmya	cyclobenzaprine	Tonix/ Vela	muscle relaxant	Post-traumatic stress disorder (PTSD)	PO/SL/ Transmucosal	FastTrk/ Breakthru	1Q2019	N	N
Lotemax Gel Nex Gen	loteprednol etabonate	Valeant	corticosteroid	Ocular inflammation	TOP	InTrial	1Q2019	N	N
PW-4142 (T-111)	nalbuphine ER	Trevi Therapeutics/ Endo	opioid agonist/ antagonist	Prurigo nodularis	PO	InTrial	1Q2019	N	N
Roclatan	latanoprost/ netarsudil mesylate	Aerie	prostaglandin agonist/ rho kinase-norepinephrine transport protein inhibitor	Glaucoma/ Ocular hypertension	TOP	InTrial	1Q2019	N	N
Edsivo	celiprolol HCl	Acer Therapeutics	alpha-2/beta-1 adrenergic agent	vascular Ehlers-Danlos Syndrome	PO	InTrial	1Q2019	Y	Y
NN-7088	turoctocog alfa pegol	Novo Nordisk	glyco-PEGylated factor VIII derivative	Hemophilia	IV/SC	InTrial	1Q2019	Y	N
Thiola	tiopronin	Retrophin	reducing agent	Cystinuria	PO	InTrial	1Q2019	N	N
Resolor	prucalopride	Shire	5-HT-4 receptor agonist	Chronic constipation	PO	InTrial	1Q2019	N	N
iclaprim	iclaprim	Motif Bio	tetrahydrofolate dehydrogenase inhibitor	Bacterial infections	IV	FastTrk/ Breakthru	1Q2019	Y	Y

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
IMMU-132	sacituzumab govitecan	Seattle Genetics	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	FastTrk/ Breakthru	1Q2019	Y	Y
Rexista XR	oxycodone ER	Intellipharma	opioid agonist	Pain	PO	CRL	1Q2019	N	N
Feraccru	ferric trimaltol	Shield Therapeutics/ AOP Orphan Pharma	iron replacement	Anemia/ Irritable bowel syndrome (IBS)	PO	InTrial	1Q2019	N	N
BHV-0223	riluzole	Portage/ Biohaven/ Catalent	glutamate release inhibitor	Amyotrophic lateral sclerosis (ALS)/ Migraines/ Social anxiety disorder	SL/ Transmucosal	InTrial	1Q2019	N	Y
Vancocin	vancomycin HCl	ANI	antibacterial	Clostridium difficile infection (CDI)/ Enterocolitis	PO	InTrial	1Q2019	N	N
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	FastTrk/ Breakthru	1H2019	Y	Y
Firdapse	amifampridine phosphate	BioMarin/ Catalyst	potassium channel blocker	Congenital myasthenic syndrome (CMS)/ Lambert-Eaton myasthenic syndrome	PO	CRL	2Q2019	Y	Y
EGP-437	dexamethasone phosphate (iontophoretic)	EyeGate	corticosteroid	Uveitis	OP	InTrial	2Q2019	Y	N
NKTR-181	NKTR-181	Nektar	opioid agonist	Pain	PO	FastTrk/	2Q2019	N	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
						Breakthru			
Carbaglu	carglumic acid	Recordati	N-acetylglutamate (NAG) analog	Acidemia	PO	InTrial	2Q2019	N	Y
APN-311	dinutuximab beta	EUSA/ Aperion/ Endo/ Gen Ilac/ Medison	disialoganglioside	Neuroblastoma	SC	InTrial	2Q2019	Y	Y
PSD-502	lidocaine/ prilocaine	Plethora/Sciele	sodium channel blocker	Premature ejaculation	TOP	InTrial	Mid-2019	N	N
FG-4592	roxadustat	FibroGen/ Astellas/ AstraZeneca	hypoxia-inducible factor prolyl hydroxylase	Anemia	PO	InTrial	Mid-2019	Y	N
