

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
2017 Possible launch date									
Ontinua ER	arbaclofen extended-release	Osmotica	muscle relaxant	Spasticity	PO	Filed NDA	2017	Y	N
Xeglyze	abametapir	Hatchtech	metalloprotease inhibitor	Lice	TOP	Filed NDA	2017	N	N
Zenavod	doxycycline	Dr. Reddy's Laboratories	tetracyclines	Rosacea	PO	Tentative Approval	2017	N	N
Remodulin Implantable System	treprostinil	United Therapeutics	prostacyclin analog	Pulmonary arterial hypertension	IV/SC	Filed sNDA	2017+	Y	Y
SER-120	desmopressin	Allergan/Serenity	antidiuretic	Nocturia	Intranasal	Filed NDA	1Q2017	N	N
Amphora	Amphora	Evoform	spermicidal agent	Pregnancy prevention	VG	Filed NDA	1Q2017	N	N
empagliflozin/metformin ER	empagliflozin/metformin ER	Boehringer Ingelheim	sodium glucose co-transporter-2 (SGLT-2) inhibitor/biguanide	Diabetes mellitus	PO	Filed NDA	1Q2017	N	N
CL-108	promethazine/hydrocodone/acetaminophen	Charleston Laboratories	anti-emetic/opioid/analgesic	Nausea/Vomiting/Pain	PO	Filed NDA	1/31/2017	N	N
Parsabiv	etelcalcetide (velcalcetide, telcalcetide)	Amgen	calcimimetic	Hyperparathyroidism	IV	Filed NDA	2/9/2017	Y	N
MP-104	deflazacort	Marathon	corticosteroid	Duchenne muscular dystrophy	PO	Filed NDA	2/9/2017	Y	Y

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Mitizax	ALK-Abello (HDM AIT, MK-8237)	Abbott/ALK-Abello/Torii	vaccine	Dust mite allergic rhinitis	SL	Filed BLA	2/10/2017	N	N
Siliq	brodalumab	AstraZeneca/Valeant	interleukin-17 (IL-17) receptor inhibitor	Psoriasis/Psoriatic arthritis	SC	Filed BLA	2/16/2017	Y	N
naloxone	naloxone	Amphastar	opioid antagonist	Opioid dependence	Intranasal	Filed NDA	2/19/2017	N	N
telotristat etiprate	telotristat etiprate	Lexicon	tryptophan hydroxylase antagonist	Carcinoid syndrome	PO	Filed NDA	2/28/2017	Y	Y
MVA-MUC1-IL2	TG-4010	Transgene	vaccine	Non-small cell lung cancer (NSCLC)	SC	FastTrk/Breakthru	12/1/2017	N	N
Xadago	safinamide	Newron	alpha-aminoamide derivative	Parkinson's disease	PO	Filed NDA	3/21/2017	N	N
Symproic	naldemedine	Shionogi/Purdue	opioid receptor antagonist	Opioid-induced constipation	PO	Filed NDA	3/23/2017	N	N
Dextenza	dexamethasone sustained-release	Ocular Therapeutix	corticosteroid	Pain/Allergic conjunctivitis	OP	Filed NDA	3/24/2017	N	N
Ocrevus	ocrelizumab	Genentech	anti-CD20 monoclonal antibody	Multiple sclerosis	IV	Filed BLA	3/28/2017	Y	N
Dupixent	dupilumab	Sanofi/Regeneron	interleukin-4/13 (IL-4/IL-13) inhibitor	Atopic dermatitis (AD)/Asthma/Sinusitis/Nasal polyposis/Eosinophilic esophagitis	SC	Filed BLA	3/29/2017	Y	N
sarilumab (REGN-88)	sarilumab	Regeneron/Sanofi-Aventis	anti-interleukin-6 receptor (IL-6R) monoclonal antibody	Rheumatoid arthritis/Uveitis	SC	CRL	3/30/2017	Y	N
abaloparatide-SC	abaloparatide-SC	Radius	human parathyroid hormone-related protein (hPTHrP) analog	Osteoporosis	SC	Filed NDA	3/30/2017	Y	N
RI-002	RI-002	ADMA Biologics	immunoglobulin	Primary immunodeficiency/Respiratory syncytial virus (RSV)/Bacterial infections	IV	CRL	2Q2017	Y	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
AC-170	cetirizine	Nicox	antihistamine	Allergic conjunctivitis	TOP	CRL	2Q2017	N	N
ZS-9	sodium zirconium cyclosilicate	ZS Pharma	potassium-binding agent	Hyperkalemia	PO	Filed NDA	2Q2017	N	N
CTL-019	CTL-019	Novartis	chimeric antigen receptor (CAR) T cell therapy	Acute lymphoblastic leukemia (ALL)/Diffuse large B-cell lymphoma (DLBCL)/Chronic lymphocytic leukemia (CLL)	IV	FastTrk/ Breakthru	2Q2017	Y	Y
ACH-3102 (ACH-0143102)	odasvir	Achillion	NS5A inhibitor	Hepatitis C (HCV)	PO	FastTrk/ Breakthru	2Q2017	Y	N
N9-GP (NN-7999, NNC-0156-0000-0009, PEG-rFIX)	nonacog beta pegol	Novo Nordisk	coagulation factor	Hemophilia	IV	Filed BLA	2Q2017	Y	Y
durvalumab	durvalumab	AstraZeneca/ Celgene/Eli Lilly/ Juno Therapeutics	anti-PDL-1 antibody	Bladder cancer/Non-small cell lung cancer (NSCLC)/ Head and neck cancer/ Malignant melanoma	IV	Filed BLA	2Q2017	Y	N
LEE-011	ribociclib	Novartis/Otsuka	CDK4 and CDK6 inhibitor	Breast cancer	PO	Filed NDA	2Q2017	Y	N
KTE-C19	axicabtagene ciloleucel	Kite	chimeric antigen receptor (CAR) T cell therapy	Mantle cell lymphoma/ Indolent Non-Hodgkin lymphoma/Diffuse Large B-Cell Lymphoma (DLBCL)/Chronic lymphocytic leukemia (CLL)/ Small cell lymphocytic lymphoma (SLL)	IV	Filed NDA	2Q2017 - 4Q2017	Y	Y
Austedo	deutetrabenazine	Auspex	vesicular monoamine transporter-2 (VMAT) inhibitor	Huntington's disease/ Tourette's syndrome/Tardive dyskinesia	PO	Filed NDA	4/3/2017	Y	Y

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Remune	HIV-1 vaccine	Immune Response BioPharma	vaccine	HIV	IM	Filed BLA	4/5/2017	Y	Y
Ingrezza	valbenazine	Neurocrine Biosciences/ Mitsubishi Tanabe	vesicular monoamine transporter-2 (VMAT) inhibitor	Tardive dyskinesia/ Tourette's syndrome	PO	Filed NDA	4/11/2017	N	N
baricitinib	baricitinib	Eli Lilly/Incyte	janus associated kinase 1/2 (JAK1/2) inhibitor	Rheumatoid arthritis/Psoriasis/Diabetic nephropathy	PO	Filed NDA	4/19/2017	Y	N
CCP-07	CCP-07	Vernalis/Tris Pharma	undisclosed	Cough and cold	PO	Filed NDA	4/20/2017	N	N
BMN-190	cerliponase alfa	BioMarin	enzyme replacement	Neuronal ceroid lipofuscinosis type 2 (CLN2)	Intracerebral	Filed BLA	4/27/2017	Y	Y
AP-113 (AP-26113)	brigatinib	ARIAD	anaplastic lymphoma kinase (ALK) inhibitor	Non-small cell lung cancer (NSCLC)	PO	Filed NDA	4/29/2017	Y	Y
Isentress	raltegravir	Merck	integrase inhibitor	HIV	PO	Filed sNDA	5/27/2017	Y	N
avelumab	avelumab	Merck/Pfizer	programed death ligand-1 (PD-L1) inhibitor	Merkel cell carcinoma (MCC)/Gastric cancers/ Non-small cell lung cancer (NSCLC)/Ovarian cancer/ Urothelial cancer/Renal cell carcinoma	IV	Filed BLA	5/29/2017	Y	Y
Luveniq	voclosporin	ILJIN	calcineurin inhibitor	Lupus nephritis/Psoriasis/ Transplant rejection	PO	FastTrk/ Breakthru	Mid-2017	Y	Y
