OPTUMRx®

RxOutlook®

3rd Quarter 2019

Welcome to RxOutlook®, the OptumRx quarterly report summarizing the latest pipeline drug information, trend news, upcoming generic launches, and emerging therapies in today's pharmaceutical market.

This edition focuses on twelve near-term pipeline drugs that are expected to receive an FDA approval decision by the end of 2019, with an emphasis on the 4th quarter. These drugs are notable because of their potential for clinical impact, economic impact, or public health interest. This edition is a slight departure from previous issues because many of the highlighted drugs are intended for mainstream conditions affecting large populations, whereas previous issues focused on rare conditions and orphan drugs, many of which were specialty drugs.

Eight drugs in this issue will be available as oral formulations while four could be covered under the medical benefit due to their route of administration (eg, intraocular injection, implant). The central nervous system therapeutic category is featured very prominently with five drugs including two new treatments for acute migraine headache, a condition that has not seen a new mechanism of action in two decades. Migraine headache is an area that will continue to see ongoing development activity in 2020. Finally, many of the drugs included in this report are entering therapeutic areas with multiple existing treatment options, including generic alternatives. Understanding the defining characteristics of these pipeline drugs will be vital to identifying their potential place in therapy and recognizing what questions remain to be answered.

Key pipeline drugs with FDA approval decisions expected by the end of the 4th quarter 2019

Drug Name	Manufacturer	Indication/Use	Expected FDA Decision Date
Darolutamide	Bayer	Prostate cancer	7/30/2019 (Approved)
Fedratinib	Celgene	Primary or secondary myelofibrosis*	8/16/2019 (Approved)
Tenapanor	Ardelyx	Irritable bowel syndrome with constipation	9/13/2019
Diroximel fumarate	Alkermes/Biogen	Multiple sclerosis	10/17/2019
Brolucizumab	Novartis	Neovascular age-related macular degeneration	11/2019
Lasmiditan	Eli Lilly	Acute migraine headache	11/14/2019
Ubrogepant	Allergan	Acute migraine headache	12/2019
RVT-802	Enzyvant/Roivant	Congenital athymia*	12/2019
Luspatercept	Celgene/Acceleron	Beta-thalassemia*; myelodysplastic syndromes (MDS)*	12/4/2019 (beta-thalassemia)
Lemborexant	Eisai/Imbrium Therapeutics	Insomnia	12/27/2019
Lumateperone	Intra-Cellular Therapies	Schizophrenia	12/27/2019
Cabotegravir/ rilpivirine	ViiV Healthcare	HIV-1 infection	12/29/2019

* Orphan Drug Designation

OptumRx closely monitors and evaluates the drug development pipeline to identify noteworthy upcoming drug approvals and reports the essential findings here in RxOutlook. The report is organized in in the following manner:

Detailed Drug Insights

This section reviews the important characteristics (eg, therapeutic use, clinical profile, competitive environment and regulatory timeline) for key pipeline drugs with potential FDA approvals by the end of the 4th quarter.

Read more

Extended Generic Pipeline Forecast

This section provides a summary of upcoming first-time generic drugs and biosimilars that may be approved in the upcoming two years.

Read more

Extended Brand Pipeline Forecast

This table provides a summary of developmental drugs, including both traditional and specialty medications that may be approved in the upcoming two years.

Read more

Key Pending Indication Forecast

This table provides a summary of key new indications that are currently under review by the FDA and may be approved in the upcoming 12 months.

Read more

Past and future reviews

Please note that RxOutlook highlights select near-term approvals. Some drugs may not appear in this issue because they have been reviewed in previous editions of RxOutlook. Drugs of interest that are earlier in development or with expected approvals beyond 4th quarter 2019 may appear in future reports; however, for those who need an initial look at the full pipeline, please refer to the Brand Pipeline Forecast Table found later in this report.

Drugs reviewed in detail in the 1Q:2019 and 2Q:2019 report:

- Afamelanotide
- Celiprolol (Edsivo™)
- Dolutegravir/lamivudine (Dovato®)
- Entrectinib
- Esketamine (Spravato™)
- Golodirsen
- Mannitol (inhaled formulation)
- Metoclopramide (Gimoti™)
- NKTR-181
- Onasemnogene abeparvovec (Zolgensma®)
- Pexidartinib
- Pitolisant
- Polatuzumab vedotin
- Quizartinib
- Risankizumab (Skyrizi™)
- Selinexor (Xpovio™)
- Semaglutide (oral formulation)
- Tafamidis (Vyndaqel®) and tafamidis meglumine (Vyndamax®)
- Upadacitinib

Past issues of RxOutlook can be found at https://professionals.optumrx.com/publications.html.

Getting acquainted with pipeline forecast terms

Clinical trial phases

Phase I trials	Researchers test an experimental drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
Phase II trials	The experimental study drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
Phase III trials	The experimental study drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.
Phase IV trials	Post marketing studies delineate additional information including the drug's risks, benefits, and optimal use.

Pipeline acronyms

ANDA	Abbreviated New Drug Application
BLA	Biologic License Application
CRL	Complete Response Letter
FDA	Food and Drug Administration
MOA	Mechanism of Action
NME	New Molecular Entity
NDA	New Drug Application
sBLA	Supplemental Biologic License Application
sNDA	Supplemental New Drug Application
OTC Drugs	Over-the-Counter Drugs
PDUFA	Prescription Drug User Fee Act
REMS	Risk Evaluation and Mitigation Strategy

Detailed insights on key drugs

Darolutamide (Brand Name: Nubeqa®)

Manufacturer: Bayer/Orion
Regulatory designations: Fast Track
FDA approval date: 7/30/2019 *(approved ahead of originally anticipated approval date)*

Therapeutic use

- Treatment of patients with nmCRPC

Darolutamide was approved for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC).

Prostate cancer is the third most commonly diagnosed malignancy in the U.S. In 2019, it is estimated that there will be 174,650 new cases of prostate cancer and an estimated 31,620 people will die of the disease.

CRPC is an advanced form of the disease where the cancer keeps progressing even when the amount of testosterone is reduced to very low levels in the body. Most men with advanced prostate cancer eventually stop responding to androgen deprivation therapy (ie, castration) and require additional therapy when prostate specific antigen (PSA) levels begin to rapidly rise.

Clinical profile

- Androgen receptor inhibitor
- Oral formulation
- Median MFS: 40.4 months vs. 18.4 months for placebo ($p < 0.0001$)
- Common AEs: fatigue, pain in extremity, rash
- Dosing: twice a day

Darolutamide is an androgen receptor inhibitor with a distinct chemical structure that competitively inhibits androgen binding, androgen receptor nuclear translocation, and androgen receptor-mediated transcription. Darolutamide decreased prostate cancer cell proliferation in vitro and tumor volume in mouse xenograft models of prostate cancer.

Pivotal trial data:
Darolutamide was evaluated in a double-blind, placebo-controlled, randomized study (ARAMIS) in 1,509 patients with nmCRPC. All patients received a gonadotropin-releasing hormone analog (GnRH) concurrently or had a bilateral orchiectomy. The major efficacy endpoint was metastasis free survival (MFS). The median MFS was 40.4 months for darolutamide-treated patients vs. 18.4 months for the placebo group (hazard ratio 0.41; 95% CI: 0.34, 0.50; $p < 0.0001$). Overall survival data were not mature at the time of final MFS analysis.

Safety:
The most common adverse events with darolutamide use were fatigue, pain in extremity, and rash.

Dosing:
The recommended dose of darolutamide is 600 mg (two 300 mg tablets) orally, twice daily. Patients receiving darolutamide should also receive a GnRH analog concurrently or should have had a bilateral orchiectomy.

Darolutamide (Brand Name: Nubeqa) (continued...)

Competitive environment

Darolutamide provides an additional oral treatment option for patients with nmCRPC. Erleada™ (apalutamide) and Xtandi® (enzalutamide) are androgen receptor inhibitors also approved for nmCRPC; however, darolutamide's distinct chemical structure appears to provide a superior safety profile vs. both of those products (eg, Erleada and Xtandi both carry a warning for increased risk of falls/fractures and seizures).

However, the efficacy (eg, improvement in median MFS) of darolutamide appears to be similar to Erleada and Xtandi and darolutamide was not compared against either product in clinical trials. In addition, darolutamide must be dosed orally twice a day whereas Erleada and Xtandi are both once a day.

The WAC for darolutamide is $11,550 per 30 days.

- Advantages: additional treatment option for nmCRPC, safety advantages vs. competitors (Erleada, Xtandi), oral
- Disadvantages: similar efficacy to existing treatment options, lack of head-to-head trial data vs. Erleada and Xtandi, twice a day dosing
- WAC = $11,550 per 30 days

Fedratinib (Brand Name: Inrebic®)

Manufacturer: Celgene
Regulatory designations: Orphan Drug
FDA approval date: 8/16/2019

Therapeutic use

Fedratinib was approved for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF)

Myelofibrosis is a rare bone marrow disorder that disrupts the body's normal production of blood cells. Bone marrow is gradually replaced with fibrous scar tissue, which limits the ability of the bone marrow to make red blood cells. A key hallmark of the disease is an enlarged spleen. In the U.S. myelofibrosis occurs in 1.5 of every 100,000 people each year.

The only curative treatment is hematopoietic stem cell transplantation (HSCT) which is reserved for patients with severe myelofibrosis.

- Treatment of patients with primary or secondary myelofibrosis

Fedratinib (continued...)

Clinical profile

Fedratinib is a highly selective Janus Associated Kinase 2 (JAK2) inhibitor. Abnormal activation of JAK2 is associated with myeloproliferative neoplasms, including myelofibrosis and polycythemia vera.

Pivotal trial data:
Fedratinib was evaluated in a double-blind, placebo-controlled, randomized study (JAKARTA) in 289 patients with primary or secondary myelofibrosis, as well as a single-arm, open-label study (JAKARTA2) in 97 patients with primary or secondary myelofibrosis previously exposed to Jakafi® (ruxolitinib). Jakafi is a JAK1/JAK2 inhibitor also approved for myelofibrosis. The primary endpoint in both studies was spleen response rate at week 24 (or 6 cycles), defined as the proportion of patients who had a reduction in spleen volume (as determined by a blinded CT and MRI) of at least 35%.

In the JAKARTA study, a significant reduction in spleen volume was achieved in 37% of patients receiving fedratinib vs. 1% with placebo ($p < 0.0001$). In JAKARTA2 (previous treatment with ruxolitinib), 31% (95% CI: 22, 41) of patients treated with fedratinib achieved the primary endpoint of spleen volume reduction.

Safety:
The most common adverse events with fedratinib use were anemia, diarrhea, nausea, and vomiting.

Dosing:
In the pivotal trials, fedratinib was administered orally once a day.

- JAK2 inhibitor
- Oral formulation
- Spleen response rate: 37% vs. 1% with placebo ($p < 0.0001$)
- Spleen response rate (in prior Jakafi-treated patients): 31% (95% CI: 22, 41)
- anemia, diarrhea, nausea, vomiting
- Dosing: once daily

Competitive environment

Fedratinib offers an additional treatment option for myelofibrosis. There is a high unmet need for treatment of this condition, particularly in patients who are non-responders or cannot tolerate Jakafi. In addition, fedratinib is dosed orally once a day while Jakafi is dosed twice a day.

However, a safety signal for Wernicke's encephalopathy, a rare neurological disorder associated with vitamin B1 deficiency, was identified after the JAKARTA trial which originally halted development for fedratinib. A boxed warning for encephalopathy is included in the fedratinib drug label.

In addition, there are no head-to-head data comparing fedratinib vs. Jakafi and no overall survival (OS) data is currently available for fedratinib.

For reference, the WAC price for Jakafi is $13,000 per 30 days.

- Advantages: additional treatment option for myelofibrosis, high unmet need, oral, once a day
- Disadvantages: boxed warning for encephalopathy, lack of head-to-head data vs. Jakafi, lack of OS data
- Reference WAC (Jakafi) = $13,000 per 30 days

Tenapanor (Brand Name: Ibsrela)

Manufacturer: Ardelyx
Expected FDA decision: 9/13/2019

Therapeutic use

Tenapanor is in development for the treatment of patients with irritable bowel syndrome with constipation (IBS-C).

IBS is a chronic gastrointestinal (GI) disorder characterized by abdominal pain and altered bowel habits. In patients with IBS-C, chronic abdominal pain is associated with constipation. It is estimated that about 11 million people in the U.S. are affected by IBS-C.