Pixuvri	pixantrone	Cell Therapeutics	anthracycline derivative	Diffuse large B-cell lymphoma (DLBCL)/ Follicular lymphoma/ Non-Hodgkin's lymphoma (NHL)	IV	CRL	Mid-2019	Y	N
ZEBOV	VS-EBOV	Merck/ NewLink Genetics	vaccine	Ebola	IM	InTrial	Mid-2019	Y	N
ITI-007 (ITI-722)	lumateperone	Intra-Cellular Therapies/ Bristol-Myers Squibb	antipsychotic	Schizophrenia/ Bipolar disorder/ Alzheimer's disease (AD)	PO	FastTrk/ Breakthru	Mid-2019	N	N
ND-0612L	levodopa/ carbidopa	NeuroDerm	dopamine precursor/ dopa-decarboxylase inhibitor	Parkinson's disease (PD)	SC	InTrial	Mid-2019	Y	N
ND-0612H	levodopa/ carbidopa	NeuroDerm	dopamine precursor/ dopa-decarboxylase inhibitor	Parkinson's disease (PD)	SC	InTrial	Mid-2019	Y	N
Trevyent	trevyent	SteadyMed	prostacyclin analog	Pulmonary arterial hypertension (PAH)	SC	CRL	Mid-2019	Y	Y
PRO-140	PRO-140	CytoDyn	C-C chemokine receptor 5 (CCR5) antagonist	Human immunodeficiency virus (HIV)/ Graft vs. host disease (GvHD)	IV/SC	FastTrk/ Breakthru	2H2019	Y	Y

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
TTP-488	azeliragon	vTv Therapeutics	RAGE antagonist	Alzheimer's disease	PO	FastTrk/ Breakthru	2H2019	N	N
Brabafen	fenfluramine	Zogenix	serotonin receptor agonist	Dravet syndrome	PO	FastTrk/ Breakthru	2H2019	Y	Y
CNS-7056	remimazolam	Cosmo/ Hana/ Paion/ Pharmascience/ R- Pharm/ Yichang Humanwell	benzodiazepine	Procedural sedation	IV	InTrial	2H2019	Y	N
LY-573144	lasmiditan	CoLucid/ Ill dong/ Eli Lilly	neurally Acting Anti- Migraine Agent (NAAMA)	Migraines	PO	InTrial	2H2019	Y	N
Viaskin Peanut	Viaskin Peanut	DBV Technologies	immunotherapy	Peanut allergy	TOP	FastTrk/ Breakthru	2H2019	Y	N
RDX-5791	tenapanor	Ardelyx	sodium-hydrogen exchanger-3 inhibitor	Irritable bowel syndrome (IBS)/ Hyperphosphatemia	PO	InTrial	2H2019	N	N
Tivopath	tivozanib	Aveo/ Astellas/ Kyowa Hakko Kirin	VEGF inhibitor	Renal cell cancer	PO	InTrial	2H2019	Y	N
AKB-6548	vadadustat	Akebia Therapeutics	hypoxia-inducible factor- prolyl hydroxylase (HIF-PH) inhibitor	Anemia	PO	InTrial	2H2019	Y	N
ABT-494	upadacitinib	AbbVie	janus associated kinase (JAK) inhibitor	Rheumatoid arthritis (RA)/ Psoriatic arthritis/ Crohn's disease (CD)/ Atopic dermatitis (AD)	PO	FastTrk/ Breakthru	2H2019	N	N
VTS-270	kleptose	Sucampo/ INDPA	sugar molecule	Niemann-Pick disease	Intracerebral/ Intrathecal	FastTrk/ Breakthru	2H2019	Y	Y
Corplex	donepezil transdermal system	Corium International	anticholinergic	Alzheimer's disease	TOP	InTrial	2H2019	N	N
ALKS-8700 (RDC- 1559)	ALKS-8700 (RDC-1559)	Biogen/ Alkermes	prodrug	Multiple sclerosis (MS)	PO	InTrial	2H2019	Y	N
HTX-011	bupivacaine/ meloxicam	Heron Therapeutics	anesthetic/ Nonsteroidal Anti-inflammatory Drug	Pain	Instillation	FastTrk/ Breakthru	2H2019	N	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
			(NSAID)						
Tivicay/ Epivir	dolutegravir/ lamivudine	GlaxoSmithKline/ Shionogi	integrase inhibitor/ NRTI	Human immunodeficiency virus (HIV)	PO	InTrial	2H2019	Y	N