Travivo	gepirone ER	GSK/Fabre-Kramer	5-HT-1A receptor agonist	Major depressive disorder (MDD)	PO	CRL	Mid-2017	N	N
CM-AT, CM 4612	CM-AT, CM 4612	Curemark	protein absorption enhancer	Autism	PO	InTrial	Mid-2017	Y	N
Vesneo	latanoprostene bunod	Bausch and Lomb/NicOx	nitric oxide-donating prostaglandin F2-alpha	Glaucoma/Ocular hypetension	TOP	CRL	Mid-2017	N	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
			analog						
Berinert	human C1-esterase inhibitor concentrate	CSL Limited	C1 inhibitor	Angioedema	SC	Filed BLA	Mid-2017	Y	N
Radicava	edaravone	Mitsubishi Tanabe	free radical scavenger	Amyotrophic lateral sclerosis (ALS)	IV	Filed NDA	6/16/2017	Y	Y
Baxdela	delafloxacin	Melinta/Wakunaga	fluoroquinolone	Bacterial infections	IV/PO	Filed NDA	6/19/2017	Y	N
Cotempla XR-ODT	methylphenidate XR-ODT	Neos Therapeutics	CNS stimulant	Attention deficit hyperactivity disorder (ADHD)	PO	Filed NDA	6/20/2017	N	N
SHP-465	amphetamine/dextroamphetamine salts	Shire	adrenergic receptor agonists	Attention deficit hyperactivity disorder (ADHD)	PO	Filed NDA	6/20/2017	N	N
GF-00100100	ozenoxacin	Medimetriks/Cipher	quinolone (non-fluorinated)	Bacterial infections	TOP	Filed NDA	6/22/2017	N	N
MK-4448	betrixaban	Portola/Millennium	factor Xa inhibitor	Deep vein thrombosis (DVT)/Pulmonary embolism (PE)	PO	Filed NDA	6/24/2017	N	N
niraparib	niraparib	Merck/TESARO	poly (ADP-ribose) polymerase (PARP) inhibitor	Ovarian cancer/Breast cancer	PO	Filed NDA	6/30/2017	Y	N
TX-004HR, TX-12-004HR	estradiol	TherapeuticsMD	estrogen receptor agonist	Vaginal atrophy	Intravaginal	Filed NDA	2H2017	N	N
SUN-101 (EP-101)	glycopyrrolate	Sunovion	long-acting muscarinic receptor antagonist	Chronic obstructive pulmonary disease (COPD)	INH	Filed NDA	2H2017	N	N
MEK-162	binimetinib	Array BioPharma/Novartis	MEK inhibitor	Fallopian tube cancer/Melanoma/Ovarian cancer/Peritoneal cancer	PO	Filed NDA	2H2017	Y	N
PKC-412	midostaurin	Novartis	protein kinase C-alpha (PKC-alpha) inhibitor	Acute myeloid leukemia (AML)/Mastocytosis	PO	Filed NDA	2H2017	Y	Y
SaxaDapa	dapagliflozin/saxagliptin	Bristol Meyers Squibb/AstraZeneca	sodium-dependent glucose cotransporter 2 (SGLT-2)	Diabetes	PO	CRL	2H2017	N	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
			inhibitor/DPP-4 inhibitor						
Tbria	salmon calcitonin	Tarsa/Unigene Laboratories	osteoclast inhibitor	Osteoporosis	PO	Filed NDA	2H2017	N	N
Zalviso	sufentanil, ARX-01	AcelRx	opioid analgesic	Pain	SL	CRL	2H2017	Y	N
clonidine (ARC-4558)	clonidine	Arcion Therapeutics/BioDelivery Sciences	alpha-2-adrenoceptor agonist	Diabetic neuropathy	TOP	FastTrk/Breakthru	2H2017	N	N
inotuzumab ozogamicin	inotuzumab ozogamicin	Pfizer /UCB	antibody-drug conjugate (CD-22 mAb linked to calicheamicin, a cytotoxic agent)	Acute myeloid leukemia (AML)	IV	FastTrk/Breakthru	2H2017	Y	Y
etirinotecan pegol (NKTR-102)	etirinotecan pegol	Nektar	topoisomerase inhibitor	Breast cancer/Colorectal cancer/Ovarian cancer	IV	FastTrk/Breakthru	2H2017	Y	Y
ularitide acetate	ularitide acetate	Cardiorientis/Cornerstone Therapeutics	vasodilator (synthetic human natriuretic peptide)	Heart failure	IV	FastTrk/Breakthru	2H2017	Y	N
NeuVax	nelipepimut-S	Galena	vaccine	Breast cancer	intradermal	FastTrk/Breakthru	2H2017	Y	N
benralizumab	benralizumab	AstraZeneca	interleukin-5 receptor (IL-5R) alpha inhibitor	Asthma/Chronic obstructive pulmonary disease (COPD)	SC	InTrial	2H2017	Y	N
Simdax	levosimendan	Tenax Therapeutics	calcium sensitizing phosphodiesterase inhibitor	Septic shock/Heart failure/Low cardiac output syndrome (LCOS)	IV	FastTrk/Breakthru	2H2017	Y	N
APD-421	amisulpride	Acacia	dopamine receptor antagonist	Nausea/Vomiting	IV	InTrial	2H2017	N	N
LGX-818	encorafenib	Novartis	rapidly accelerated fibrosarcoma (RAF) inhibitor	Melanoma	PO	InTrial	2H2017	Y	Y
masitinib	masitinib	AB Science	protein tyrosine kinase	Asthma/GST/Mastocytosis/	PO	InTrial	2H2017	N	Y

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
			inhibitor	Multiple myeloma/Prostate cancer/Crohn's disease/ Multiple sclerosis/ Rheumatoid arthritis/ Pancreatic cancer/ Amyotrophic lateral sclerosis (ALS)					
Peg-Pal	pegylated phenylalanine ammonia lyase	BioMarin	enzyme replacement	Phenylketonuria (PKU)	SC	InTrial	2H2017	Y	Y
buprenorphine	buprenorphine	Insys Therapeutics	opioid receptor agonist (partial)	Pain	SL/ Transmucosal	InTrial	2H2017	N	N
CardiaPill	aspirin/lisinopril/ simvastatin	CardioPharma	aspirin/angiotensin converting enzyme inhibitor/HMG Co-A reductase inhibitor	Cardiovascular disease	PO	InTrial	2H2017	N	N
LY-03004	risperidone ER	Luye	atypical antipsychotic	Schizophrenia/ Schizoaffective disorder	IM	InTrial	2H2017	Y	N
IVIG-SN	human normal immunoglobulin G	Green Cross	immune globulin (IVIG)	Primary immunodeficiency	IV	CRL	2H2017	Y	N
TV-46763	hydrocodone bitartrate/acetaminophen	Teva	opioid receptor agonist/analgesic	Pain	PO	InTrial	2H2017	N	N
HM-61713 (BI-1482694)	olmutinib	ZAI/Hanmi	kinase inhibitor	Non-small cell lung cancer (NSCLC)	PO	FastTrk/ Breakthru	2H2017	Y	N
A-101 (V-101)	hydrogen peroxide	Aclaris Therapeutics	peroxide	Benign pigmented lesions	TOP	InTrial	2H2017	Y	N
neratinib	neratinib	Puma Biotechnology	irreversible pan-ErbB receptor tyrosine kinase inhibitor	Breast cancer	PO	Filed NDA	2H2017	Y	N
Zorblisa	allantoin	Scioderm	antioxidant	Bacterial infections	TOP	Filed NDA	2H2017	Y	Y
Benlysta	belimumab	GlaxoSmithKline	B-lymphocyte stimulator (BLyS)-specific inhibitor	Systemic lupus erythematosus (SLE)	SC	Filed BLA	7/2017	Y	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
HEPLISAV-B	HBV vaccine	Merck/Dynavax	vaccine	Hepatitis B (HBV)	IM	CRL	7/1/2017	N	N
NutreStore	L-glutamine	Emmaus Medical	amino acid	Sickle beta thalassemia/ Sickle cell anemia	PO	Filed NDA	7/7/2017	N	Y