- Treatment of patients with IBS-C

Clinical profile

Tenapanor is a novel sodium transporter sodium-hydrogen exchanger 3 (NHE3) inhibitor. It is believed to work in IBS-C by reducing sodium absorption in the GI tract which increases intestinal fluid. Data from preclinical studies also suggest that tenapanor reduces abdominal pain caused by IBS-C through the inhibition of transient receptor potential vanilloid 1 (TRPV-1) dependent signaling. TRPV-1 is a pain target known for transmitting painful stimuli.

- Sodium transporter NHE3 inhibitor
- Oral formulation
- Responder rate: 27.0% to 36.5% vs. 18.7 to 23.7% with placebo
- Common AEs: diarrhea, nausea, abdominal distension
- Dosing: twice a day

Pivotal trial data:
Tenapanor was evaluated in two, double-blind, placebo-controlled, randomized trials (T3MPO-1 and T3MPO-2) in 1,203 patients with IBS-C. The primary endpoint was the combined responder rate (6/12 weeks), which was defined as at least a 30% reduction in abdominal pain and an increase of one or more complete spontaneous bowel movements in the same week for at least 6 of the 12 weeks of the treatment period.

In the T3MPO-1 trial, a greater proportion of tenapanor-treated patients vs. placebo-treated patients achieved the primary endpoint (27.0% vs. 18.7%, respectively; $p = 0.02$). Similar results were observed in T3MPO-2, with 36.5% and 23.7% of patients meeting the primary endpoint with tenapanor and placebo, respectively ($p < 0.001$).

Safety:
The most common adverse events with tenapanor use were diarrhea, nausea, and abdominal distension.

Dosing:
In the pivotal trials, tenapanor was administered orally twice a day.

Tenapanor (continued...)

Competitive environment

Tenapanor offers a novel mechanism of action (MOA) for the treatment of IBS-C. There is an unmet need for novel therapies for IBC, particularly due to the heterogeneity of the condition. In addition, tenapanor is also in development for the treatment of hyperphosphatemia, which could potentially add to its future market potential.

While tenapanor does offer a novel MOA for the treatment of IBS-C, it is a relatively late market entry and there are several alternatives available, including Linzess® (linaclotide), Trulance® (plecanatide), and Amitiza® (lubiprostone). Tenapanor also demonstrated modest efficacy in the trials and compared indirectly, does not appear to be more efficacious vs. existing treatment options. Tenapanor also must be dosed twice a day whereas several treatment options currently available may be dosed once a day (eg, Trulance, Linzess).

For reference, the WAC price for Linzess and Trulance is approximately $5,000 per year.

- Advantages: novel MOA, unmet need, oral, also in development for the treatment of hyperphosphatemia
- Disadvantages: alternatives available, modest efficacy, twice a day dosing
- Reference WAC (Linzess, Trulance) = ~$5,000 per year

Diroximel fumarate (Brand Name: Vumerity)

Manufacturer: Alkermes/Biogen
Expected FDA decision: 10/17/2019

Therapeutic use

- Treatment of relapsing forms of MS

Diroximel fumarate is in development for the treatment of relapsing forms of multiple sclerosis (MS).

MS is a chronic, inflammatory, autoimmune disease of the central nervous system. MS affects nearly 1 million people in the U.S. and it is among the most common causes of neurological disability in young adults.

Clinical profile

- Nrf2 pathway activator
- Oral formulation
- ARR: 79% reduction over one year when compared to baseline
- Common AEs: flushing, pruritus, GI side effects
- Dosing: twice a day

Diroximel fumarate is designed to be rapidly metabolized to monomethyl fumarate, which is the active metabolite of Tecfidera® (dimethyl fumarate). Tecfidera is also approved for the treatment of relapsing MS.

The mechanism by which fumarate products exert their therapeutic effect in MS is unknown. Monomethyl fumarate has been shown to activate the Nuclear factor (erythroid-derived 2)-like 2 (Nrf2) pathway. The Nrf2 pathway is involved in the cellular response to oxidative stress.

Pivotal trial data:
Alkermes/Biogen are seeking approval of diroximel fumarate under the 505(b)(2) regulatory pathway, referencing Tecfidera efficacy data. In addition, the FDA filing was also supported by an open-label, two-year safety study in patients with relapsing forms of MS. In 696 MS patients, diroximel fumarate showed a significant reduction in the annualized relapse rate (ARR) by 79% over one year when compared to baseline.

Safety:
The most common adverse events with diroximel fumarate use were flushing, pruritus, and GI side effects.

The GI tolerability of diroximel fumarate was compared vs. Tecfidera in a double-blind, active-controlled, five-week trial. The primary endpoint was the number of days patients reported GI symptoms with a symptom intensity score ≥ 2 on the Individual Gastrointestinal Symptom and Impact Scale (IGISIS) (0 = not at all; 10 = extreme). Diroximel fumarate was statistically superior to Tecfidera, with patients treated with diroximel fumarate self-reporting significantly fewer days of key GI symptoms with intensity scores ≥ 2 on the IGISIS ($p = 0.0003$). The most common adverse events reported in the study for both treatment groups were flushing, diarrhea and nausea (32.8%, 15.4% and 14.6% for diroximel fumarate; 40.6%, 22.3% and 20.7% for Tecfidera). The proportion of patients with an adverse event leading to study discontinuation was 1.6% for diroximel fumarate and 6.0% for Tecfidera. Of those, the proportion of patients who discontinued due to GI adverse events was 0.8% for diroximel fumarate and 4.8% for Tecfidera.

Dosing:
In the pivotal trials, diroximel fumarate was administered orally twice a day.

Diroximel fumarate (continued...)

Competitive environment

If approved, diroximel fumarate would provide an additional oral treatment option for MS with potentially superior GI tolerability vs. Tecfidera.

However, diroximel fumarate would be entering a crowded marketplace with several oral and injectable alternatives available for treating relapsing forms of MS. Diroximel fumarate has a similar clinical profile as Tecfidera with no data suggesting improved efficacy. Like Tecfidera, it must also be dosed twice a day.

For reference, the WAC price for Tecfidera is approximately $95,000 per year.

- Advantages: potentially superior GI tolerability vs. Tecfidera, oral
- Disadvantages: alternatives available, similar clinical profile as Tecfidera, twice a day
- Reference WAC (Tecfidera) = ~$95,000 per year

Brolucizumab (Brand Name: Beovu)

Manufacturer: Novartis
Expected FDA decision: 11/2019

Therapeutic use

Brolucizumab is in development for the treatment of neovascular (wet) age-related macular degeneration (AMD).

The American Academy of Ophthalmology estimates that 15 million North Americans currently have AMD with about 10% to 15% suffering from neovascular (wet) AMD. Wet AMD is a degenerative disease of the central portion of the retina characterized by growth of abnormal vessels in the subretinal space; this results in loss of central vision and, if untreated, can lead to blindness.

- Treatment of neovascular (wet) AMD

Brolucizumab (continued...)

Clinical profile

Brolucizumab is a vascular endothelial growth factor (VEGF) inhibitor. Increased signaling through the VEGF pathway is associated with pathologic ocular angiogenesis and retinal edema. Inhibition of the VEGF pathway has been shown to reduce the growth of neovascular lesions, resolve retinal edema and improve vision in patients with retinal vascular diseases.

Brolucizumab differs from currently available VEGF inhibitors because it is a humanized single-chain antibody fragment (others are full length monoclonal antibodies). Due to their small size, single-chain antibody fragments can provide enhanced tissue penetration and rapid clearance from systemic circulation.

Pivotal trial data:
The efficacy of brolucizumab was evaluated in two double-masked, active-controlled, randomized studies (HAWK and HARRIER) in 1,817 untreated wet AMD patients. Patients were randomized to brolucizumab or Eylea® (aflibercept). Brolucizumab was administered as a maintenance dose every 8 or 12 weeks (depending on disease activity) vs. every 8 weeks for Eylea. At week 48 in both trials, brolucizumab demonstrated noninferiority to Eylea for the primary endpoint of mean best-corrected visual acuity (BCVA) change from baseline ($p < 0.001$).

At week 16, fewer brolucizumab patients had disease activity vs. Eylea in HAWK (24.0% vs. 34.5%; $p = 0.001$) and HARRIER (22.7% vs. 32.2%; $p = 0.002$). Other anatomic retinal fluid outcomes also favored brolucizumab.

Safety:
The most common adverse events with brolucizumab use were conjunctival hemorrhage, reduced visual acuity, and eye pain.

Dosing:
In the pivotal trials, brolucizumab was administered as an intravitreal injection. Patients received a loading dose of three monthly injections, followed by injections every 12 weeks. The interval could be adjusted to every 8 weeks if disease activity was present.

- VEGF inhibitor
- Intravitreal formulation
- Non-inferior to Eylea for mean BCVA change from baseline
- Demonstrated superiority to Eylea for improvements in disease activity and other anatomical retinal fluid outcomes
- Common AEs: conjunctival hemorrhage, reduced visual acuity, eye pain
- Maintenance dosing: every 8 to 12 weeks

Competitive environment

If approved, brolucizumab would provide an additional VEGF inhibitor treatment option for wet AMD. Other approved VEGF inhibitors for wet AMD include Eylea and Lucentis® (ranibizumab). While brolucizumab did not demonstrate superiority for the primary endpoint, key secondary outcomes did favor brolucizumab vs. Eylea. Brolucizumab may also be administered every 12 weeks. The recommended dosing frequency for Eylea is every 8 weeks. The dosing frequency for Eylea can be extended to every 12 weeks after one year of effective therapy but it is not as effective as the recommended every 8 week dosing regimen. The recommended dosing frequency for Lucentis is once every month (approximatly 28 days)

However, in the clinical trials about 50% of brolucizumab-treated patients required dosing every 8 weeks. In addition, brolucizumab is a relatively late market entry for the treatment of wet AMD and the other VEGF inhibitors are also approved for other ophthalmic indications (eg, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy). Brolucizumab may also face future competition as Allergan's abicipar pegol could be available in late 2020.

For reference, the WAC price for Eylea is approximately $30,000 per year.

- Advantages: potential improved efficacy vs. Eylea, potential for fewer intravitreal injections (every 12 weeks)
- Disadvantages: ~50% of patients still required injections every 8 weeks, late market entry, currently available VEGF inhibitors are also approved for other ophthalmic indications, potential future competition (eg, abicipar pegol)
- Reference WAC (Eylea) = ~$30,000 per year

Lasmiditan (Brand Name: To be determined)

Manufacturer: Eli Lilly
Expected FDA decision: 11/14/2019

Therapeutic use

Lasmiditan is in development for the acute treatment of migraine headaches in adults.

Patients suffering from migraines have recurrent episodes of severe headache accompanied by other symptoms including nausea, vomiting, sensitivity to light and sound, and changes in vision. An estimated 30 million adults in the U.S. experience migraine headaches.

- Acute treatment of migraine headaches in adults

Clinical profile

Lasmiditan is a first-in-class drug which selectively targets serotonin 5-HT1F receptors, including those expressed in the trigeminal pathway.

Triptans such as sumatriptan and rizatriptan are the current standard of care for the acute treatment of migraine headaches. Triptans are serotonin 5-HT1B/1D receptor agonists. They can cause vasoconstriction due to activation of the 5-HT1B receptors which is thought to drive a small increased risk of serious cardiovascular adverse events.

Pivotal trial data:
The efficacy of lasmiditan was evaluated in two double-blind, placebo-controlled, randomized trials (SAMURAI and SPARTAN). The co-primary endpoints were the proportion of patients headache pain-free and most bothersome symptom (MBS)-free (eg, sensitivity to light or sound, or nausea) at 2 hours post-dose.

In SAMURAI, more patients dosed with lasmiditan 100 mg and 200 mg were free of headache pain at 2 hours after dosing vs. placebo (28.2% and 32.2% vs. 15.3%, respectively; $p < 0.001$ for both doses). More patients dosed with lasmiditan 100 mg and 200 mg were also free of their MBS compared with placebo (40.9% and 40.7% vs. 29.5%; $p < 0.001$ for both doses).

Similar results were observed in the SPARTAN trial. Lasmiditan was associated with significantly more patients free of headache at 2 hours post-dose (lasmiditan 200 mg: 38.8%, $p < 0.001$; 100 mg: 31.4%, $p < 0.001$; 50 mg: 28.6%, $p = 0.003$ vs. placebo 21.3%) and freedom from MBS (lasmiditan 200 mg: 48.7%, $p < 0.001$; 100 mg: 44.2%, $p< 0.001$; 50 mg: 40.8%, $p = 0.009$ vs. placebo 33.5%).