ALXN-1210	ALXN-1210	Alexion	C-5 monoclonal antibody	Paroxysmal nocturnal hemoglobinuria (PNH)/ Hemolytic uremic syndrome (HUS)	IV	InTrial	2H2019	Y	Y
SL-401	SL-401	Stemline Therapeutics	interleukin-3 (IL-3) receptor antagonist	Blastic plasmacytoid dendritic cell neoplasm (BPDCN)/ Acute myelogenous leukemia (AML)/ Myelodysplastic syndrome (MDS)/ Multiple myeloma (MM)/ Hypereosinophilic syndrome/ Myelofibrosis/ Chronic myelomonocytic leukemia (CMML)	IV	InTrial	2H2019	Y	Y
Ongentys	opicapone	Neurocrine Biosciences/ Bial/ Ono	catechol-O-methyltransferase (COMT) inhibitor	Parkinson disease	PO	InTrial	2H2019	N	N
E-2006	lemborexant	Eisai/ Purdue	orexin receptor antagonist	Insomnia/ Sleep-wake rhythm disorder	PO	InTrial	2H2019	N	N
ACZ-885	canakinumab	Novartis	human monoclonal anti-IL-1 beta antibody	Acute coronary syndrome (ACS)	SC	InTrial	2H2019	Y	N
TG-101348 (SAR-503, SAR-302503)	fedratinib	Impact Biomedicines	janus kinase 2 (JAK-2) inhibitor	Myelofibrosis (MF)	PO	InTrial	2H2019	Y	N
BMN-195 (SMT-C1100)	ezutromid	Summit Therapeutics	utrophin inducer	Duchenne muscular dystrophy (DMD)	PO	FastTrk/ Breakthru	2H2019	Y	Y

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
ublituximab (LFB-R603, TG20, TGTX-1101, TG-1101, Utuxin)	ublituximab	TG Therapeutics	CD-20 monoclonal antibody	Chronic lymphocytic leukemia (CLL)/ Small cell lymphocytic lymphoma (SLL)/ Mantle cell lymphoma (MCL)/ Multiple sclerosis	IV	InTrial	3Q2019	Y	Y
TLE-400	tenofovir disoproxyl fumarate/ lamivudine/ efavirenz	Mylan	nucleoside reverse transcriptase inhibitor (NRTI)/ NRTI/ non-nucleoside reverse transcriptase inhibitor (NNRTI)	Human immunodeficiency virus (HIV)	PO	Tentative Approval	3Q2019	Y	N
Cingal	hyaluronic acid/ triamcinolone hexacetonide	Anika	hyaluronic acid/ corticosteroid	Osteoarthritis	Intra-articular	InTrial	4Q2019	Y	N
GFT-505	elafibranor	Genfit	selective peroxisome proliferator-activated receptor (PPAR) modulator	Non-alcoholic steatohepatitis (NASH)/ Primary biliary cirrhosis	PO	FastTrk/ Breakthru	4Q2019	N	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
ADAIR	dextroamphetamine	Alcobra	CNS stimulant	Attention deficit hyperactivity disorder (ADHD)	PO	InTrial	4Q2019	N	N
Xyrosa	doxycycline	Sun Pharma	tetracyclines	Rosacea	PO	Tentative Approval	4Q2019	N	N
MABT-5102A	crenezumab	Roche/ AC Immune	amyloid beta-protein inhibitor	Alzheimer's disease	IV/SC	InTrial	12/1/2019	Y	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
SPI-2012	eflapegrastim	Spectrum/ Hanmi	granulocyte colony-stimulating factor (GCSF)	Neutropenia	SC	InTrial	Late 2019	Y	N
Luveniq	voclosporin	ILJIN	calcineurin inhibitor	Lupus nephritis/ Psoriasis/ Transplant rejection	PO	FastTrk/ Breakthru	Late 2019	Y	Y