epinephrine	epinephrine	Adamis	catecholamine	Emergency allergic reactions	INJ	Filed NDA	7/16/2017	N	N
Evenity	romosozumab	Amgen	anti-sclerostin monoclonal antibody	Osteoporosis	SC	Filed BLA	7/19/2017	Y	N
Benjorna	methylphenidate modified-release	Highland Therapeutics	CNS stimulant	Attention deficit hyperactivity disorder (ADHD)	PO	Filed NDA	7/30/2017	N	N
tafenoquine	tafenoquine	GSK/MMV	apoptosis modulator	Malaria	PO	FastTrk/ Breakthru	3Q2017	N	Y
BKM-120	buparlisib	Novartis	1 phosphatidylinositol 3 kinase inhibitor	Breast cancer	PO	InTrial	3Q2017	Y	N
BAX-817	BAX-817	Baxter	factor VIIa stimulant	Hemophilia	IV	InTrial	3Q2017	Y	N
FIAsp	insulin aspart (ultra fast acting)	Novo Nordisk	fast-acting insulin	Diabetes mellitus	SC	CRL	3Q2017	N	N
Varubi	rolapitant	Tesaro/Opko Health	neurokinin-1 (NK-1) receptor antagonist	Nausea and vomiting	IV	CRL	3Q2017	Y	N
APN-311	dinutuximab beta	EUSA/Aperion/Endo/ Gen Ilac/Medison	disialoganglioside	Neuroblastoma	SC	InTrial	2H2017	Y	Y
EP-5101	pemetrexed	Eagle Pharmaceuticals	folate analog metabolic inhibitor	Non-small cell lung cancer (NSCLC)/Mesothelioma	IV	Filed NDA	3Q2017	Y	N
ARX-04	sufentanil	AcelRx	opioid analgesic	Pain	SL	Filed NDA	3Q2017	Y	N
LY-2835219	bemaciclib (abemaciclib)	Eli Lilly	cyclin-dependent kinases	Breast cancer/Non-small cell lung cancer (NSCLC)/Mantle cell lymphoma	PO	FastTrk/ Breakthru	3Q2017	Y	N
SPK-RPE65	voretigene neparvovec	Spark Therapeutics	gene therapy	Nyctalopia	Intraocular	Filed BLA	3Q2017	Y	Y

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
QVAR BAI	beclomethasone	Teva	corticosteroid	Asthma	INH	InTrial	3Q2017	N	N
Vyxeos	cytarabine /daunorubicin (CPX-351)	Celator	pyrimidine antimetabolite/ anthracycline	Acute myeloid leukemia (AML)	IV	Filed NDA	2H2017	Y	Y
amphetamine XR-liquid	amphetamine extended-release	Neos Therapeutics	stimulant	Attention deficit hyperactivity disorder (ADHD)	PO	Filed NDA	3Q2017	N	N
ATI-5923	tecarfarin	ARYx Therapeutics/ Armetheon	vitamin K epoxide reductase enzyme inhibitor	Anticoagulation	PO	InTrial	3Q2017	N	N
fostamatinib	fostamatinib	Rigel	oral SYK inhibitor	Immune thrombocytopenia purpura	PO	InTrial	3Q2017	Y	Y
Medidur	fluocinolone acetonide	Alimera/pSivida	corticosteroid	Posterior uveitis	INJ	InTrial	3Q2017	Y	N
Duzallo	lesinurad/allopurinol	AstraZeneca	urate transporter1 and organic anion transporter 4 inhibitor/hypoxanthine analog	Gout	PO	Filed NDA	8/3/2017	N	N
CCP-08	CCP-08	Vernalis/Tris Pharma	undisclosed	Viral rhinitis	PO	Filed NDA	8/4/2017	Y	N
sofosbuvir/velpatasvir/ voxilaprevir	sofosbuvir/velpatasvir/ voxilaprevir	Gilead	NS5A inhibitor/nucleotide analog NS5B polymerase inhibitor/pan-genotypic NS3 protease inhibitor	Hepatitis C (HCV)	PO	Filed NDA	8/6/2017	Y	N
ABT-493/ABT-530	glecaprevir/pibrentasvir	AbbVie	NS3 protease inhibitor/NS5A inhibitor	Hepatitis C (HCV)	PO	Filed NDA	8/19/2017	Y	N
Nurelin	amantadine ER	Adamas	antiviral	Dyskinesia in Parkinson's disease	PO	Filed NDA	8/24/2017	N	Y
KamRAB	anti-rabies immunoglobulin (human)	Kamada /Kedrion	immune globulin	Rabies	IM	Filed BLA	8/29/2017	Y	N
Solosec	secnidazole	Symbiomix	5-nitroimidazole antibiotic	Urinary tract infection	PO	Filed NDA	9/19/2017	N	N
ITCA-650 (sustained)	exenatide sustained-	Intarcia/Quintiles/	glucagon-like peptide-1	Diabetes	SC implant	Filed NDA	9/21/2017	N	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
release exenatide)	release	Servier	(GLP-1) receptor agonist						
fluticasone furoate/umeclidinium/vilanterol	fluticasone furoate/umeclidinium/vilanterol	GSK/Innoviva	inhaled corticosteroid (ICS)/long-acting muscarinic agent (LAMA)/long-acting beta agonist (LABA)	Chronic obstructive pulmonary disease (COPD)	INH	Filed NDA	9/21/2017	N	N
sirukumab	sirukumab	Janssen /GSK	interleukin-6 (IL-6) monoclonal antibody	Rheumatoid arthritis	SC	Filed BLA	9/2017	Y	N
Rexista XR	oxycodone ER	Intellipharma	opioid agonist	Pain	PO	Filed NDA	9/25/2017	N	N
tadalafil pharmafilm	tadalafil pharmafilm	MonoSol Rx	phosphodiesterase-5 (PDE-5) inhibitor	Erectile dysfunction	PO	Filed NDA	9/28/2017	Y	N
OptiNose	fluticasone propionate	OptiNose AS	corticosteroid	Nasal polyps	Intranasal	Filed NDA	9/30/2017	N	N
ertugliflozin	ertugliflozin	Merck/Pfizer	SGLT2 inhibitor	Diabetes	PO	InTrial	4Q2017	N	N
Zemcolo	rifamycin	Cosmo/Dr. Falk	DNA-dependent RNA polymerase inhibitor	Traveler's diarrhea	PO	InTrial	4Q2017	N	N
Cyclokat	cyclosporine A (Nova-22007)	Santan SAS	immunosuppressant	Dry eye/Vernal keratoconjunctivitis	TOP	InTrial	4Q2017	Y	Y
Apealea (Paclical)	paclitaxel	Oasmia	taxane	Ovarian cancer	IV	InTrial	4Q2017	Y	Y
Prostvac	rilimogene glafolivec	BN ImmunoTherapeutics	vaccine	Prostate cancer	SC	FastTrk/Breakthru	4Q2017	Y	N
Pixuvri	pixantrone	Cell Therapeutics	anthracycline derivative	Diffuse large B-cell lymphoma (DLBCL)/Follicular lymphoma/Non-Hodgkin's lymphoma (NHL)	IV	CRL	4Q2017	Y	N
AndexXa	andexanet alfa	Portola/Pfizer/Bristol-Myers Squibb	recombinant Factor Xa inhibitor antidote	Reversal agent	IV	CRL	4Q2017	Y	N
tildrakizumab (MK-3222)	tildrakizumab (MK-3222)	Merck	interleukin-23 (IL-23) inhibitor	Psoriasis	SC	InTrial	4Q2017	Y	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
reparixin	reparixin	Dompe	interleukin-8 (IL-8) inhibitor	Pancreatic islet transplantation	IV	InTrial	4Q2017	Y	Y
NX-1207 (NYM-4805, REC 0482)	fexapotide trifluate	Nymox	pro-apoptotic	Benign prostatic hyperplasia (BPH)/Prostate cancer	Intratumoral	InTrial	4Q2017	Y	N
Civacir	hepatitis C immunoglobulin	Biotest	immunoglobulin	Hepatitis C (HCV)	IV	FastTrk/ Breakthru	4Q2017	Y	Y
Zeftera	ceftobiprole	Basilea	cephalosporin antibiotic	Bacterial infections	IV	InTrial	4Q2017	Y	N
DCVax-L, DCVax-Brain	glioblastoma multiforme vaccine	Northwest Biotherapeutics	vaccine	Glioblastoma	SC	InTrial	4Q2017	Y	Y