Safety:
The most common adverse events with lasmiditan use were dizziness, somnolence, and paresthesia.

Dosing:
In the pivotal trials, lasmiditan was administered orally as needed after onset of migraine headache.

- Serotonin 5-HT1F receptor agonist
- Oral formulation
- Headache pain-free at 2 hrs post-dose: 32.2% to 38.8% with lasmiditan 200 mg vs. 15.3% to 21.3% with placebo
- MBS-free at 2 hrs post-dose: 40.7% to 48.7% with lasmiditan 200 mg vs. 29.5% to 33.5% with placebo
- Safety: dizziness, somnolence, paresthesia
- Dosing: as needed after onset of migraine headache

Lasmiditan (continued...)

Competitive environment

If approved, lasmiditan would add to the treatment armamentarium for acute migraine treatment and it has a novel MOA as a selective serotonin 5-HT1F agonist. Lasmiditan's selectivity for 5-HT1F could make it a potentially attractive alternative treatment option in patients who have contraindications or are non-responders to triptan therapies.

The triptans and lasmiditan both target serotonin activity, but with different sub-receptor selectivity. There are lingering questions whether this difference in MOA will result in true efficacy or safety differences between the two classes. Lasmiditan would likely be reserved as a second-line agent due to the availability of several generic triptan alternatives and a lack of head-to-head data for lasmiditan vs. triptans. In addition, lasmiditan will potentially have competition for this niche of patients (triptan non-responders and patients unable to use triptans) as oral anti-calcitonin related-gene peptide (CGRP) antagonists are also in development for acute treatment of migraine.

The projected average WAC price for lasmiditan is approximately $1,750 per year; however this will vary patient to patient since lasmiditan is administered as needed.

- Advantages: novel MOA, unmet need in patients who do not respond or cannot use triptans, oral
- Disadvantages: generic alternatives available, lack of head-to-head data vs. triptans, potential future competition with oral CGRP antagonists
- Projected WAC = ~$1,750 per year

Ubrogepant (Brand Name: To be determined)

Manufacturer: Allergan
Expected FDA decision: 12/2019

Therapeutic use

Similar to lasmiditan, ubrogepant is also in development for the acute treatment of migraine headaches in adults.

- Acute treatment of migraine headaches in adults

Clinical profile

Ubrogepant is a highly potent CGRP receptor antagonist. CGRP and its receptors are expressed in regions of the nervous system associated with migraine pathophysiology.

- CGRP antagonist
- Oral formulation
- Headache pain-free at 2 hrs post-dose: 19.2% to 21.8% vs. 11.8% to 14.3% with placebo
- MBS-free at 2 hrs post-dose: 37.7% to 38.9% vs. 27.4% to 27.8% with placebo
- Common AEs: nausea, somnolence, dry mouth, liver enzyme elevations
- Dosing: as needed after onset of migraine headache

Pivotal trial data:
The efficacy of ubrogepant was evaluated in two double-blind, placebo-controlled, randomized studies (ACHIEVE I and ACHIEVE II). The co-primary endpoints were the proportion of patients that were headache pain-free and MBS-free at 2 hours post-dose.

In the ACHIEVE I trial, more patients dosed with ubrogepant 50 mg and 100 mg were free of headache pain at 2 hours after dosing vs. placebo (19.2% and 21.2% vs. 11.8%, respectively; 50 mg vs. placebo p = 0.0023, 100 mg vs. placebo, p = 0.0003). More patients treated with ubrogepant were also free of their MBS compared with placebo, (38.6% and 37.7% vs. 27.8%, respectively, p = 0.0023 for both doses).

Similar results were observed in the ACHIEVE II trial, which evaluated ubrogepant 25 mg and 50 mg. More patients dosed with ubrogepant were free of headache pain at 2 hours after dosing vs. placebo (20.7% and 21.8% vs. 14.3%, respectively; 25 mg vs. placebo, p = 0.0285, 50 mg vs. placebo, p = 0.0129). Compared with placebo, more patients dosed with ubrogepant 50 mg were also free of their MBS (38.9% vs. 34.1%, p = 0.0129). However, ubrogepant 25 mg failed to demonstrate statistical significance vs. placebo for this endpoint (p = 0.0711).

Safety:
The most common adverse events with ubrogepant use were nausea, somnolence, dry mouth, and liver enzyme elevations.

Dosing:
In the pivotal trials, ubrogepant was administered orally as needed after onset of migraine headache.

Ubrogepant (continued...)

Competitive environment

If approved, ubrogepant would represent the first approved oral CGRP antagonist. Subcutaneously administered CGRP antagonists are only approved for migraine prophylaxis. Similar to lasmiditan, ubrogepant would be a potential treatment option in acute migraine patients who have contraindications to triptans or who are non-responders to triptan therapy.

Ubrogepant would likely be reserved as a second-line agent due to the availability of generic triptan alternatives and a lack of head-to-head data vs. triptans, the well-established standard of care. It would also be competing with lasmiditan and other oral CGRP antagonists in development for acute migraine treatment (eg, rimegepant), which are expected to enter the market in 2020.

Compared indirectly vs. lasmiditan, ubrogepant appears to be better tolerated but also appears to be less efficacious for acute migraine treatment; however, it is difficult to compare results across different clinical trials.

The projected average WAC price for ubrogepant is approximately $1,750 per year; however this will vary from patient to patient since it is administered as needed.

- Advantages: potentially first approved oral CGRP antagonist, unmet need in patients who do not respond to or cannot use triptans, oral
- Disadvantages: generic alternatives available, lack of head-to-head data vs. triptans, potential future competition with lasmiditan and other oral CGRP antagonists (eg, rimegepant)
- Projected WAC = ~$1,750 per year

RVT-802 (Brand Name: To be determined)

Manufacturer: Enzyvant/Roivant
Regulatory designations: Orphan Drug, Breakthrough Therapy, Regenerative Medicine Advanced Therapy
Expected FDA decision: 12/2019

Therapeutic use

RVT-802 is in development for the treatment of primary immune deficiency resulting from congenital athymia.

Congenital athymia is a rare condition where patients are born without a thymus, resulting in a severe immunodeficiency due to the inability to produce normally functioning T cells. In a healthy, functioning immune system, T cells that start as stem cells in bone marrow become fully developed in the thymus. Approximately 20 infants are born each year in the U.S. with congenital athymia, which is fatal if untreated. Death typically occurs in the first 24 months of life due to infection.

Currently, there are no FDA-approved therapies for this condition and the standard of care has been investigational thymic tissue transplantation or HSCT.

- Treatment of primary immune deficiency resulting from congenital athymia

RVT-802 (continued...)

Clinical profile

RVT-802 is an allogeneic cultured postnatal thymus tissue-derived product manufactured from tissue obtained from unrelated donors under the age of 9 months. RVT-802 is designed to replicate this process in the absence of a thymus.

Pivotal trial data:
At the time of the FDA filing, a total of 93 patients received RVT-802 across multiple clinical studies, including 85 patients who met the criteria for inclusion in the efficacy analysis. The Kaplan-Meier estimates of survival at year 1 and year 2 post-treatment were 76% (95% CI: 66, 84) and 75% (95% CI: 66, 83), respectively. For patients surviving 12 months post-treatment, there was a 93% probability of surviving 10 years post-treatment.

Safety:
The most commonly reported adverse events with RVT-802 use include thrombocytopenia, neutropenia, pyrexia, and proteinuria.

Dosing:
RVT-802 is administered as a one-time therapy. It is inserted into a patient's quadriceps muscles by means of an open surgical procedure.

- Tissue-based therapy (allogeneic thymic tissue)
- Implantation via quadriceps
- Survival at year 2 post-treatment: 75% (95% CI: 66, 83)
- Common AEs: thrombocytopenia, neutropenia, pyrexia, proteinuria
- Dosing: one-time therapy

Competitive environment

While RVT-802 has been available as an investigational therapy, it could potentially be the first FDA-approved therapy for congenital athymia. There is a significant unmet need for the treatment of congenital athymia as death typically occurs in children within 24 months if untreated.

While the number of patients treated with RVT-802 over several clinical studies is small, the survival estimates do appear to be strong (75% at two years post-treatment). RVT-802 does require implantation into the quadriceps muscles and administration may be limited to specific centers that are able to perform the procedure.

- Advantages: potentially first FDA-approved therapy for congenital athymia, significant unmet need
- Disadvantages: implantation via an open surgical procedure, administration likely to be limited to specific centers of care

Luspatercept (Brand Name: To be determined)

Manufacturer: Celgene/Acceleron
Regulatory designations: Orphan Drug, Fast Track
Expected FDA decision: 12/4/2019 (beta-thalassemia); 4/4/2020 (myelodysplastic syndromes [MDS])

Therapeutic use

Luspatercept is in development for the treatment of adult patients who require red blood cell (RBC) transfusions with: beta-thalassemia-associated anemia or very low to intermediate-risk MDS-associated anemia.

Beta-thalassemia is a rare hereditary blood disorder characterized by reduced levels of functional hemoglobin. Symptomatic cases occur in approximately 1 in 100,000 individuals. HSCT can be curative; however it is limited by availability of donors and risks associated with the procedure. The current standard of care for management of severe beta-thalassemia is life-long RBC transfusions and iron chelation.

MDS are a rare group of blood disorders that occur as a result of disordered development of blood cells within the bone marrow. RBCs, white blood cells and platelets are affected. In some affected individuals, MDS may progress to life-threatening failure of the bone marrow or develop into an acute leukemia. Approximately 20,000 new cases of MDS are diagnosed each year in the U.S. Similar to beta-thalassemia, HSCT is the only curative treatment. Supportive care for patients with anemia can include erythropoietin stimulating agents (ESAs) or RBC transfusions.

- Treatment of adult patients with beta-thalassemia-associated anemia or very low to intermediate-risk MDS-associated anemia

Luspatercept (continued...)

Clinical profile

Luspatercept is a novel, first-in-class erythroid maturation agent. Luspatercept inhibits members of the TGF-beta superfamily which are involved in late stages of erythropoiesis and which inhibit RBC maturation. Luspatercept attempts to restore RBC production.

Pivotal trial data:
The efficacy of luspatercept was evaluated in a double-blind, placebo-controlled, randomized study (BELIEVE) in 336 adult patients with beta-thalassemia-associated anemia who require RBC transfusions. Patients received luspatercept or placebo and all patients received background best supportive care. The primary endpoint was the proportion of patients experiencing a reduction in transfusion burden (≥ 33%) during weeks 13 to 24. Overall, 21.4% of patients receiving luspatercept experienced a reduction in transfusion burden vs. 4.5% with placebo (p <0.0001).

Luspatercept was also evaluated in a double-blind, placebo-controlled, randomized trial (MEDALIST) in 229 adults with RBC transfusion-dependent MDS who were either refractory, intolerant, or not candidates for ESA therapy. Transfusion independence for ≥ 8 weeks during first 24 weeks of the trial was achieved in 37.9% of patients treated with luspatercept vs. 13.2% with placebo (p < 0.0001).

Safety:
The most common adverse events with luspatercept use were thromboembolic events (deep venous thrombosis, pulmonary embolism, portal vein thrombosis, ischemic stroke, thrombophlebitis, and superficial phlebitis), bone pain, hypertension, diarrhea, and nausea.

Dosing:
In the pivotal trials, luspatercept was administered subcutaneously (SC) every 21 days.

- Erythroid maturation agent
- SC formulation
- Beta-thalassemia – reduction in transfusion burden at wks 13 to 24: 21.4% vs. 4.5% with placebo (p < 0.0001)
- MDS – transfusion independence (for ≥ 8 wks of 24 wks): 37.9% vs. 13.2% with placebo (p < 0.0001)
- Common AEs: thromboembolic events, bone pain, hypertension, diarrhea/nausea
- Dosing: every 21 days

Competitive environment

Luspatercept offers a novel MOA for the treatment of both beta-thalassemia and MDS. There is a high unmet need for treatments for both conditions and it would potentially be the first FDA-approved therapy for beta-thalassemia. Aside from curative HSCT, these conditions have primarily been managed with blood transfusions which can be costly and associated with complications (eg, iron overload).