ATI-5923	tecarfarin	ARYx Therapeutics/ Armetheon	vitamin K epoxide reductase enzyme inhibitor	Anticoagulation	PO	InTrial	Late 2019	N	N
Xinlay	atrasentan	AbbVie	selective endothelin-A receptor antagonist	Diabetic nephropathy	PO	InTrial	Late 2019	Y	N
arimoclomol	arimoclomol	Orphazyme	cytoprotectives	Niemann-Pick Disease (NPD)/ Sporadic Inclusion Body Myositis (IBM)/ Amyotrophic lateral sclerosis (ALS)	PO	FastTrk/ Breakthru	Late 2019	Y	Y
Travivo	gepirone ER	GSK/Fabre-Kramer	5-HT-1A receptor agonist	Major depressive disorder (MDD)	PO	CRL	Late 2019	N	N
gantenerumab	gantenerumab	Roche	beta-amyloid (Abeta) inhibitor	Alzheimer's disease	SC	InTrial	Late 2019	Y	N
PXT-3003	baclofen/ naltrexone/ sorbitol	Pharnext	gamma-aminobutyric acid (GABA)-ergic agonist/ opioid receptor antagonist/ sorbitol combination	Charcot-Marie Tooth disease	PO	InTrial	Late 2019	N	Y
Anti-VEGF DARPIn	abicipar pegol	Allergan	VEGF-A inhibitor	Age-related macular degeneration (AMD)	Intravitreal	InTrial	Late 2019	Y	N
PRT-201	vonapanitase	Proteon Therapeutics	human elastase (recombinant)	End stage renal disease (ESRD)/Peripheral artery disease (PAD)/ Vascular access in hemodialysis	TOP	FastTrk/ Breakthru	Late 2019	Y	Y

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Talicia	rifabutin/ amoxicillin/ pantoprazole	RedHill Biopharma	RNA polymerase inhibitor/ penicillin/ proton pump inhibitor	Bacterial infections	PO	FastTrk/ Breakthru	Late 2019	N	N
MGN-1703	lefitolimod	Molgen	Toll-like receptor 9 (TLR9) agonist	Colorectal cancer	SC	InTrial	Late 2019	Y	N
ETC-1002	bempedoic acid	Esperion Therapeutics	ATP citrate (pro-S)-lyase and stimulating AMP-activated protein kinase	Hypercholesterolemia	PO	InTrial	Late 2019	N	N
Amphora	Amphora	Neothetics	spermicidal agent	Pregnancy prevention	VG	CRL	Late 2019	N	N
ALKS-3831	olanzapine/ samidorphan	Alkermes	dopamine receptor antagonist/ opioid receptor antagonist	Schizophrenia/ Bipolar disorder	PO	InTrial	Late 2019	N	N
PEGPH-20	PEGPH-20	Halozyme/ Nektar	hyaluronic acid	Pancreatic cancer/ Non-small cell lung cancer (NSCLC)	IV	FastTrk/ Breakthru	Late 2019	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 (COPD)/ Asthma	INH	InTrial	Late 2019	N	N
AR-101 (AR101)	AR-101 (AR101)	Aimmune/ Regeneron/ Sanofi	peanut protein capsule	Peanut allergy	PO	FastTrk/ Breakthru	Late 2019	Y	N
ALD-403	eptinezumab	Alder	calcitonin gene-related peptide (CGRP) antagonist	Migraine prevention	IV/SC	InTrial	Late 2019	Y	N
S-265744 LAP	cabotegravir (long-acting)	GlaxoSmithKline/ Pfizer/ Shionogi	HIV integrase inhibitor	Human immunodeficiency virus (HIV)	SC	InTrial	Late 2019	Y	N
RG-7388	idasanutlin	Roche	MDM2 antagonist	Acute myelogenous leukemia (AML)/ Polycythemia vera (PV)/ Non-Hodgkin lymphoma (NHL)	PO	InTrial	Late 2019	Y	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
OSE-2101	tedopi	OSE Pharma/ Takeda	vaccine	Non-small cell lung cancer (NSCLC)	SC	InTrial	Late 2019	Y	Y