tertomotide (GV-1001)	tertomotide (GV-1001)	KAEL-GemVax	vaccine	Non-small cell lung cancer (NSCLC)/Melanoma	Intradermal	InTrial	4Q2017	Y	N
RHB-105	rifabutin/amoxicillin/ pantoprazole	RedHill Biopharma	RNA polymerase inhibitor/ penicillin/proton pump inhibitor (PPI)	H. pylori eradication	PO	InTrial	4Q2017	N	N
ISIS 304801 (ISIS-APOCIIRx)	volanesorsen	Ionis	antisense drug	Familial chylomicronemia syndrome/Lipodystrophy	SC	InTrial	4Q2017	Y	Y
Cipro Inhale	ciprofloxacin DPI	Nektar/Bayer	fluoroquinolone	Cystic fibrosis bacterial infections/Non-cystic fibrosis bronchiectasis	INH	InTrial	4Q2017	N	Y
ABX-203	ABX-203	Abivax	vaccine	Hepatitis B (HBV)	SC/intranasal	InTrial	4Q2017	N	N
ITI-007 (ITI-722)	ITI-007 (ITI-722)	Bristol-Myers Squibb	antipsychotic	Schizophrenia	PO	InTrial	4Q2017	N	N
BBI-608	napabucasin	Sumitomo Dainippon	stem cell inhibitor	Colorectal cancer/Gastric cancer	PO	InTrial	4Q2017	Y	Y
Osmolex ER (OS-320)	amantadine extended-release	Osmotica	antiviral	Dyskinesia	PO	InTrial	4Q2017	N	Y
MDL	moxidectin	Medicines Development for	chloride channel agonist	Parasitic infections	PO	InTrial	4Q2017	N	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
		Global Health							
ertugliflozin/sitagliptin	ertugliflozin/sitagliptin	Merck/Pfizer	sodium glucose transporter type 2 (SGLT-2) inhibitor/dipeptidyl peptidase-4 (DPP-4) inhibitor	Diabetes	PO	InTrial	4Q2017	N	N
AG-221 (AGI-6780; CC-900007)	enasidenib	Celgene/Agios	isocitrate dehydrogenase 2 inhibitor	Acute myelogenous leukemia (AML)/Solid tumors	PO	FastTrk/Breakthru	4Q2017	Y	Y
Aeroquin	levofloxacin HCl	Raptor	fluoroquinolone	Cystic fibrosis	INH	InTrial	4Q2017	Y	Y
ertugliflozin/metformin	ertugliflozin/metformin	Merck/Pfizer	SGLT2 inhibitor/biguanide	Diabetes	PO	InTrial	4Q2017	N	N
Recentin	cediranib	AstraZeneca	vascular endothelial growth factor receptor (VEGF) antagonists	Ovarian cancer/Biliary tract cancer	PO	InTrial	4Q2017	Y	Y
FMX-102 (FXFM-244)	minocycline	Foamix	tetracyclines	Impetigo	TOP	InTrial	4Q2017	N	N
Shingrix (GSK-1437173A)	herpes zoster vaccine	GSK	vaccine	Herpes zoster	IM	Filed BLA	4Q2017	Y	N
Rhopressa	netarsudil mesylate	Aerie	rho kinase-norepinephrine transport protein inhibitor	Glaucoma/Ocular hypertension	TOP	InTrial	4Q2017	N	N
RESOLVE	mometasone controlled-release	Intersect ENT	corticosteroid	Sinusitis	Sinus implant	InTrial	4Q2017	Y	N
guselkumab	guselkumab	Johnson & Johnson	interleukin-23 (IL-23) inhibitor	Psoriasis/Psoriatic arthritis	SC	Filed BLA	4Q2017	Y	N
BMN-673	talazoparib	BioMarin	poly (ADP-ribose) polymerase (PARP) inhibitor	Breast cancer	PO	InTrial	4Q2017	Y	N
ELI-200	oxycodone/naltrexone	Elite	opioid agonist	Pain	PO	CRL	4Q2017	N	N
ACP-196	acalabrutinib	Acerta/Merck	tyrosine kinase inhibitor	Chronic lymphocytic leukemia (CLL)/Small cell lymphocytic lymphoma (SLL)	PO	InTrial	4Q2017	Y	Y

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
ALKS-5461	buprenorphine/ samidorphan	Alkermes	opioid receptor agonist (partial)/opioid receptor antagonist	Major depressive disorder (MDD)	PO	FastTrk/ Breakthru	Late 2017	N	N
CVT-301	levodopa	Acorda	antiparkinson	Parkinson's disease	INH	InTrial	Late 2017	N	N
Scenesse	afamelanotide	Clinuvel	melanocortin receptor 1 (MC-1) agonist	Erythropoietic protoporphyria (EPP)/Polymorphous light eruption (PLE/PMLE)/Vitiligo	SC implant	Filed NDA	Late 2017	Y	Y
ISIS-TTRRx (ISIS-420915; GSK-2998728)	ISIS-TTRRx (ISIS-420915; GSK-2998728)	GSK/Ionis	antisense RNA modulator	Transthyretin (TTR) amyloidosis/Transthyretin (TTR) cardiomyopathy	SC	FastTrk/ Breakthru	Late 2017	Y	Y
Ampion	aspartyl-alanyl diketopiperazine (DA-DKP)	Ampio Pharmaceuticals	immunomodulator	Osteoarthritis	Intra-articular	InTrial	Late 2017	Y	N
human plasminogen	human plasminogen	Kedrion	plasminogen	Plasminogen deficiency	TOP	InTrial	Late 2017	Y	Y
ELI-202	opioid (undisclosed)	Elite	opioid agonist	Pain	PO	InTrial	Late 2017	N	N
VersaFilm	rizatriptan	IntelGenx /Red Hill Biopharma	triptans	Headache	PO	CRL	Late 2017	N	N
sapacitabine	sapacitabine	Cyclacel /Daiichi Sankyo	antimetabolite	Acute myeloid leukemia (AML)	PO	InTrial	Late 2017	Y	Y
ARQ-197	tivantinib	ArQule/Daiichi Sankyo	c-Met receptor tyrosine kinase inhibitor	Hepatic cancer	PO	InTrial	Late 2017	Y	N
HP802-247	HP802-247	Healthpoint Biotherapeutics	allogeneic neonatal keratinocytes and fibroblasts	Venous leg ulcer	TOP	InTrial	Late 2017	Y	N
anamorelin	anamorelin	Helsinn/Novo Nordisk	growth hormone secretagogue receptor (GHSR) agonist	Anorexia/Cachexia (cancer-related)	PO	FastTrk/ Breakthru	Late 2017	Y	N
lubiprostone	lubiprostone	Takeda/Sucampo	chloride channel activator	Constipation	PO	InTrial	Late 2017	N	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
NBI-56418	elagolix	Abbott/Neurocrine Biosciences	gonadotropin-releasing hormone (GnRH) receptor antagonist	Endometriosis/Menstrual bleeding	PO	InTrial	Late 2017	N	N
CYT-387	momelotinib	Gilead	janus associated kinase (JAK) inhibitor	Myeloproliferative disorders/Pancreatic cancer	PO	InTrial	Late 2017	Y	Y
VivaGel	astodimer sodium (SPL-7013)	Starpharma	viral attachment inhibitor	Bacterial infections	VG	FastTrk/Breakthru	Late 2017	N	N
CEM-101	solithromycin	Cempra	macrolide	Bacterial infections	IV/PO	CRL	Late 2017	N	N
midazolam (USL-261)	midazolam (USL-261)	Upsher-Smith	benzodiazepine	Seizures	Intranasal	FastTrk/Breakthru	Late 2017	N	Y
quizartinib	quizartinib	Ambit Biosciences	FLT-3 receptor tyrosine kinase inhibitor	Acute myeloid leukemia (AML)	PO	InTrial	Late 2017	Y	N
moxetumomab pasudotox	moxetumomab pasudotox	MedImmune	CD22 antigen inhibitor	Hairy cell leukemia	IV	InTrial	Late 2017	Y	Y
HyperAcute Lung	tergenpantucel-L (turgempumatucel-L, tergenpumatucel-L)	NewLink Genetics	immunotherapy	Non-small cell lung cancer (NSCLC)	IV	InTrial	Late 2017	Y	N