Luspatercept does require SC administration by a healthcare provider and while it may reduce or eliminate the need for blood transfusions in some patients, luspatercept is a chronic therapy and it may soon have competition from a potentially curative therapy. LentiGlobin/Zynteglo is a one-time gene therapy treatment for beta-thalassemia that is preparing to file with the FDA and could become available in mid-to-late 2020.

Additionally, luspatercept was associated with a higher overall rate of thromboembolic events (3.6% vs. 0.9% with placebo) in the beta-thalassemia trial; although, all luspatercept-affected patients reportedly had multiple risk factors for thrombotic events.

- Advantages: novel MOA, potentially first approved therapy for beta-thalassemia, high unmet need (can reduce or eliminate the need for blood transfusions)
- Disadvantages: requires SC administration by a healthcare provider, not curative, potential future gene therapy competition for beta-thalassemia, potential safety signal for thromboembolic events

Lemborexant (Brand Name: To be determined)

Manufacturer: Eisai/Imbrium Therapeutics
Expected FDA decision: 12/27/2019

Therapeutic use

- Treatment of insomnia in adult patients

Lemborexant is in development for the treatment of insomnia in adult patients.

Insomnia affects approximately 30% of the adult population worldwide and is characterized by difficulty falling asleep, staying asleep, or both.

Clinical profile

- Orexin receptor 1 and 2 antagonist
- Oral formulation
- Superiority vs. placebo for all primary and key secondary sleep endpoints
- Common AEs: somnolence, headache, nasopharyngitis
- Dosing: once a day at bedtime

Lemborexant inhibits orexin signaling by binding competitively to both orexin receptor subtypes (orexin receptor 1 and 2). In individuals with sleep-wake disorders, orexin signaling is believed to regulate wakefulness and inhibiting inappropriate orexin signaling may enable initiation and maintenance of sleep.

Pivotal trial data:
The efficacy of lemborexant was evaluated in a double-blind, placebo-controlled, active comparator, randomized trial (SUNRISE-1) in 1,006 patients 55 years and older with insomnia disorder. In this study, patients were randomized to receive placebo or one of three treatment regimens (lemborexant 5 mg, lemborexant 10 mg, zolpidem ER 6.25 mg). In addition, lemborexant was evaluated in a double-blind, placebo-controlled, randomized study (SUNRISE-2) in 949 patients between the ages of 18 to 88 years. SUNRISE-2 did not include zolpidem ER as an active control. The primary endpoint was sleep onset, as measured by latency to persistent sleep.

In the pooled analysis of both trials, median reductions from baseline in subjective sleep onset latency were larger for lemborexant 5 mg and 10 mg vs. placebo during the first seven days of treatment (-12.9 minutes for lemborexant 5 mg, -13.6 minutes for lemborexant 10 mg, -2.9 minutes for placebo) and at the end of month one of treatment (-16.1 minutes for lemborexant 5 mg, -17.9 minutes for lemborexant 10 mg, -5.2 minutes for placebo). Lemborexant also demonstrated superiority vs. placebo for key secondary sleep endpoints (eg, sleep efficiency, wake after sleep onset [WASO]) and demonstrated statistical superiority vs. zolpidem ER for WASO in the second half of the night.

Safety:
The most common adverse events with lemborexant use were somnolence, headache, and nasopharyngitis.

Dosing:
In the pivotal trials, lemborexant was administered orally once a day at bedtime.

Lemborexant (continued...)

Competitive environment

Insomnia represents a large market with approximately 30% of the population affected by the disorder. The FDA also recently added a boxed warning for several insomnia drugs (ie, eszopiclone, zaleplon, and zolpidem), for rare but serious injuries due to sleep behaviors, including sleepwalking, sleep driving, and engaging in other activities while not fully awake. The label for Belsomra® (suvorexant), another orexin receptor antagonist, was not updated with this boxed warning; therefore it is unlikely that lemborexant would be impacted by this limitation as well.

However, many of the drugs used for insomnia are available generically and lemborexant is a late market entry. Aside from drugs with different MOAs, Belsomra has also been available since 2014. Similar to other insomnia drugs, including Belsomra, lemborexant would likely require DEA scheduling.

For reference, the WAC price for Belsomra is approximately $350 per 30 days.

- Advantages: potential superiority vs. zolpidem ER, large market, oral, once a day
- Disadvantages: generic alternatives available, late market entry, likely DEA scheduling
- Reference WAC (Belsomra) = ~$350 per 30 days

Lumateperone (Brand Name: To be determined)

Manufacturer: Intra-Cellular Therapies
Regulatory designations: Fast Track
Expected FDA decision: 12/27/2019

Therapeutic use

Lumateperone is in development for the treatment of adult patients with schizophrenia.

Schizophrenia is a common severe mental illness that affects approximately 2.4 million people in the U.S. It is characterized by positive symptoms (eg, hallucinations, delusions, disorganized thoughts), negative symptoms (eg, diminished expression, apathy), and impairments in cognition. Mood and anxiety symptoms are also common in schizophrenia.

- Treatment of adult patients with schizophrenia

Lumateperone (continued...)

Clinical profile

Lumateperone is a first-in-class serotonin, dopamine, and glutamate modulator. Lumateperone is a potent serotonin 5-HT2A receptor antagonist, a dopamine receptor phosphoprotein modulator acting as a presynaptic partial agonist and postsynaptic antagonist at dopamine D2 receptors, and a dopamine D1 receptor-dependent indirect modulator of glutamate. In addition, lumateperone also has serotonin reuptake inhibitor properties.

Pivotal trial data:
The efficacy of lumateperone was evaluated in three double-blind, placebo-controlled, randomized pivotal trials. In two of the trials, risperidone, a second generation atypical antipsychotic, was also included as an active control. The primary endpoint in all three studies was the change from baseline in the Positive and Negative Syndrome Scale (PANSS) total score. In a pooled analysis of the three trials, lumateperone 60 mg demonstrated a statistically significant improvement in the PANSS total score vs. placebo ($p = 0.003$). The exact numerical differences between lumateperone and placebo from the pooled analysis have not been reported. However, in 1 of the 3 individual trials, lumateperone failed to demonstrate superiority vs. placebo.

Safety:
The most common adverse events with lumateperone use were somnolence and sedation.

Dosing:
In the pivotal trials, lumateperone was administered orally once a day.

- Serotonin, dopamine, and glutamate modulator
- Oral formulation
- Statistically significant improvement in the PANSS total score vs. placebo in a pooled analysis of three pivotal studies; failed to achieve primary endpoint in 1 of the 3 pivotal trials
- Common AEs: somnolence, sedation
- Dosing: once daily

Competitive environment

Lumateperone offers a novel MOA for the treatment of schizophrenia. Second-generation antipsychotics are the standard of care for schizophrenia treatment and they work as modulators of serotonin and dopamine. However, these drugs are primarily only effective in treating the positive symptoms of schizophrenia and can be associated with significant AEs. Of note, lumateperone demonstrated fewer metabolic disturbances and less weight gain vs. risperidone in the clinical trials.

However, there are many alternative oral treatment options for schizophrenia, some of which are available generically. Long-acting injectable antipsychotics are also available for patients who do not want the daily reminder of oral medications. In addition, while lumateperone may confer safety benefits vs. the current standard of care, lumateperone failed to achieve its primary endpoint vs. placebo in one of the pivotal trials and there is no data suggesting that lumateperone is superior to existing treatment options.

For reference, the WAC price for Vraylar® (cariprazine), a recently approved oral antipsychotic, is approximately $14,500 per year.

- Advantages: novel MOA, potentially fewer AEs vs. second-generation atypical antipsychotics, oral, once a day
- Disadvantages: generic oral and long-acting injectable alternatives available, failed to achieve primary endpoint vs. placebo in one clinical trial, lack of data demonstrating superiority vs. standard of care
- Reference WAC (Vraylar) = ~$14,500 per year

Cabotegravir/rilpivirine (Brand Name: To be determined)

Manufacturer: ViiV Healthcare
Expected FDA decision: 12/29/2019

Therapeutic use

Cabotegravir/rilpivirine is in development for the treatment of human immunodeficiency virus (HIV)-1 infection in adults whose viral load is suppressed and who are not resistant to cabotegravir or rilpivirine.

Clinical profile

Cabotegravir is a novel HIV integrase inhibitor and rilpivirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI).

Pivotal trial data:
The efficacy of cabotegravir/rilpivirine was evaluated in two open-label, active-controlled, randomized non-inferiority pivotal trials (ATLAS and FLAIR) in over 1,100 patients with HIV-1 infection. In the ATLAS trial, cabotegravir/rilpivirine was assessed vs. continuation of a patient's current three-drug oral antiretroviral therapy. In the FLAIR trial, all patients received 20 weeks of induction therapy with Triumeq® tablets (abacavir, dolutegravir, and lamivudine) and then were randomized to cabotegravir/rilpivirine or continuation of Triumeq therapy.

In the ATLAS trial, cabotegravir/rilpivirine demonstrated non-inferiority as measured by the proportion of participants with detectable HIV, defined as plasma HIV-1 RNA ≥ 50 copies/mL (cabotegravir/ rilpivirine: 1.6% vs. current antiretroviral therapy: 1.0%; $p < 0.05$). Similar viral results and non-inferiority were observed in the FLAIR trial.

Safety:
The most common adverse events with cabotegravir/rilpivirine use were injection site reactions, nasopharyngitis, headache, and diarrhea.

Dosing:
In the pivotal trials, cabotegravir/rilpivirine was administered as an intramuscular (IM) injection every 4 weeks.

As part of the regulatory submission package to the FDA, ViiV Healthcare also submitted a second New Drug Application for a single-agent, oral tablet formulation of cabotegravir. The oral formulation would be taken as a lead-in with an already-approved, once-daily, oral tablet formulation of rilpivirine.

Cabotegravir/rilpivirine (continued...)

- Treatment of HIV-1 infection in adults whose viral load is suppressed
- Cabotegravir: HIV integrase inhibitor; rilpivirine: NNRTI
- IM formulation
- Non-inferior for viral suppression vs. continuation of current antiretroviral therapy or Triumeq
- Common AEs: injection site reactions, nasopharyngitis, headache, diarrhea
- Dosing: once every 4 weeks

Competitive environment

If approved, cabotegravir/rilpivirine would be the first long-acting regimen for treatment of HIV-1 infection. The current standard of care includes multi-drug, oral regimens that require daily administration. A once monthly dosing schedule could be attractive in a niche of HIV-infected patients who struggle with adherence to oral medications or would otherwise benefit from less-frequent once monthly dosing. In the pivotal trials, the two-drug regimen was shown to be non-inferior to commonly used first-line, three-drug HIV regimens. In addition, an every 2 month dosing schedule is being investigated with topline results expected in the third quarter of 2019.

While cabotegravir/rilpivirine does offer an alternative long-acting treatment option, it is entering a crowded marketplace with many once daily oral options already available. Cabotegravir/rilpivirine also requires administration in a healthcare setting via IM injection into the gluteal muscles. Resistance is also a lingering concern with new two-drug HIV regimens vs. traditional three-drug regimens. This concern is heightened with cabotegravir/rilpivirine because a missed clinic visit or appointment could result in a prolonged duration of time that a patient is without antiretroviral therapy.

For reference, the WAC price for Dovato® (dolutegravir/lamivudine), a recently approved oral two-drug HIV regimen, is approximately $28,000 per year.