Lenti-D	adrenoleucodystrophy gene therapy	Bluebird Bio	gene therapy	Adrenomyeloneuropathy	Undisclosed	InTrial	Late 2019	Y	Y
QAW-039 (NVP-QAW-039)	fevipirant	Novartis	chemoattractant receptor-homologous molecule (CRTH2) antagonist	Asthma/ Atopic dermatitis	PO	InTrial	Late 2019	Y	N
RTH-258 (ESBA-1008, DLX-1008)	brolicizumab	Novartis/ Delenex	anti-VEGF antibody	Macular degeneration	Intraocular/ Subretinal/ Subconjunctival	InTrial	Late 2019	Y	N
FT-218	sodium oxybate extended-release	Avadel	dopamine receptor agonist	Narcolepsy	PO	InTrial	Late 2019	Y	N
KP-415	D-threo-methylphenidate controlled-release	KemPharm	CNS stimulant	Attention deficit hyperactivity disorder (ADHD)	PO	InTrial	Late 2019	N	N
Oralair Mites	dust mite peptide	Stallergenes/ Shionogi	vaccine	Dust mite allergic rhinitis	SL	InTrial	Late 2019	Y	N
SA-237	satralizumab	Roche/ Chugai	interleukin-6 (IL-6) monoclonal antibody	Neuromyelitis optica	SC	InTrial	Late 2019	Y	Y
isatuximab	isatuximab	Sanofi/ ImmunoGen	CD38 antagonist	Multiple myeloma/ Acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL)	IV	InTrial	Late 2019	Y	Y
Lentiglobin	lentiviral beta-globin gene transfer	Bluebird Bio	gene therapy	Sickle cell disease/ Beta thalassemia	IV	FastTrk/ Breakthru	Late 2019	Y	Y
RT-002	daxibotulinumtoxinA	Revance Therapeutics	botulinum toxins	Cervical dystonia/ Plantar fasciitis/ Cosmetic	IM	InTrial	Late 2019	Y	Y
skQ1	visomitin	Mitotech	plastoquinone derivative	Dry eyes	OP	InTrial	Late 2019	Y	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Betalutin	177 lu-dota-tetulumab (177 lu-tetrexetan-tetulumab, 177 lu-lilotomab satetraxetan, 177 lu-DOTA-HH1)	Nordic Nanovector	anti-CD37 antibody radionuclide	Non-Hodgkin lymphoma (NHL)	IV	InTrial	Late 2019	Y	Y
RG-7916 (RO-7034067)	RG-7916 (RO-7034067)	Roche/ PTC Therapeutics	SMN2 splicing modifier	Spinal muscular atrophy	PO	InTrial	Late 2019	Y	Y
Humacyl	human acellular vessel	Humacyte	cellular therapy	End-stage renal disease (ESRD)/ Peripheral artery disease (PAD)	Implant	FastTrk/ Breakthru	Late 2019	Y	N
DigiFab	digoxin immune fab (DIF)	AMAG/ Velo	digitalis-like factor antagonist	Preeclampsia	IV	FastTrk/ Breakthru	Late 2019	Y	Y
bb-2121	bb-2121	Celgene/ Bluebird Bio	chimeric antigen receptor (CAR) T cell therapy	Multiple myeloma/ Brain cancer	IV	InTrial	Late 2019	Y	Y
BMS-927711 (BHV-3000)	rimegepant sulfate	Portage Biotech/ Biohaven/ Bristol-Myers Squibb	calcitonin gene-related peptide (CGRP)	Acute Migraines	PO	InTrial	Late 2019	Y	N
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	FastTrk/ Breakthru	Late 2019	Y	Y
Cinqair (SC)	reslizumab	Teva	interleukin-5 (IL-5) antagonist	Asthma	SC	InTrial	Late 2019	Y	N
QMF-149	indacaterol maleate/ mometasone furoate	Novartis/ Merck	long-acting beta 2 agonist/ corticosteroid	Asthma	INH	InTrial	Late 2019	N	N