Lutathera	[177]Lutetium-DOTA[0]-Tyr[3]-Octreotate (177-Lu-Dotatate)	Advanced Accelerator Applications	somatostatin receptor agonist	Gastroenteropancreatic neuroendocrine tumors	INJ	CRL	Late 2017	Y	Y
Hepacid	ADI-PEG-20	Polaris	pegylated arginine deiminase	Hepatic cancer	IM	InTrial	Late 2017	Y	Y
glufosfamide	glufosfamide	Threshold Pharmaceuticals/ Eleison	alkylating agent	Pancreatic cancer	IV	FastTrk/Breakthru	Late 2017	Y	Y
somatropin	somatropin	Opko/Pfizer	enzyme replacement	Growth hormone deficiency/Small for gestational age (SGA)	SC	InTrial	Late 2017	Y	Y

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
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	Late 2017	Y	N
Epidiolex	cannabidiol	GW Pharmaceuticals	cannabinoid product	Seizures	PO	FastTrk/ Breakthru	Late 2017	Y	Y
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 2017	Y	N
NER-1006	NER-1006	Norgine	polyethylene glycol-based preparation	Bowel preparation	PO	InTrial	Late 2017	N	N
Carbavance	meropenem/RPX-7009	Medicines Company	carbapenem/beta-lactamase inhibitor	Bacterial infections	IV	FastTrk/ Breakthru	Late 2017	N	N
VS-EBOV (rVSV-EBOV; rVSV-ZEBOV)	VS-EBOV (rVSV-EBOV; rVSV-ZEBOV)	Merck/NewLink Genetics	vaccine	Ebola	IM	InTrial	Late 2017	Y	N
CNS-7056 (ONO-2745)	remimazolam	Paion	benzodiazepine	Procedural sedation	IV	InTrial	Late 2017	Y	N
Deltyba	delamanid	Otsuka	mycolic acid biosynthesis inhibitor	Tuberculosis	PO	InTrial	Late 2017	N	N
rilpivirine/dolutegravir	rilpivirine/dolutegravir	GlaxoSmithKline/J&J	non-nucleoside reverse transcriptase inhibitor (NNRTI)/Integrase strand transfer inhibitor (ISTI)	Human immunodeficiency virus (HIV)	PO	InTrial	Late 2017	Y	N
exenatide	exenatide	AstraZeneca/ Alkermes/Bristol-Myers Squibb/Eli Lilly	glucagon-like peptide-1 (GLP-1) receptor agonist	Diabetes mellitus	SC	InTrial	Late 2017	N	N
Primatene HFA	epinephrine	Amphastar	catecholamine	Asthma	INH	CRL	Late 2017	N	N
APL-130277	apomorphine	Sumitomo Dainippon/MonoSol Rx	non-ergoline dopamine agonist	Parkinson's disease	PO/SL	FastTrk/ Breakthru	Late 2017	N	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
ACE-910 (RG-6013, hBS-910, RO-5534262)	emicizumab	Roche/Chugai	factor IXa/factor X bi-specific antibody	Hemophilia	SC	FastTrk/ Breakthru	Late 2017	Y	Y
TX-001HR (TX-12-001HR)	estradiol/progesterone	TherapeuticsMD	estrogen receptor agonist/progesterone receptor agonist	Menopause	PO	InTrial	Late 2017	N	N
Seciera (OTX-101)	cyclosporine	Auven Therapeutics	immunosuppressant	Dry eyes	TOP	InTrial	Late 2017	Y	N
TLE-400	tenofovir disoproxil fumarate/lamivudine/efavirenz	Mylan	nucleoside reverse transcriptase inhibitor (NRTI)/NRTI/non-nucleoside reverse transcriptase inhibitor (NNRTI)	Human immunodeficiency virus (HIV)	PO	InTrial	Late 2017	Y	N
Makena	hydroxyprogesterone caproate	Lumara Health	progestin	Preterm labor	SC	InTrial	Late 2017	Y	Y
SEP-225289 (DSP-225289, SEP-289)	dasotraline	Sumitomo Dainippon/Sunovion	triple reuptake inhibitor	Attention deficit hyperactivity disorder (ADHD)/Eating disorders	PO	InTrial	Late 2017	N	N
EZN-2285	calaspargase pegol	Baxalta	enzyme therapy	Acute lymphocytic leukemia (ALL)	IM/IV	InTrial	Late 2017	Y	N
RBP-6000	buprenorphine depot	Indivior/QLT	opioid receptor agonist (partial)	Drug addiction	SC	FastTrk/ Breakthru	Late 2017	Y	N
TNX-355 (TMB-355, Hu-5A8)	ibalizumab	Biogen/Roche/ TaiMed	viral entry inhibitor	Human immunodeficiency virus (HIV)	IM/IV/SC	FastTrk/ Breakthru	Late 2017	Y	Y
human plasminogen	human plasminogen	ProMetic/Hematech	plasminogen	Plasminogen deficiency	IV	Filed BLA	Late 2017	Y	Y
ursodeoxycholic acid	ursodeoxycholic acid	Retrophin/Asklepiion	bile acid derivative	Primary biliary cirrhosis/cholangitits	PO	InTrial	Late 2017	Y	N
tamsulosin DRS	tamsulosin DRS	Female Health/Aspen	alpha-adrenergic antagonist	Benign prostatic hyperplasia (BPH)	PO	InTrial	Late 2017	N	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Opsiria	sirolimus	Santen	mammalian target of rapamycin (mTOR) inhibitor	Uveitis	Intraocular/ Subretinal/PO/ Topical	InTrial	Late 2017	Y	Y
Zilretta	triamcinolone acetonide	Flexion	corticosteroid	Osteoarthritis	Intra-articular	Filed NDA	10/12/2017	Y	N
Vibex QST (QuickShot Testosterone)	testosterone	Antares	androgen	Hypogonadism	SC	Filed NDA	10/22/2017	N	N
Cinvanti	aprepitant	Heron Therapeutics	neurokinin-1 (NK1) receptor antagonist	Nausea and vomiting (N/V)	IV	Filed NDA	11/12/2017	N	N
semaglutide	semaglutide	Novo Nordisk	glucagon-like peptide-1 (GLP-1) receptor agonist	Diabetes	SC/PO	Filed NDA	12/5/2017	Y	N
2018 Possible launch date									
PF-00299804	dacomitinib	Pfizer	pan-HER inhibitor	Non-small cell lung cancer (NSCLC)	PO	InTrial	2018	Y	N
MLN-8237	alisertib	Millennium	aurora kinase A inhibitor	Ovarian cancer/Non-Hodgkin's lymphoma (NHL)/Small cell lung cancer (SCLC)/Breast cancer/Peripheral T-cell lymphoma	PO	InTrial	2018	Y	Y
Xinlay	atrasentan	AbbVie	selective endothelin-A receptor antagonist	Diabetic nephropathy	PO	InTrial	2018	Y	N
scyllo-cyclohexanehexol (ELND-005, D-5, D-005, AZD-103, scylloinositol)	scyllo-cyclohexanehexol (ELND-005, D-5, D-005, AZD-103, scylloinositol)	Transition Therapeutics/Perrigo	beta-amyloid (Abeta) oligomerization inhibitor	Alzheimer's disease/Down's syndrome	PO	InTrial	2018	N	N
arimoclolomol	arimoclolomol	CytRx	cytoprotectives	Niemann-Pick Disease (NPD)/Amyotrophic lateral sclerosis (ALS)	PO	FastTrk/ Breakthru	2018	Y	Y
Tarvacin	bavituximab	Peregrine	phosphatidylserine receptor antagonist	Non-small cell lung cancer (NSCLC)	IV	FastTrk/ Breakthru	2018	Y	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Zybrestat	combretastatin A4 phosphate (fosbretabulin tromethamine)	OXIGENE	vascular targeting agent (VTA)	Ovarian cancer/ Neuroendocrine tumors (NET)/Glioma	IV	FastTrk/ Breakthru	2018	Y	Y