- Advantages: potentially first long-acting regimen for HIV, non-inferiority demonstrated vs. commonly used oral three-drug regimens
- Disadvantages: alternatives available, requires IM injection by a healthcare provider, concerns about long-term emergence of resistance
- Reference WAC (Dovato) = ~$28,000 per year

3rd Quarter 2019

Extended generic pipeline forecast

OptumRx generic pipeline forecast

Brand name	Generic name	Brand manufacturer	Dosage form	Strengths available as generic	Possible launch date
2019 Possible launch date					
CUVPOSA	glycopyrrolate	Merz	Oral solution	All	2019
PREPOPIK	citric acid/magnesium oxide/sodium picosulfate	Ferring Pharmaceuticals	Oral packet	All	2019
TRAVATAN Z	travoprost	Alcon	Ophthalmic	All	2019
BYETTA	exenatide	AstraZeneca	Subcutaneous	All	2019
DESONATE	desonide	LEO Pharma	Gel	All	2019
SUPRENZA	phentermine	Citius/Akrimax	Tablet, orally disintegrating	All	2019
VIVLODEX	meloxicam	Iroko/iCeutica	Capsule	All	2019
PRESTALIA	perindopril/amlodipine	Symplmed	Tablet	All	2019
APTENSIO XR	methylphenidate	Rhodes	Capsule, extended-release	All	2H-2019
NUVARING	etonogestrel/ethinyl estradiol	Merck	Vaginal ring	All	2H-2019
RITUXAN	rituxumab	Genentech/Roche/Biogen Idec	Intravenous	All	2H-2019
SAMSCA	tolvaptan	Otsuka	Tablet	All	2H-2019
PYLERA	bismuth subcitrate potassium/metronidazole/ tetracycline	Allergan/Aptalis	Capsule	All	2H-2019
EVZIO	naloxone	Kaléo Pharma	Injection	All	2H-2019
ENBREL	etanercept	Amgen	Subcutaneous	All	2H-2019
RESTASIS	cyclosporine	Allergan	Ophthalmic	All	2H-2019
FORTEO	teriparatide	Eli Lilly	Injection	All	2H-2019
APRISO	mesalamine	Bausch Health	Capsule, extended-release	All	08-2019
EDLUAR	zolpidem	Meda/Orexo	Tablet, sublingual	All	09-2019
MYOBLOC	botulinum toxin type B	US WorldMeds	Intramuscular	All	09-2019
EMEND	fosaprepitant dimeglumine	Merck	Intravenous	150 mg	09-2019
FERRIPROX	deferiprone	ApoPharma/Apotex	Tablet	All	4Q-2019

Brand name	Generic name	Brand manufacturer	Dosage form	Strengths available as generic	Possible launch date
ZOHYDRO ER	hydrocodone	Persion/Currax	Capsule, extended-release	All	4Q-2019
JADENU	deferasirox	Novartis	Tablet; oral granules	All	10-2019
VERMOX	mebendazole	Janssen	Tablet, chewable	All	10-2019
OSMOPREP	sodium biphosphate/sodium phosphate	Bausch Health	Tablet	All	11-2019
AMELUZ	aminolevulinic acid	Biofrontera	Gel	All	11-2019
DUREZOL	difluprednate	Alcon	Ophthalmic	All	11-2019
OMNARIS	ciclesonide	Covis	Intranasal	All	12-2019
THALOMID	thalidomide	Celgene	Capsule	All	12-2019
2020 Possible launch date					
MYCAMINE	micafungin	Astellas	Intravenous	All	2020
CIPRODEX	ciprofloxacin/ dexamethasone	Alcon	Otic	All	2020
DORYX MPC	doxycycline hyclate	Mayne	Oral solution	All	2020
SYNDROS	dronabinol	Insys Therapeutics	Tablet, delayed-release	All	2020
SAPHRIS	asenapine	Allergan	Tablet, sublingual	All	1H-2020
NOXAFIL	posaconazole	Merck	Tablet; oral suspension	All	01-2020
DALIRESP	roflumilast	AstraZeneca	Tablet	All	01-2020
SILENOR	doxepin	Pernix	Tablet	All	01-2020
ELIGARD	leuprolide	QLT/Tolmar	Subcutaneous	All	03-2020
SOMATULINE DEPOT	lanreotide	Ipsen	Subcutaneous	All	03-2020
TAYTULLA	ethinyl estradiol/ norethindrone/ ferrous fumarate	Allergan	Tablet	All	03-2020
MOXEZA	moxifloxacin	Alcon	Ophthalmic	All	03-2020
ZORTRESS	everolimus	Novartis	Tablet	All	03-2020
RENOVA	tretinoin	Bausch Health	Cream	All	03-2020
TOTECT	dexrazoxane	Cumberland	Injection	All	03-2020
APTIVUS	tipranavir	Boehringer Ingelheim	Capsule; oral solution	All	04-2020
DEPO-SUBQ PROVERA	medroxyprogesterone	Pfizer	Subcutaneous	All	05-2020
NYMALIZE	nimodipine	Arbor	Oral solution	All	05-2020

Brand name	Generic name	Brand manufacturer	Dosage form	Strengths available as generic	Possible launch date
MYDAYIS	amphetamine/ dextroamphetamine mixture	Shire	Capsule, extended-release	All	06-2020
DEXILANT	dexlansoprazole	Takeda	Capsule, delayed-release	All	06-2020
DENAVIR	penciclovir	Mylan	Cream	All	06-2020
LUCENTIS	ranibizumab	Roche	Intravitreal	All	06-2020
ENTEREG	alvimopan	Merck	Capsule	All	2H-2020
VELPHORO	sucroferric oxyhydroxide	Fresenius	Tablet, chewable	All	3Q-2020
KINERET	anakinra	Swedish Orphan Biovitrum/Savient/Amgen	Subcutaneous	All	07-2020
SYNERA	lidocaine/tetracaine	Galen	Transdermal patch	All	07-2020
PEGASYS	peginterferon alfa-2A	Roche	Subcutaneous	All	08-2020
PEG-INTRON	peginterferon alfa-2B	Merck	Subcutaneous	All	08-2020
MARQIBO KIT	vincristine	Talon Therapeutics/Spectrum	Intravenous	All	09-2020
TYKERB	lapatinib	Novartis	Tablet	All	09-2020
BIDIL	isosorbide dinitrate/hydrazaline	Arbor	Tablet	All	09-2020
TRUVADA	emtricitabine/tenofovir	Gilead	Tablet	200 mg/300 mg	09-2020
ATRIPLA	efavirenz/emtricitabine/ tenofovir	Gilead/Bristol-Myers Squibb	Tablet	All	09-2020
KUVAN	sapropterin	BioMarin	Tablet; oral solution	All	10-2020
RISPERDAL CONSTA	risperidone	Janssen	Injection, extended-release	All	11-2020
XOLEGEL	ketoconazole	Almirall	Gel	All	11-2020
DULERA	formoterol fumarate/ mometasone furoate	Merck	Inhalation	All	11-2020
EPIDUO FORTE	adapalene/ benzoyl peroxide	Galderma	Gel	All	12-2020
OFIRMEV	acetaminophen	Mallinckrodt	Intravenous	All	12-2020
ABSORICA	isotretinoin	Sun	Capsule	All	12-2020
TOVIAZ	fesoterodine	Pfizer	Tablet, extended-release	All	12-2020
2021 Possible launch date					
BEPREVE	bepotastine	Bausch Health	Ophthalmic	All	2021
ACTEMRA	tocilizumab	Roche/Chugai	Intravenous; subcutaneous	All	2021

Brand name	Generic name	Brand manufacturer	Dosage form	Strengths available as generic	Possible launch date
KERYDIN	tavaborole	Pfizer	Topical solution	All	2021
VIIBRYD	vilazodone	Forest/Allergan	Tablet	All	2021
EMTRIVA	emtricitabine	Gilead	Oral; capsule	All	1H-2021
AMITIZA	lubiprostone	Sucampo/Takeda	Capsule	All	01-2021
VELCADE	bortezomib	Takeda	Intravenous	All	01-2021
CRIXIVAN	indinavir	Merck	Capsule	All	02-2021
NORTHERA	droxidopa	H. Lundbeck	Capsule	All	02-2021
MYALEPT	metreleptin	Aegerion	Subcutaneous	All	02-2021
FORTICAL	calcitonin salmon recombinant	Upsher-Smith	Intranasal	All	02-2021
YONSA	abiraterone	Sun	Tablet	All	03-2021
IMPAVIDO	miltefosine	Knight Therapeutics	Capsule	All	03-2021
ACTOPLUS MET XR	pioglitazone/metformin	Takeda	Tablet, extended-release	All	03-2021
OVIDREL	choriogonadotropin	EMD Serono/Merck	Intramuscular; subcutaneous	All	03-2021
NEUPRO	rotigotine	UCB	Transdermal patch	All	03-2021
LYRICA CR	pregabalin	Pfizer	Tablet, extended-release	All	04-2021
ERAXIS	anidulafungin	Pfizer	Intravenous	All	04-2021
TECFIDERA	dimethyl fumarate	Biogen	Capsule, delayed-release	All	05-2021
ZOMIG	zolmitriptan	Impax/Grunenthal	Intranasal	All	05-2021
QUTENZA	capsaicin	Grunenthal	Transdermal patch	All	06-2021
PERFOROMIST	formoterol fumarate	Mylan	Inhalation	All	06-2021
APTIOM	eslicarbazepine	Sunovion/Bial	Tablet	All	06-2021
SEEBRI NEOHALER	glycopyrrolate	Novartis	Inhalation	All	06-2021
INTELENCE	etravirine	Janssen	Tablet	All	06-2021
FLOVENT HFA	fluticasone propionate	GlaxoSmithKline	Inhalation; aerosol	All	2H-2021
ORENCIA	abatacept	Bristol-Myers Squibb	Intravenous; subcutaneous	All	07-2021

Brand name	Generic name	Brand manufacturer	Dosage form	Strengths available as generic	Possible launch date
FERAHEME	ferumoxytol	AMAG Pharmaceuticals	Intravenous	All	07-2021
RESCULA	unoprostone isopropyl	R-Tech Ueno	Ophthalmic	All	07-2021
ALTRENO	tretinoin	Bausch Health	Lotion	All	08-2021
BALCOLTRA	levonorgestrel/ethinyl estradiol/ferrous bisglycinate	Avion	Tablet	All	08-2021
SUTENT	sunitinib	Pfizer	Capsule	All	08-2021
SELZENTRY	maraviroc	ViiV Healthcare	Tablet	All	08-2021
POMALYST	pomalidomide	Celgene	Capsule	All	08-2021
VERAMYST	fluticasone fumarate	GlaxoSmithKline	Intranasal	All	08-2021
JEVTANA KIT	cabazitaxel	Sanofi	Intravenous	All	09-2021
BYSTOLIC	nebivolol	Allergan	Tablet	All	09-2021
PRADAXA	dabigatran etexilate mesylate	Boehringer Ingelheim	Capsule	All	4Q-2021
INNOPRAN XL	propranolol	Ani Pharmaceuticals	Capsule, extended-release	All	10-2021
BIJUVA	estradiol/progesterone	TherapeuticsMD	Capsule	All	10-2021
MIRCERA	methoxy polyethylene glycol-epoetin beta	Roche/Royalty Pharma	Subcutaneous	All	11-2021
ENTYVIO	vedolizumab	Takeda	Intravenous	All	11-2021
BRYHALI	halobetasol	Bausch Health	Lotion	All	11-2021
BROVANA	arformoterol	Sunovion	Inhalation	All	11-2021
ONEXTON	clindamycin/benzoyl peroxide	Bausch Health	Gel	All	12-2021
EPANED KIT	enalapril	Silvergate	Oral solution	All	12-2021
CHANTIX	varenicline	Pfizer	Tablet	All	12-2021
CAYSTON	aztreonam lysine	Gilead	Inhalation	All	12-2021
BETHKIS	tobramycin	Chiesi	Inhalation	All	12-2021
MYTESI	crofelemer	Napo	Table, delayed-release	All	12-2021
EXPAREL	bupivacaine	Pacira	Injection	All	12-2021
SUPREP BOWEL PREP KIT	magnesium sulfate anhydrous/potassium sulfate / sodium sulfate	Braintree	Oral solution	All	12-2021