DS-300	DS-300	Eton	undisclosed	Ophthalmological disease	SC	InTrial	Late 2019	N/A	N
DS-200	DS-200	Eton	undisclosed	Ophthalmological disease	SC	InTrial	Late 2019	N/A	N
DS-100	DS-100	Eton	undisclosed	Ophthalmological disease	SC	InTrial	Late 2019	N/A	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
dronabinol XL AdVersa	dronabinol controlled-release	Tetra Bio-Pharma/ IntelGenx	cannabinoid receptor agonist	Anorexia/ Nausea and vomiting (N/V)	Buccal	InTrial	Late 2019	N	N
GSK-2696274	GSK-2696274	GlaxoSmithKline	gene therapy	Leukodystrophy	IV	InTrial	Late 2019	Y	N
RE-024	fosmetpantotenate	Retrophin	phosphopantothenate replacement therapy	Neurodegeneration	IV	FastTrk/ Breakthru	Late 2019	Y	Y
CLS-1001	triamcinolone acetonide	Clearside	corticosteroid	Macular edema	intraocular/ subretinal	InTrial	Late 2019	Y	N
ETC-1002/ ezetimibe	bempedoic acid/ ezetimibe	Esperion Therapeutics	ATP citrate (pro-S)-lyase and stimulating AMP-activated protein kinase/cholesterol absorption inhibitor	Hypercholesterolemia	PO	InTrial	Late 2019	N	N
FP-001 (LMIS)	leuprolide mesylate	Foresee	gonadotropin-releasing hormone (GnRH) analog	Prostate cancer	SC	InTrial	Late 2019	Y	N
2020 Possible launch date									
MK-8931	verubecestat	Merck	β -amyloid precursor protein site-cleaving enzyme (BACE) inhibitor	Alzheimer's disease	PO	InTrial	2020	Y	N
AGS-003	rocapuldencel-T	Argos Therapeutics	immunotherapy	Renal cell cancer	INJ	FastTrk/ Breakthru	2020	Y	N
atacept (TACI-Ig)	atacept (TACI-Ig)	EMD Serono / Bristol-Myers Squibb	transmembrane activator and CAML interactor (TACI) receptor-immunoglobulin	Systemic lupus erythematosus (SLE)	SC	InTrial	2020	Y	N
JNJ-872 (VX-787)	JNJ-872 (VX-787)	Johnson & Johnson/ Vertex	viral protein inhibitor	Influenza	PO	FastTrk/ Breakthru	2020	N	N
JNJ-42160443	fulranumab	Amgen/ Takeda	nerve growth factor antagonist	Pain	SC	InTrial	2020	Y	N
BGJ-398	infigratinib	Novartis	FGFR inhibitor	Biliary tract cancer/ Brain cancer/ Solid tumors	PO	InTrial	2020	Y	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
S-033188 (RG-6152)	S-033188 (RG-6152)	Shionogi/ Roche/	endonuclease inhibitor	Influenza	PO	InTrial	2020	N	N
MK-1602 (AGN-241689)	ubrogepant	Allergan/ Merck	calcitonin gene-related peptide (CGRP) receptor antagonist	Acute Migraines	PO	InTrial	2020	Y	N
NN-9924 (OG-217SC)	semaglutide	Novo Nordisk/ Emisphere Technologies	glucagon-like peptide-1 (GLP-1) receptor agonist	Diabetes mellitus	PO	InTrial	1Q2020	Y	N
cabotegravir (long-acting)/ rilpivirine (long-acting)	cabotegravir (long-acting)/ rilpivirine (long-acting)	ViiV Healthcare	HIV integrase inhibitor/ non-nucleoside reverse transcriptase inhibitor (NNRTI)	HIV	IM/SC	InTrial	1H2020	Y	N

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



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