PREOB	bone marrow-derived mesenchymal stem cell therapy	Bone Therapeutics	stem cell therapy	Fracture/Bone necrosis	Intraosseus	InTrial	2018	Y	N
JNJ-56021927 (ARN-509, JNJ-927)	apalutamide	Janssen	androgen receptor antagonist	Prostate cancer	PO	InTrial	2018	N	N
GRN-163L	imetelstat	Geron/Johnson & Johnson	telomerase inhibitor	Myelofibrosis (MF)/ Myelodysplastic syndrome (MDS)/Acute myelogenous leukemia (AML)	IV	InTrial	2018	Y	Y
DSC-127 (USB-001, NorLeu-3-A(1-7))	aclerastide	Derma Sciences	angiotensin II analog	Diabetic foot ulcers	TOP	InTrial	2018	N	N
KAE-609	cipargamin	Novartis	protein synthesis inhibitor	Malaria	PO	InTrial	2018	N	N
LCI-699	osilodrostat	Novartis	aldosterone synthase inhibitor	Cushing's syndrome	PO	InTrial	2018	N	Y
TRV-130	oliceridine	Trevena	opioid receptor agonist	Pain	IV	FastTrk/ Breakthru	2018	N	N
UX-003 (rhGUS)	beta-glucuronidase (recombinant)	Ultragenyx	enzyme replacement	Mucopolysaccharidosis VII (MPS-VII)	IV	InTrial	2018	Y	Y
IVIG	IVIG	Prometic	immune globulin	Primary immunodeficiency	IV	InTrial	2018	Y	N
ALKS-8700 (RDC-1559)	ALKS-8700 (RDC-1559)	Alkermes	prodrug	Multiple sclerosis (MS)	PO	InTrial	2018	Y	N
MabThera	rituximab	Roche/Halozyme	CD20 antigen monoclonal antibody	Chronic lymphocytic leukemia (CLL)/ Non-Hodgkin lymphoma (NHL)/Diffuse large B-cell lymphoma (DLBCL)	SC	Filed BLA	2018+	Y	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
PSD-502	lidocaine/prilocaine	Plethora/Sciele	sodium channel blocker	Premature ejaculation	TOP	InTrial	1Q2018	N	N
Pulmaquin	ciprofloxacin	Aradigm/Grifols	fluoroquinolone	Cystic fibrosis/Non-cystic fibrosis bronchiectasis	INH	FastTrk/ Breakthru	1Q2018	Y	Y
IMMU-132	sacituzumab govitecan	Immunomedics	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	1Q2018	Y	Y
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	1Q2018	Y	Y
ZTlido	lidocaine	Scilex	sodium channel blocker	Postherpetic neuralgia (PHN)	TOP	CRL	1Q2018	N	N
KIT-302	celecoxib/amlodipine	Kitov	nonsteroidal anti-inflammatory drug (NSAID)/calcium channel blocker (CCB)	Hypertension/Osteoarthritis	PO	InTrial	1Q2018	N	N
Rova-T	rovalpituzumab tesirine	AbbVie	anti-DLL3 monoclonal antibody	Small cell lung cancer (SCLC)	IV	InTrial	1Q2018	Y	Y
IDP-118	tazarotene/halobetasol	Valeant	retinoid/corticosteroid	Psoriasis	TOP	InTrial	1Q2018	N	N
selumetinib	selumetinib	AstraZeneca	selective MEK kinase inhibitor	Non-small cell lung cancer (NSCLC)/Thyroid cancer/Uveal melanoma	PO	InTrial	2Q2018	Y	Y
RPC-1063	ozanimod	Receptos	sphingosine-1-phosphate	Multiple sclerosis/Ulcerative	PO	InTrial	2Q2018	Y	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
			receptor 1 (SP-1) modulator	colitis (UC)					
MK-8228	letermovir	Merck	quinazoline	Cytomegalovirus (CMV)	IV/PO	FastTrk/ Breakthru	2Q2018	N	Y
Zoptrex	zoptarelin doxorubicin	Aeterna Zentaris	anthracycline derivative	Endometrial cancer	IV	InTrial	2Q2018	Y	N
Iomab-B	anti-CD45 monoclonal-antibody BC8-I-131	Actinium	anti-CD45 monoclonal antibody	Acute myeloid leukemia (AML)/Myelodysplastic syndrome (MDS)	IV	InTrial	2Q2018	Y	Y
CK-2017357 (CK-357)	tirasemtiv	Cytokinetics	troponin activator	Amyotrophic lateral sclerosis (ALS)	PO	FastTrk/ Breakthru	2Q2018	Y	Y
ropeginterferon alfa-2b	ropeginterferon alfa-2b	PharmaEssentia/AO P Orphan	interferon	Polycythemia vera (PV)/ Myelofibrosis (MF)/Essential thrombocythemia (ET)	SC	InTrial	1H2018	Y	Y
Twirla	ethinyl estradiol/levonorgestrel	Agile Therapeutics	hormonal combination contraceptive	Pregnancy	TOP	CRL	1H2018	N	N
RayVa (Vitaros)	alprostadil	Actavis/Apicus	prostaglandin (PG) receptor agonist	Erectile dysfunction	TOP	CRL	Mid-2018	N	N
CMX001	brincidofovir hexadecyloxypropyl ester	Chimerix	DNA-directed DNA polymerase inhibitor	Adenovirus/Cytomegalovirus (CMV)	PO	FastTrk/ Breakthru	Mid-2018	N	N
BAY-41-6551	amikacin	Nektar/Bayer	aminoglycoside	Bacterial infections	INH	FastTrk/ Breakthru	Mid-2018	Y	Y
Multikine	Leukocyte Interleukin (CS-001P3)	CEL-SCI	immunomodulator	Head and Neck cancer/ Squamous cell carcinoma	SC	InTrial	Mid-2018	Y	Y
AGB-101	levetiracetam	AgeneBio	synaptic vesicle protein modulator	Alzheimer's disease	PO	InTrial	Mid-2018	N	N
S-649266	cefiderocol	Shionogi/GlaxoSmith Kiline	cephalosporin antibiotic	Bacterial infections	IV	InTrial	Mid-2018	Y	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
XaraColl	bupivacaine implant	Innocoll	sodium channel blocker	Pain	implant	CRL	Mid-2018	Y	N
ND-0612H	levodopa/carbidopa	NeuroDerm	dopamine precursor/ dopa-decarboxylase inhibitor	Parkinson's disease (PD)	SC	InTrial	Mid-2018	Y	N
Trevyent	trevyent	SteadyMed	prostacyclin analog	Pulmonary arterial hypertension (PAH)	SC	InTrial	Mid-2018	Y	Y
N-1539	meloxicam	Recro Pharma/Alkermes	nonsteroidal anti-inflammatory drug (NSAID)	Post-surgical pain	IV	InTrial	Mid-2018	Y	N
CAM-2038	buprenorphine	Camurus/Braeburn	opioid receptor agonist (partial)	Opioid dependence/Pain	SC	FastTrk/ Breakthru	Mid-2018	Y	N
Feraccru (ferric iron, ST-10, ST10-021)	ferric trimaltol	Shield Therapeutics/AOP Orphan Pharma	iron replacement	Anemia/Irritable bowel syndrome (IBS)	PO	InTrial	Mid-2018	N	N
PRO-140	PRO-140	CytoDyn	C-C chemokine receptor 5 (CCR5) antagonist	Human immunodeficiency virus (HIV)	IV/SC	FastTrk/ Breakthru	2H2018	Y	N
Semprana	dihydroergotamine mesylate (DHE)	MAP Pharmaceuticals/Allergan	dihydroergotamine	Headache	INH	InTrial	2H2018	N	N
Macrilen	macimorelin acetate	Aeterna Zentaris	ghrelin agonist	Growth hormone deficiency	PO	CRL	2H2018	Y	Y
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-associated diarrhea (CDAD)	PO	FastTrk/ Breakthru	2H2018	N	N
LMTX	methylthionium	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
RGN-259 (GBT-201;	thymosin beta 4	RegeneRx	actin regulating peptide	Neurotrophic keratitis	TOP	InTrial	2H2018	N	Y

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