+ = may launch during the stated date or later

Extended brand pipeline forecast

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
2019 Possible launch date									
S-649266	cefiderocol	Shionogi/ GlaxoSmithKiline	cephalosporin antibiotic	Bacterial infections	IV	Filed NDA	8/14/2019	Yes	No
Nouriast	istradefylline	Kyowa Hakko Kogyo	A2A adenosine receptor antagonist	Parkinson's disease	PO	Filed NDA	8/27/2019	No	No
Rexista XR	oxycodone ER	IntelliPharmaCeutic	opioid agonist	Pain	PO	Filed NDA	8/28/2019	No	No
NKTR-181	NKTR-181	Nektar	opioid agonist	Pain	PO	Filed NDA	8/29/2019	No	No
tadalafil VersaFilm	tadalafil VersaFilm	IntelGenx	phosphodiesterase-5 (PDE-5) inhibitor	Erectile dysfunction	PO	Filed NDA	Mid-2019	Yes	No
fosphenytoin sodium/ sulfobutylether beta-cyclodextrin sodium	fosphenytoin sodium/ sulfobutylether beta-cyclodextrin sodium	Sedor	anticonvulsant	Seizures	IM/IV	Filed NDA	Mid-2019	Yes	No
XeriSol Glucagon	glucagon	Xeris	glucagon analog	Diabetes mellitus	SC	Filed NDA	9/10/2019	No	No
RDX-5791 (AZD-1722)	tenapanor	Ardelyx	sodium-hydrogen exchanger-3 (NHE-3) inhibitor	Irritable bowel syndrome-constipation	PO	Filed NDA	9/13/2019	No	No
Imvamune; MVA-BN	Imvamune; MVA-BN	Bavarian Nordic	vaccine	Smallpox	SC	Filed BLA	9/15/2019	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
NN-9924 (OG-217SC)	semaglutide (oral)	Novo Nordisk/ Emisphere Technologies	glucagon-like peptide-1 (GLP-1) receptor agonist	Diabetes mellitus	PO	Filed NDA	9/20/2019	Yes	No
Valtoco	diazepam	Neurelis	benzodiazepine	Seizures	Intranasal	Filed NDA	2H2019	No	Yes
Fasenra (self-administered)	benralizumab	AstraZeneca	interleukin-5 receptor (IL-5R) alpha inhibitor	Asthma	SC	Filed sNDA	2H2019	Yes	No
Scenesse	afamelanotide	Clinuvel	melanocortin receptor 1 (MC-1) agonist	Erythropoietic protoporphyria (EPP)/ Polymorphous light eruption (PLE/PMLE)/ Vitiligo	SC	Filed NDA	10/6/2019	Yes	Yes
PF-708	teriparatide	Pfenex/ Alvogen	parathyroid hormone	Osteoporosis	SC	Filed NDA	10/7/2019	Yes	No
Vumerity	monomethyl fumarate (diroximel fumarate)	Biogen/ Alkermes	Nrf2 pathway activator	Multiple sclerosis (MS)	PO	Filed NDA	10/17/2019	Yes	No
HP-3070	asenapine maleate	Noven Hisamitsu Pharmaceutical	5-HT2a and dopamine D1/D2 antagonist	Schizophrenia	TOP	Filed NDA	10/17/2019	No	No
Xipere	triamcinolone acetonide	Clearside	corticosteroid	Macular edema	intraocular/ subretinal	Filed NDA	10/19/2019	Yes	No
synthetic ACTH depot	cosyntropin	Assertio	adrenocorticotropic hormone (ACTH)	adrenocortical insufficiency	INJ	Filed NDA	10/19/2019	Yes	No
FMX-101 (ARK-E021)	minocycline	Foamix	tetracyclines	Acne vulgaris	TOP	Filed NDA	10/20/2019	No	No
ET-202	phenylephrine	Eton	alpha-1 adrenergic receptor agonist	Hypotension	IV	Filed NDA	10/21/2019	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
JDP-205	cetirizine	JDP Therapeutics	second generation antihistamine	Urticaria	IV	Filed NDA	10/30/2019	No	No
Zimhi	naloxone	Adamis	opioid antagonist	Opioid dependence	IM	Filed NDA	10/31/2019	No	No
RediTrex	methotrexate	Cumberland	dihydrofolate reductase (DHFR) inhibitor	Psoriasis; arthritis	SC	Filed NDA	11/1/2019	Yes	No
Talicia	rifabutin/ amoxicillin/ pantoprazole	RedHill Biopharma	RNA polymerase inhibitor/ penicillin/ proton pump inhibitor (PPI)	Bacterial infections	PO	Filed NDA	11/2/2019	No	No
Tlando	testosterone	Lipocine	androgen	Hypogonadism	PO	Filed NDA	11/9/2019	No	No
LY-573144 (COL-144)	lasmiditan	Eli Lilly	serotonin 5-HT1F receptor agonist	Acute migraines	PO	Filed NDA	11/14/2019	No	No
RTH-258 (ESBA-1008, DLX-1008)	brolucizumab	Novartis	anti-VEGF antibody	wet age-related (neovascular) macular degeneration (AMD)	Intravitreal	Filed BLA	11/15/2019	Yes	No
Twirla	ethinyl estradiol/ levonorgestrel	Agile Therapeutics	hormonal combination contraceptive	Pregnancy prevention	TOP	Filed NDA	11/17/2019	No	No
YKP-3089	cenobamate	SK Biopharmaceuticals	undisclosed	Seizure	PO	Filed NDA	11/21/2019	Yes	No
AQST-117	riluzole	Aquestive Therapeutics	glutamate release inhibitor	Amyotrophic lateral sclerosis (ALS)	SL/ Transmucosal	Filed NDA	11/30/2019	No	Yes
ACE-536 (RAP-536)	luspatercept	Celgene/ Acceleron	Modified type II activin receptor recombinant fusion protein	Anemia	SC	Filed BLA	12/4/2019	Yes	Yes
RVT-802	RVT-802	Enzyvant/Roivant	Tissue-based therapy	Congenital athymia	Implant	Filed NDA	12/2019	Yes	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
MK-1602 (AGN-241689)	ubrogepant	Allergan/ Merck	calcitonin gene-related peptide (CGRP) receptor antagonist	Acute migraines	PO	Filed NDA	12/15/2019	No	No
IDP-123	IDP-123	Bausch Health	retinoid	Acne	TOP	Filed NDA	12/22/2019	No	No
Brinavess (Kynapid)	vernakalant	Correvio	potassium channel blocker	Arrhythmia	IV	Filed NDA	12/24/2019	Yes	No
E-2006	lemborexant	Eisai/ Purdue	orexin receptor antagonist	Insomnia	PO	Filed NDA	12/27/2019	No	No
ITI-007 (ITI-722)	lumateperone	Intra-Cellular Therapies	antipsychotic	Schizophrenia	PO	Filed NDA	12/27/2019	No	No
Posidur	SABER-bupivacaine CR	Novartis/ Durect	local anesthetic	Pain	SC	Filed NDA	12/27/2019	No	No
S-265744 (S/GSK-1265744)	cabotegravir	ViiV Healthcare	HIV integrase inhibitor	Human immunodeficiency virus (HIV)	PO	Filed NDA	12/29/2019	Yes	No
TMC-278-LA	cabotegravir (long-acting)/ rilpivirine (long-acting)	ViiV Healthcare	HIV integrase inhibitor/ non-nucleoside reverse transcriptase inhibitor (NNRTI)	HIV-1	IM	Filed NDA	12/29/2019	Yes	No
MitoGel	mitomycin C	UroGen	alkylating agent	Bladder cancer	Intravesical	InTrial	4Q2019	No	Yes
Xyrosa	doxycycline	Sun Pharma	tetracyclines	Rosacea	PO	Tentative Approval	4Q2019	No	No
2020 Possible launch date									
OMS-721	narsoplimab	Omeros	anti-MASP-2	Hemolytic uremic	IV/SC	InTrial	2020	Yes	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
			monoclonal antibody	syndrome (HUS)/ Renal diseases					
CCP-08	CCP-08	Tris Pharma	undisclosed	Viral rhinitis	PO	CRL	2020	Yes	No
tamsulosin DRS	tamsulosin delayed-release	Veru	alpha-adrenergic antagonist	Benign prostatic hyperplasia (BPH)	PO	InTrial	2020	No	No
Zalviso	sufentanil, ARX-01	AcelRx	opioid analgesic	Pain	SL	CRL	2020	Yes	No
ELI-200	oxycodone/ naltrexone	Elite	opioid agonist	Pain	PO	CRL	2020	No	No
APL-130277	apomorphine	Sumitomo Dainippon/ MonoSol Rx/ Sunovion	non-ergoline dopamine agonist	Parkinson's disease	SL	CRL	2020	No	No
Entyvio (SC formulation)	vedolizumab	Takeda	integrin receptor antagonist	Ulcerative colitis (UC)/ Crohn's disease (CD)	SC	Filed sBLA	1/1/2020	Yes	No
AR-101	AR-101	Aimmune/ Regeneron/ Sanofi	peanut protein capsule	Peanut allergy	PO	Filed BLA	1/2020	No	No
SEG-101	crizanlizumab	Novartis	P-selectin antagonist	Sickle cell disease	IV	Filed BLA	1/15/2020	Yes	Yes
E-7438 (EPZ-6438)	tazemetostat	Epizyme/ Eisai	methyltransferase EZH2 inhibitor	Sarcoma	PO	Filed NDA	1/23/2020	Yes	Yes
Rykindo	risperidone ER	Luye	atypical antipsychotic	Schizophrenia/ Schizoaffective disorder	IM	Filed NDA	1/28/2020	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
FP-001 (LMIS)	leuprolide mesylate	Foresee	gonadotropin-releasing hormone (GnRH) analog	Prostate cancer	SC	Filed NDA	1/29/2020	Yes	No
ALN-AS1	givosiran	Alnylam	RNAi therapeutic agent	Porphyria	SC	Filed NDA	2/4/2020	Yes	Yes
BLU-285	avapritinib	Blueprint Medicines	selective KIT and PDGFRa inhibitor	Gastrointestinal stromal tumors (GIST)	PO	Filed NDA	2/14/2020	Yes	Yes
BMS-927711 (BHV-3000)	rimegepant sulfate	Portage Biotech/ Biohaven/ Bristol-Myers Squibb	calcitonin gene-related peptide (CGRP) receptor antagonist	Acute migraines	PO	Filed NDA	2/20/2020	Yes	No
ETC-1002	bempedoic acid	Esperion Therapeutics	ATP citrate (pro-S)-lyase and stimulating AMP-activated protein kinase (AMPK)	Hypercholesterolemia	PO	Filed NDA	2/21/2020	No	No
ALD-403	eptinezumab	Alder	calcitonin gene-related peptide (CGRP) receptor antagonist	Migraine prevention	IV/SC	Filed BLA	2/22/2020	No	No
ETC-1002/ ezetimibe	bempedoic acid/ ezetimibe	Esperion Therapeutics	ATP citrate (pro-S)-lyase and stimulating AMP-activated protein kinase (AMPK)/ cholesterol absorption inhibitor	Hypercholesterolemia	PO	Filed NDA	2/26/2020	No	No
CD-5789	trifarotene	Galderma	retinoid receptor agonist	Acne	TOP	Filed NDA	2/28/2020	No	No
RV-001 (Roche-1, R-1507)	teprotumumab	Horizon/ Chugai/ Roche/ Genmab	insulin-like growth factor 1 (IGF-1) receptor antagonist	Thyroid eye disease	IV	Filed BLA	3/6/2020	Yes	Yes
naloxone nasal spray	naloxone	Insys Therapeutics	opioid antagonist	Opioid dependence	Intranasal	Filed NDA	3/15/2020	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
ASG-22M6E (ASG-22CE, ASG-22ME)	enfortumab vedotin	Astellas/ Seattle Genetics	nectin-4 antagonist	Bladder cancer	IV	Filed BLA	3/16/2020	Yes	No
ET-105	lamotrigine	Eton	anticonvulsant	Epilepsy	PO	Filed NDA	3/17/2020	No	No
VX-445	elexacaftor	Vertex	cystic fibrosis transmembrane conductance regulator (CFTR) corrector	Cystic fibrosis (CF)	PO	Filed NDA	3/20/2020	Yes	No
ozanimod	ozanimod	Celgene	sphingosine 1-phosphate 1 (S1PR1) and 5 (S1PR5) receptor modulator	Multiple sclerosis/ Ulcerative colitis (UC)	PO	Filed NDA	3/25/2020	Yes	No
Corplex	donepezil transdermal system	Corium International	anticholinergic	Alzheimer's disease	TOP	InTrial	1Q2020	No	No