RGN-352)				(NK)/Dry eyes					
BAY94-9027	damoctocog alfa pegol	Bayer	anithemophilic factor	Hemophilia	IV	InTrial	2H2018	Y	N
plazomicin	plazomicin	Achaogen/Ionis	next-generation aminoglycoside	Bacterial infections	IV	InTrial	2H2018	Y	N
iclaprim	iclaprim	Roche/Evolva SA	tetrahydrofolate dehydrogenase inhibitor	Bacterial infections	IV	FastTrk/ Breakthru	2H2018	Y	N
SPI-2012	SPI-2012	Spectrum	granulocyte colony-stimulating factor (GCSF)	Neutropenia	SC	InTrial	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
Esmya	ulipristal acetate	Actavis (Allergan)	selective progesterone receptor modulator (SPRM)	Uterine bleeding	PO	InTrial	2H2018	N	N
ivacaftor/tezacaftor	ivacaftor/tezacaftor	Vertex	corrector ion channel modulator	Cystic fibrosis	PO	InTrial	2H2018	Y	Y
LY-573144 (COL-144)	lasmiditan	CoLucid/III dong/ Eli Lilly	neurally Acting Anti-Migraine Agent (NAAMA)	Headache	PO	InTrial	2H2018	Y	N
ALN-TTR02 (GENZ438027, SAR438027)	patisiran	Alnylam/Ionis/ Sanofi/Tekmira	RNAi therapeutic	Polyneuropathy	IV	InTrial	2H2018	Y	Y
DS-5565	mirogabalin	Daiichi Sankyo	gamma-aminobutyric acid (GABA)-ergic analog	Fibromyalgia/Diabetic neuropathic pain (DNP)	PO	InTrial	2H2018	N	N
DRM-04B	DRM-04B	Dermira	anticholinergic	Hyperhidrosis	TOP	InTrial	2H2018	N	N
P-005672 (P-0005672,	sarecycline	Allergan/Paratek	tetracyclines	Acne vulgaris	PO	InTrial	2H2018	N	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
WC-3035)									
JCAR-015	anti-CD19-CD28-zeta modified CAR CD3+ T lymphocyte therapy	Juno/Celgene	chimeric antigen receptor (CAR) T cell therapy	Acute lymphocytic leukemia (ALL)	IV	FastTrk/ Breakthru	2H2018	Y	Y
ALXN-1210	ALXN-1210	Alexion	C-5 monoclonal antibody	Paroxysmal nocturnal hemoglobinuria (PNH)/Hemolytic uremic syndrome (HUS)	IV	InTrial	2H2018	Y	Y
ADX-N05 (ARL-N05, JZP-110, SKL-N05)	ADX-N05 (ARL-N05, JZP-110, SKL-N05)	Jazz Pharmaceuticals/ Aerial BioPharma	phenylalanine derivative	Narcolepsy	PO	InTrial	3Q2018	N	Y
RBP-7000	risperidone	Indivior/Reckitt Benckiser	atypical antipsychotic	Schizophrenia	SC	InTrial	2H2018	Y	N
RVT-101 (GSK-742457, SB-742457)	intepirdine	Avoxant	5HT-6 receptor antagonist	Alzheimer's disease	PO	InTrial	3Q2018	N	N
S-033188 (RG-6152)	S-033188 (RG-6152)	Shionogi/Roche/	endonuclease inhibitor	Influenza	PO	InTrial	3Q2018	N	N
IPI-145 (INK-1197)	duvelisib	AbbVie/Infinity	phosphatidylinositol 3 kinase inhibitor	Chronic lymphocytic leukemia (CLL)/Non-Hodgkin lymphoma (NHL)	PO	InTrial	3Q2018	N	Y
CLS-1001 (CLS-1003, CLS-TA)	triamcinolone acetonide	Clearside	corticosteroid	Uveitis	intraocular/ subretinal	InTrial	3Q2018	Y	N
Roclatan	latanoprost/netarsudil mesylate	Aerie	prostaglandin agonist/rho kinase-norepinephrine transport protein inhibitor	Glaucoma/Ocular hypertension	TOP	InTrial	3Q2018	N	N
anacetrapib	anacetrapib	Merck	cholesterol ester transfer protein (CETP) inhibitor	Atherosclerosis/ Hyperlipidemia	PO	InTrial	4Q2018	N	N
Remoxy	oxycodone	Pain Therapeutics	mu-opioid receptor agonist	Pain	PO	CRL	4Q2018	N	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
esketamine	esketamine	Janssen	NMDA receptor antagonist	Major depressive disorder (MDD)	Intranasal	FastTrk/ Breakthru	2018	N	N
ALKS-3831	olanzapine/samidorphan	Alkermes	dopamine receptor antagonist/opioid receptor antagonist	Schizophrenia	PO	InTrial	4Q2018	N	N
VRS-317 (hGH-XTEN)	somavaratan	Versartis/Amunix	growth hormone analog	Short stature/Growth hormone deficiency	SC	InTrial	4Q2018	Y	Y
PW-4142 (T-111)	nalbuphine ER	Trevi Therapeutics/Endo	opioid agonist/antagonist	Prurigo nodularis	PO	InTrial	4Q2018	N	N
TD-4208 (GSK-1160724)	revefenacin	Theravance Biopharma/Mylan	muscarinic antagonist	Chronic obstructive pulmonary diseaser (COPD)	INH	InTrial	4Q2018	N	N
FMX-101 (ARK-E021)	minocycline	Foamix	tetracyclines	Acne vulgaris/Rosacea	TOP	InTrial	4Q2018	N	N
DX-2930	DX-2930	Dyax	kallikrein inhibitor	Hereditary angioedema (HAE)	SC	FastTrk/ Breakthru	Late 2018	Y	Y
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
tozadenant	tozadenant	Roche/UCB	selective adenosine A2a receptor antagonist	Parkinson's disease	PO	InTrial	Late 2018	Y	N
aclidinium/ formoterol	aclidinium/formoterol	AstraZeneca/Actavis	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
eravacycline	eravacycline	Tetraphase Pharmaceuticals	fully synthetic tetracycline antibiotic	Bacterial infections	IV/PO	FastTrk/ Breakthru	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
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
aldoxorubicin	aldoxorubicin	CytRx	anthracycline derivative	Soft tissue sarcoma	IV	InTrial	Late 2018	Y	Y
AMG-334	erenumab	Amgen	calcitonin gene-related peptide (CGRP) antagonist	Headache	SC	InTrial	Late 2018	Y	N
CAT-354	tralokinumab	AstraZeneca	interleukin-13 (IL-13) inhibitor	Asthma/Idiopathic pulmonary fibrosis	SC	InTrial	Late 2018	Y	Y
ublrituximab	ublrituximab	TG Therapeutics	CD-20 monoclonal antibody	Chronic lymphocytic leukemia (CLL)/Small cell lymphocytic lymphoma (SLL)/Mantle cell lymphoma (MCL)/Multiple sclerosis	IV	InTrial	Late 2018	Y	Y
TNX-102 SL	cyclobenzaprine	Tonix/Vela	muscle relaxant	Post-traumatic stress disorder (PTSD)	PO/SL/Transmucosal	FastTrk/ Breakthru	Late 2018	N	N
PT-141	bremelanotide	Palatin	melanocortin type 4 receptor agonist	Female sexual disorder	SC	InTrial	Late 2018	Y	N
Brabafen	fenfluramine	Zogenix	serotonin receptor agonist	Dravet syndrome	PO	FastTrk/ Breakthru	Late 2018	Y	Y
Apadaz	benzhydrocodone/acetaminophen	KemPharm	opioid receptor agonist	Pain	PO	CRL	Late 2018	N	N
TEV-48125	TEV-48125	Teva	calcitonin gene-related peptide (CGRP) antagonist	Headache	SC	InTrial	Late 2018	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

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