ITCA-650 (sustained release exenatide)	exenatide sustained-release	Intarcia/ Quintiles/ Servier	glucagon-like peptide-1 (GLP-1) receptor agonist	Diabetes mellitus	SC implant	CRL	1Q2020	Yes	No
PPP-002	PPP-002	Tetra Bio-Pharma	botanical drug	Pain	Undisclosed	InTrial	1Q2020	No	No
Barhemsys	amisulpride	Acacia	dopamine receptor antagonist	Nausea/ Vomiting	IV	CRL	1Q2020	No	No
Bronchitol	mannitol	Pharmaxis	osmotic gradient enhancer; mucus clearance enhancer	Asthma/ Cystic fibrosis	INH	CRL	1Q2020	No	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Prochymal	remestemcel-L	Mesoblast/ JCR/ Mallinckrodt/ Osiris Therapeutics	mesenchymal stem cells	Graft vs. Host disease (GvHD)/ Crohn's disease/ Gastrointestinal injury post radiation exposure/ Heart failure (HF)	IV	InTrial	1Q2020	Yes	Yes
LCI-699	osilodrostat	Novartis	aldosterone synthase inhibitor	Cushing's syndrome	PO	Filed NDA	1Q2020	No	Yes
TG-1303	ublituximab/ TGR-1202	TG Therapeutics	CD-20 monoclonal antibody/ phosphoinositide-3 kinase (PI3K) delta inhibitor	Chronic lymphocytic leukemia (CLL)/ Diffuse large B-cell lymphoma (DLBCL)/ Non-Hodgkin lymphoma (NHL)	IV/PO	InTrial	1Q2020	Yes	Yes
empagliflozin, linagliptin, metformin XR	empagliflozin, linagliptin, metformin XR	Eli Lilly/ Boehringer Ingelheim	sodium glucose co-transporter-2 (SGLT-2) inhibitor, dipeptidyl peptidase 4 (DPP4) inhibitor, biguanide	Diabetes mellitus	PO	Filed NDA	1Q2020	No	No
Taclantis	paclitaxel injection concentrate for suspension	Sun Pharma Advanced Research Company (SPARC)	taxane	Breast Cancer; Lung Cancer; Pancreatic Cancer	IV	Filed NDA	1Q2020	No	No
bimatoprost sustained release	bimatoprost sustained release	Allergan	prostaglandin agonist	Glaucoma	Implant	Filed NDA	4/1/2020	N/A	No
UX-007	triheptanoin	Ultragenyx/ Baylor Research Institute/ Uniquest	medium chain fatty acid	Glucose transport type 1 deficiency syndrome (G1DS)	PO	Filed NDA	4/1/2020	Yes	Yes
CNS-7056 (ONO-	remimazolam	Cosmo/ Hana/	benzodiazepine	Procedural sedation	IV	Filed NDA	4/3/2020	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
2745)		Paion/ Pharmascience/ R-Pharm/ Yichang Humanwell							
Viaskin Peanut	Viaskin Peanut	DBV Technologies	Immunotherapy	Peanut allergy	TOP	Filed BLA	4/7/2020	No	No
Men Quad TT	meningococcal polysaccharide (serogroups A, C, Y, and W135) tetanus toxoid conjugate vaccine	Sanofi	antibacterial	meninococcus/ tetanus	IM	Filed BLA	4/25/2020	No	No
Ongentys	opicapone	Neurocrine Biosciences/ Bial/ Ono	catechol-O-methyltransferase (COMT) inhibitor	Parkinson disease	PO	Filed NDA	4/26/2020	No	No
Trevyent	treprostinil	SteadyMed	prostacyclin analog	Pulmonary arterial hypertension (PAH)	SC	Filed NDA	4/27/2020	Yes	Yes
isatuximab	isatuximab	Sanofi/ ImmunoGen	CD38 antagonist	Multiple myeloma/ Acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL)	IV	Filed BLA	4/30/2020	Yes	Yes
SEP-225289 (DSP-225289, SEP-289)	dasotraline	Sumitomo Dainippon/ Sunovion	triple reuptake inhibitor	Attention deficit hyperactivity disorder (ADHD)/ Eating disorders	PO	Filed NDA	5/14/2020	No	No
FMX-103	minocycline	Foamix	tetracyclines	Rosacea	TOP	InTrial	6/5/2020	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Bafiertam	monomethyl fumarate	Banner Life Sciences	prodrug	Multiple sclerosis	PO	Tentative Approval	6/20/2020	Yes	No
V-114	pneumococcal conjugate vaccine	Merck	vaccine	Bacterial infection	IM	InTrial	2Q2020	Yes	No
KP-415	D-threo-methylphenidate controlled-release	KemPharm	CNS stimulant	Attention deficit hyperactivity disorder (ADHD)	PO	InTrial	2Q2020	No	No
Gimoti	metoclopramide	Evoke Pharma	antidopiminergics	Diabetic gastroparesis	Intranasal	CRL	2Q2020	No	No
PEGPH-20	pegvorhyaluronidase alfa	Halozyme/ Nektar	hyaluronic acid	Pancreatic cancer/ Non-small cell lung cancer (NSCLC)	IV	InTrial	1H2020	Yes	Yes
ZEBOV	VS-EBOV (rVSV-EBOV; rVSV-ZEBOV-GP)	Merck/ NewLink Genetics	vaccine	Ebola	IM	Filed BLA	1H2020	Yes	No
Lenti-D	elivaldogene tavalentivec	Bluebird Bio	gene therapy	Adrenomyeloneuropathy	Undisclosed	InTrial	1H2020	Yes	Yes
IMMU-132	sacituzumab govitecan	Immunomedics/ Royalty Pharma	RS7-SN-38 antibody-drug conjugate	Breast cancer/ Pancreatic cancer/ Pancreatic cancer/ Small cell lung cancer (SCLC)/ Non-small cell lung cancer (NSCLC)/ Colorectal cancer/ Esophageal cancer/ Urinary bladder cancer	IV	CRL	1H2020	Yes	Yes
FT-218	sodium oxybate	Avadel	dopamine receptor	Narcolepsy	PO	InTrial	1H2020	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
	extended-release		agonist						
Apealea (Paclical)	paclitaxel	Oasmia	taxane	Ovarian cancer	IV	InTrial	1H2020	Yes	Yes
Traumakine	interferon-beta -1a	Faron/ Maruishi	interferon	Acute respiratory distress syndrome (ARDS)	IV	InTrial	1H2020	Yes	No
ropeginterferon alfa-2b	ropeginterferon alfa-2b	PharmaEssentia/ AOP Orphan	interferon	Polycythemia vera (PV)/ Myelofibrosis (MF)/ Essential thrombocythemia (ET)	SC	InTrial	1H2020	Yes	Yes
Rizaport (VersaFilm)	rizatriptan	IntelGenx / Red Hill Biopharma	triptans	Acute migraines	PO	CRL	1H2020	No	No
Zynteglo (LentiGlobin)	lentiviral beta-globin gene transfer	Bluebird Bio	gene therapy	Sickle cell disease/ Beta thalassemia	IV	InTrial	1H2020	Yes	Yes
MC2-01 (MC-201)	calcipotriene/ betamethasone	MC2 Therapeutics	vitamin D analog/ corticosteroid	Psoriasis	TOP	InTrial	1H2020	No	No
R-667 (RG-667)	palovarotene	Clementia/ Roche	selective retinoic acid receptor agonist (RAR-gamma)	Fibrodysplasia ossificans progressiva (FOP)	PO	InTrial	1H2020	Yes	Yes
DS-8201	[fam-] trastuzumab deruxtecan	Daiichi Sankyo	HER2-targeting antibody-drug conjugate	Breast cancer	IV	InTrial	1H2020	Yes	No
SA-237 (RG-6168)	satralizumab	Roche/ Chugai	interleukin-6 (IL-6) monoclonal antibody	Neuromyelitis optica (NMO)	SC	InTrial	1H2020	Yes	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
FG-4592 (ASP-1517)	roxadustat	FibroGen/ Astellas/ AstraZeneca	hypoxia-inducible factor prolyl hydroxylase (HIF-PHI)	Anemia	PO	InTrial	1H2020	Yes	No
RT-002	daxibotulinumtoxinA	Revance Therapeutics	botulinum toxins	Cosmetic/ Cervical dystonia/ Plantar fasciitis	IM	InTrial	1H2020	Yes	Yes
Ryplazim	human plasminogen	ProMetic/ Hematech	plasminogen	Plasminogen deficiency	IV	InTrial	1H2020	Yes	Yes
JCAR-017	lisocabtagene maraleucel	Juno/ Celgene	chimeric antigen receptor (CAR) T cell therapy	Diffuse large B-cell lymphoma (DLBCL)/ Acute lymphocytic leukemia (ALL)/ Follicular lymphoma/ Mantle cell lymphoma	IV	InTrial	Mid-2020	Yes	Yes
Sarasar	lonafarnib	Eiger Biopharmaceuticals	prenylation inhibitor	Hepatitis D (HDV); Hutchinson-Gilford Progeria Syndrome (HGPS or progeria) and progeroid laminopathies	PO	InTrial	Mid-2020	Yes	Yes
GSK-2857916	GSK-2857916	GlaxoSmithKline/ Seattle Genetics	anti-BCMA antibody-drug conjugate	Multiple myeloma	SC	InTrial	Mid-2020	Yes	Yes
Ryaltris	mometasone furoate/ olopatadine HCl	Glenmark	corticosteroid/ antihistamine	Allergic rhinitis	NA	CRL	Mid-2020	No	No
QVM-149	indacaterol/ glycopyrronium bromide/	Novartis/ Sosei	long-acting beta 2 adrenergic receptor agonist (LABA)/ long-	Asthma	INH	InTrial	Mid-2020	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
	mometasone furoate		acting muscarinic receptor antagonist (LAMA)/ corticosteroid						
RG-7916 (RO-7034067)	Risdiplam	Roche/ PTC Therapeutics	SMN2 splicing modifier	Spinal muscular atrophy	PO	InTrial	Mid-2020	Yes	Yes
SRP-4045	casimersen	Sarepta	morpholino antisense oligonucleotide	Duchenne muscular dystrophy (DMD)	IV	InTrial	Mid-2020	Yes	Yes
idebenone	idebenone	Santhera	co-enzyme Q-10 analog	Duchenne muscular dystrophy	PO	CRL	Mid-2020	Yes	Yes
Amphora	Amphora	Neothetics	spermicidal agent	Pregnancy prevention/ Bacterial infections	VG	CRL	Mid-2020	No	No
GBT-440 (GTx-011)	voxelotor	Global Blood Therapeutics	hemoglobin modulator	Sickle cell anemia	PO	InTrial	Mid-2020	Yes	Yes
TGR-1202	umbralisib	TG Therapeutics/ Rhizen	phosphoinositide-3 kinase (PI3K) delta inhibitor	Diffuse large B-cell lymphoma (DLBCL)/ Chronic lymphocytic leukemia (CLL)	PO	InTrial	Mid-2020	Yes	Yes
3-F8 (Hu-3F8)	naxitamab	Y-mAbs Therapeutics	GD2 antagonist	Neuroblastoma	IV	InTrial	Mid-2020	Yes	Yes
Winlevi/ Breezula	cortexolone 17alpha-propionate (CB-03-01)	Intrepid	androgen antagonist	Acne vulgaris/ alopecia	TOP	InTrial	Mid-2020	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Darzalex	daratumumab (with recombinant human hyaluronidase)	Johnson & Johnson / Genmab	humanized anti-CD38 monoclonal antibody	Multiple myeloma/ Amyloidosis	SC	Filed BLA	7/10/2020	Yes	Yes
BMN-270	valoctocogene roxaparvovec	BioMarin	gene therapy	Hemophilia	IV	InTrial	3Q2020	Yes	Yes
TBR-652 (TAK-652, CVC)	cenicriviroc	Tobira Therapeutics/ Takeda	C-C chemokine receptor 5 (CCR5) and receptor 2 antagonist	HIV/ Non-alcoholic steatohepatitis (NASH)	PO	InTrial	3Q2020	Yes	No
BCX-7353	BCX-7353	BioCryst	kallikrein inhibitor	Hereditary angioedema (HAE)	PO	InTrial	3Q2020	Yes	Yes
PPP-001	delta-9-tetrahydrocannabinol/ cannabidiol	PhytoPain Pharma	cannabinoid product	Pain	INH	InTrial	3Q2020	Yes	Yes
TRC-101	TRC-101	Tricida	carrier protein modulator	Chronic kidney disease (CKD)	PO	InTrial	3Q2020	Yes	No
Brixadi	buprenorphine	Camurus/ Braeburn	opioid receptor agonist (partial)	Opioid dependence/ Pain	SC	Tentative Approval	11/1/2020	Yes	No
IdeS (immunoglobulin G-degrading enzyme of Streptococcus pyogenes)	imlifidase	Hansa Medical	bacterial enzyme	Kidney transplant/ Thrombotic thrombocytopenic purpura (TTP)/Goodpasture's disease	IV	InTrial	2H2020	Yes	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