SAGE-547	allopregnanolone	SAGE/Ligand	gamma aminobutyric acid-A (GABA-A) receptor allosteric modulator	Seizures/Postpartum depression	IV	FastTrk/ Breakthru	Late 2018	Y	Y
Viaskin Peanut	Viaskin Peanut	DBV Technologies	immnotherapy	Peanut allergy	TOP	FastTrk/ Breakthru	Late 2018	Y	N
BC-3781	lefamulin	Nabriva Therapeutics	pleuromutilins	Bacterial infections	IV/PO	FastTrk/ Breakthru	Late 2018	Y	N
STS	sodium thiosulfate	Fennec	reducing agent	Hearing loss	IV	InTrial	Late 2018	Y	Y
OTO-104	dexamethasone sustained-release	Otonomy	corticosteroid	Meniere's disease	Intratympanic	FastTrk/ Breakthru	Late 2018	Y	N
AR-101 (AR101)	AR-101 (AR101)	Aimmune	peanut protein capsule	Peanut allergy	PO	FastTrk/ Breakthru	Late 2018	Y	N
LY-2951742	galcanezumab	Eli Lilly/Arteaus	calcitonin gene-related peptide (CGRP) antagonist	Headache	SC	FastTrk/ Breakthru	Late 2018	Y	N
PTK-0796 (MK-2764, BAY-73-7388, BAY-73-6944)	omadacycline	Paratek	aminomethylcyclines (AMC)	Bacterial infections	IV/PO	FastTrk/ Breakthru	Late 2018	N	N
Pollinex Quattro Grass (MPL-103, Ragweed MATA MPL)	birch pollen allergen extract	Allergy Therapeutics/Endo/ GSK/Teva	vaccine	Allergic rhinitis	SC	InTrial	Late 2018	Y	N
ALD-403	ALD-403	Alder	calcitonin gene-related peptide (CGRP) antagonist	Headache	IV/SC	InTrial	Late 2018	Y	N
PRX-102	alpha galactosidase	Protalix	enzyme replacement	Fabry's disease	IV	InTrial	Late 2018	Y	N
Arestvyr	tecovirimat	SIGA Technologies/ PharmAthene	antiviral	Smallpox	IV/PO	FastTrk/ Breakthru	Late 2018	Y	Y
QVM-149	indacaterol/glycopyrronium bromide/mometasone furoate	Novartis/Sosei	long-acting beta 2 adrenergic receptor agonist (LABA)/long-acting muscarinic receptor	Asthma	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
			antagonist (LAMA)/ corticosteroid						
RTH-258 (ESBA-1008, DLX-1008)	brolocizumab	Novartis/Delenex	anti-VEGF antibody	Macular degeneration	Intraocular/ Subretinal/ Subconjunctival	InTrial	Late 2018	Y	N
GDC-0032 (RG7604)	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
DFN-02 (DFP-02)	DFN-02 (DFP-02)	Dr. Reddy's Laboratories	triptans	Headache	Intranasal	InTrial	Late 2018	N	N
AM-111 (D-JNKI-1, XG-102)	AM-111 (D-JNKI-1, XG-102)	Xigen/Auris Medical	JNK stress kinase inhibitor	Hearing loss/Ocular inflammation	Intratympanic/ Intraocular	InTrial	Late 2018	Y	Y
KP-415	D-threo-methylphenidate controlled-release	KemPharm	CNS stimulant	Attention deficit hyperactivity disorder (ADHD)	PO	InTrial	Late 2018	N	N
SA-237 (RG-6168)	SA-237 (RG-6168)	Roche/Chugai	interleukin-6 (IL-6) monoclonal antibody	Neuromyelitis optica	SC	InTrial	Late 2018+	Y	Y
LOXO-101	larotrectinib	Loxo Oncology	tyrosine kinase inhibitor	Solid tumors/Sarcoma	PO	FastTrk/ Breakthru	Late 2018	Y	Y
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)	IV/PO	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
lopinavir/ritonavir	lopinavir/ritonavir	Cipla	HIV-1 protease inhibitor/CYP3A4 inhibitor	Human immunodeficiency virus (HIV)	PO	Tentative Approval	Late 2018	Y	N
SHP-621	budesonide	Shire	corticosteroid	Eosinophilic esophagitis	PO	FastTrk/ Breakthru	2018 - 2019	Y	Y

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
2019 Possible launch date									
azacitidine	azacitidine	Celgene	DNA methylation inhibitor	Acute myleoid leukemia (AML)/Myelodysplastic syndromes	PO	FastTrk/ Breakthru	2019	Y	Y
ACAM-CDIFF	Clostridium difficile toxoid vaccine	Sanofi Pasteur	vaccine	Clostridium difficile infection (CDI)	IM	FastTrk/ Breakthru	2019	Y	N
ALS-8176 (ALS-008176, JAL-8176)	ALS-8176 (ALS-008176, JAL-8176)	Johnson & Johnson	RSV polymerase inhibitor	Respiratory syncytial virus (RSV)	PO	InTrial	2019	N	N
JNJ-42756493 (JNJ-493)	JNJ-42756493 (JNJ-493)	Johnson & Johnson/ Otsuka	pan-fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitor	Urothelial cancer	PO	InTrial	2019	Y	N
PLX108-01 (PLX-3397)	pexidartinib	Daiichi Sankyo	selective macrophage colony stimulating factor 1 receptor inhibitor	Pigmented Villonodular Synovitis	PO	FastTrk/ Breakthru	2019	N	Y
FG-4592 (ASP-1517)	roxadustat	FibroGen/Astellas/ AstraZeneca	hypoxia-inducible factor prolyl hydroxylase (HIF-PHI)	Anemia	PO	InTrial	Mid-2019	Y	N
ND-0612L	levodopa/carbidopa	NeuroDerm	dopamine precursor/ dopa-decarboxylase inhibitor	Parkinson's disease	SC	InTrial	Mid-2019	Y	N
atazanavir/ritonavir	atazanavir/ritonavir	Emcure	protease inhibitor	HIV	PO	Tentative Approval	unknown	Y	N
BC	sodium sulfate/potassium sulfate/magnesium sulfate	Gator Pharma	osmotic laxative bowel prep	Bowel preparation	PO	Tentative Approval	unknown	N	N
lamivudine /tenofovir disoproxil fumarate /nevirapine	lamivudine /tenofovir disoproxil fumarate/ nevirapine	Aurobindo, Matrix Labs, Hetero Labs	NRTI/NRTI/NNRTI	HIV	PO	Tentative Approval	unknown	Y	N
lamivudine /tenofovir	lamivudine/tenofovir	Ranbaxy	NRTI/NRTI	HIV	PO	Tentative	unknown	Y	N

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
disoproxil fumarate	disoproxil fumarate					Approval			
EP-3101	bendamustine RTD	Eagle Pharmaceuticals	alkylating agent	Chronic lymphocytic leukemia (CLL)/indolent B-cell non-Hodgkin's lymphoma (NHL).	IV	Tentative Approval	unknown	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



The information contained herein is compiled from various sources and is provided for informational purposes only. Due to factors beyond the control of OptumRx, information related to prospective drug launches is subject to change without notice. This information should not be solely relied upon for formulary decision-making purposes.

OptumRx specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at optum.com.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners. This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxOutlook® is published by the OptumRx Clinical Services Department.

© 2017 Optum, Inc. All rights reserved. ORX6204A_160128