INCB-54828	pemigatinib	Incyte	selective FGFR1/2/3 inhibitor	Biliary tract cancer	PO	InTrial	2H2020	Yes	Yes
BMS-663068 (BMS-626529 prodrug)	fostemsavir (temsavir prodrug)	Bristol-Myers Squibb	HIV attachment inhibitor	Human immunodeficiency virus (HIV)	PO	InTrial	2H2020	Yes	No
LIQ-861	treprostinil	Liquidia Technologies	prostacyclin analog	Pulmonary arterial hypertension (PAH)	INH	InTrial	2H2020	Yes	No
Olinvo	oliceridine	Trevena	opioid receptor agonist	Pain	IV	CRL	2H2020	No	No
INP-104	POD-dihydroergotamine mesylate (POD-DHE)	Impel/ 3M	ergot derivative	Acute migraines	NA	InTrial	2H2020	No	No
BGB-3111	zanubrutinib	BeiGene	selective inhibitor of Bruton tyrosine kinase (BTK)	Waldenström's Macroglobulinemia (WM)/ Chronic lymphocytic leukemia (CLL)	PO	InTrial	2H2020	Yes	Yes
EGP-437	dexamethasone phosphate (iontophoretic)	EyeGate	corticosteroid	Uveitis	OP	InTrial	2H2020	Yes	No
Libervant	diazepam	Aquestive Therapeutics	benzodiazepine	Seizures	SL/ Transmucosal	InTrial	2H2020	No	Yes
EM-100	ketotifen	Eton	antihistamine	Allergic conjunctivitis/ Dry eyes	OP	CRL	2H2020	No	No
MAGH-22	margetuximab	MacroGenics/ Green Cross	HER2 oncoprotein antagonist	Breast cancer	IV	InTrial	2H2020	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Sci-B-Vac	hepatitis B vaccine	VBI Vaccines	vaccine	Hepatitis B (HBV)	IM	InTrial	2H2020	No	No
sulopenem	sulopenem	Iterum	carbapenem	Bacterial infection	IV/PO	InTrial	2H2020	No	No
quizartinib	quizartinib	Daiichi Sankyo	FLT-3 receptor tyrosine kinase inhibitor	Acute myeloid leukemia (AML)	PO	CRL	2H2020	Yes	Yes
VP-102	VP-102	Verrica	antiviral	Molluscum/ Verruca vulgaris	TOP	InTrial	2H2020	No	No
GLPG-0634	filgotinib	Galapagos NV/ Gilead	janus associated kinase-1 (JAK) inhibitor	Rheumatoid arthritis/ Crohn's disease/ Ulcerative colitis (UC)/ Sjogren's syndrome/ Ankylosing spondylitis/ Psoriatic arthritis	PO	InTrial	2H2020	Yes	No
NX-1207 (NYM-4805, REC 0482)	fexapotide triflutate	Nymox	pro-apoptotic	Benign prostatic hyperplasia (BPH)/ Prostate cancer	Intratumoral	InTrial	2H2020	Yes	No
AKB-6548	vadadustat	Akebia Therapeutics	hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor	Anemia	PO	InTrial	2H2020	Yes	No
NexoBrid	bromelain	MediWound/ BL&H/ CrystalGenomics/ Kaken	peptide hydrolase replacement agent	Burns/ Skin injury	TOP	InTrial	2H2020	No	Yes
LOXO-292	LOXO-292	Loxo Oncology/ Eli Lilly	RET inhibitor	Solid tumors; non-small cell lung cancer (NSCLC); thyroid cancer	PO	InTrial	2H2020	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
NPI-2358	plinabulin	BeyondSpring	tumor vascular disrupting agent (tVDA)	Neutropenia/ Non-small cell lung cancer (NSCLC)	IV	InTrial	2H2020	Yes	No
PXT-3003	baclofen/ naltrexone/ sorbitol	Pharnext	gamma-aminobutyric acid (GABA)-ergic agonist/ opioid receptor antagonist/ sorbitol combination	Charcot-Marie Tooth disease	PO	InTrial	2H2020	No	Yes
ZP-4207 (ZP-GA-1)	dasiglucagon	Zealand Pharma	glucagon analog	Diabetes mellitus	SC	InTrial	2H2020	No	Yes
Zeftera	ceftobiprole	Basilea	cephalosporin antibiotic	Bacterial infections	IV	InTrial	2H2020	Yes	No
Vicinium (VB-4-845)	oportuzumab monatox	Eleven Biotherapeutics	anti-ECAM exotoxin A fusion protein	Bladder cancer	Intravesical	InTrial	2H2020	Yes	No
LJPC-0118	LJPC-0118	La Jolla Pharmaceutical	protozoacide	Malaria	Undisclosed	InTrial	2H2020	No	No
selumetinib	selumetinib	AstraZeneca/ Array BioPharma/ Cancer Research UK	selective MEK kinase inhibitor	Uveal melanoma/ Thyroid cancer	PO	InTrial	2H2020	Yes	Yes
Mycapssa (Octreolin)	octreotide	Chiasma	somatostatin analog	Acromegaly	PO	CRL	2H2020	Yes	Yes
Doria	risperidone	Laboratorios Farmacéuticos Rovi	atypical antipsychotic	Schizophrenia	IM	InTrial	2H2020	Yes	No
Iomab-B	iodine I 131 monoclonal antibody BC8	Actinium	anti-CD45 monoclonal antibody	Acute myeloid leukemia (AML)/ Myelodysplastic syndrome (MDS)	IV	InTrial	2H2020	Yes	Yes
SPN-812	SPN-812	Supernus	selective norepinephrine reuptake inhibitor	Attention deficity hyperactivity disorder (ADHD)	PO	InTrial	2H2020	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
PRX-102	alpha galactosidase (pegunigalsidase alfa)	Protalix	enzyme replacement	Fabry disease	IV	InTrial	2H2020	Yes	No
ASTX-727	decitabine and E-7727	Otsuka/ Astex Pharmaceuticals	nucleoside metabolic inhibitor	Myelodysplastic syndrome (MDS)	PO	InTrial	2H2020	Yes	No
arimoclomol	arimoclomol	Orphazyme	cytoprotectives	Niemann-Pick Disease (NPD)/ Sporadic Inclusion Body Myositis (IBM)/ Amyotrophic lateral sclerosis (ALS)	PO	InTrial	2H2020	Yes	Yes
PRT-201	vonapanitase	Proteon Therapeutics	human elastase (recombinant)	End stage renal diease (ESRD)/Peripheral artery disease (PAD)/ Vascular access in hemodialysis	TOP	InTrial	2H2020	Yes	Yes
bb-2121	idecabtagene vicluecel	Celgene/ Bluebird Bio	chimeric antigen receptor (CAR) T cell therapy	Multiple myeloma/ Brain cancer	IV	InTrial	2H2020	Yes	Yes
KPI-121 0.25%	loteprednol etabonate	Kala	corticosteroid	Dry eyes	OP	CRL	2H2020	No	No
Anti-VEGF DARPin	abicipar pegol	Allergan	VEGF-A inhibitor	Age-related macular degeneration (AMD)	Intravitreal	InTrial	2H2020	Yes	No
AmnioFix	dehydrated human amnion/chorion membrane (dHACM)	MiMedx	amniotic tissue membrane	Plantar fasciitis/ Achilles tendonitis/ Osteoarthritis	INJ	InTrial	4Q2020	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
tramadol	tramadol	Avenue Therapeutics	opioid receptor agonist	Pain	IV	InTrial	4Q2020	No	No
Estelle	estetrol/ drospirenone	Mithra/ Fuji/ Zhejian Xianju	estrogen receptor agonist	Pregnancy prevention	PO/SL/ Transmucosal	InTrial	4Q2020	No	No
Infacort	hydrocortisone	Diurnal Group	corticosteroid	Adrenal insufficiency	PO	InTrial	4Q2020	No	Yes
MOR-208 (MOR-00208, XmAB-5574)	tafasitamab	MorphoSys/ Xencor	CD-19 antagonist	Diffuse large B-cell lymphoma (DLBCL)/ Acute lymphocytic leukemia (ALL)/ Chronic lymphocytic leukemia (CLL)	IV	InTrial	4Q2020	Yes	Yes
Melflufen (Ygalo)	melphalan-flufenamide	Oncopeptides AB	alkylating agent/ DNA synthesis inhibitor	Multiple myeloma/ Non-small cell lung cancer (NSCLC)/ Ovarian cancer	IV	InTrial	4Q2020	No	Yes
BLU-667	BLU-667	Blueprint Medicines	RET inhibitor	Non-Small Cell Lung Cancer (NSCLC)	PO	InTrial	4Q2020	Yes	Yes
Qtrypta	zolmitriptan	Zosano	triptans	Acute migraines	TOP	InTrial	4Q2020	No	No
Qarziba (Isqette)	dinutuximab beta	EUSA/ Aperion/ Endo/ Gen Ilac/ Medison	disialoganglioside	Neuroblastoma	SC	InTrial	2020	Yes	Yes
Multikine	Leukocyte Interleukin (CS-001P3)	CEL-SCI	immunomodulator	Head and Neck cancer/ Squamous cell carcinoma	SC	InTrial	2020	Yes	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
HTX-011	bupivacaine/ meloxicam	Heron Therapeutics	anesthetic/ Nonsteroidal Anti-inflammatory Drug (NSAID)	Pain	Instillation	CRL	2020	No	No
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	2020	Yes	Yes
INCB-028060	capmatinib	Novartis/ Incyte	cMET inhibitor	Non-small cell lung cancer (NSCLC)	PO	InTrial	2020	Yes	No
Oralair Mites	dust mite peptide	Stallergenes/ Shionogi	vaccine	Dust mite allergic rhinitis	SL	InTrial	2020	Yes	No
Deltyba	delamanid	Otsuka	mycolic acid biosynthesis inhibitor	Tuberculosis	PO	InTrial	2020	No	No
JNJ-872 (VX-787)	JNJ-872 (VX-787)	Johnson & Johnson/ Vertex	viral protein inhibitor	Influenza	PO	InTrial	2020	No	No
Zynquista	sotagliflozin	Sanofi/ Lexicon	sodium-dependent glucose transporter 1 (SGLT-1) and SGLT-2 inhibitor	Diabetes mellitus	PO	CRL	2020	No	No
NeoCart	autologous chondrocyte tissue implant	Histogenics/ Purpose	autologous chondrocyte tissue implant	Joint repair	Undisclosed	InTrial	2020	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
NNC-0195-0092 (NN-8640)	somapacitan	Novo Nordisk	recombinant human growth hormone (rhGH)	Short stature/ Growth hormone deficiency	SC	InTrial	2020	Yes	No
Sativex	nabiximols	GW Pharmaceuticals/ Otsuka	cannabinoid product	Multiple sclerosis (MS)/ Pain	SL/ SPR	InTrial	2020	No	No
Contepo	fosfomycin	Nabriva Therapeutics	cell wall inhibitor	Bacterial infections	IV	CRL	2020	Yes	No
VivaGel	astodrimer sodium (SPL-7013)	Starpharma	viral attachment inhibitor	Bacterial infections	VG	CRL	2020	No	No
CM-AT	CM-AT	Curemark	protein absorption enhancer	Autism	PO	InTrial	2020	Yes	No
MLN-4924 (TAK-92)	pevonedistat	Takeda	Nedd 8 Activating Enzyme (NAE) antagonist	Acute myeloid leukemia (AML)/ Chronic myelogenous leukemia (CML)/ Myelodysplastic syndrome (MDS)	PO	InTrial	2020	Yes	No
N-1539	meloxicam	Recro Pharma/ Alkermes	nonsteroidal anti-inflammatory drug (NSAID)	Pain	IV	CRL	2020	Yes	No
ND-0612H	levodopa/ carbidopa	NeuroDerm	dopamine precursor/ dopa-decarboxylase inhibitor	Parkinson's disease (PD)	SC	InTrial	2020	Yes	No
Pedmark (STS)	sodium thiosulfate	Fennec	reducing agent	Hearing loss	IV	InTrial	2020	Yes	Yes
ursodeoxycholic acid	ursodeoxycholic acid	Retrophin/ Asklepion	bile acid derivative	Primary biliary cirrhosis/cholangitits	PO	InTrial	2020	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Travivo	gepirone ER	GSK/Fabre-Kramer	5-HT-1A receptor agonist	Major depressive disorder (MDD)	PO	CRL	2020	No	No
Dexasite	dexamethasone	InSite Vision	corticosteroid	Blepharitis/ Ocular inflammation	TOP	InTrial	2020	No	No
APC-8000	tadalafil	Adamis	phosphodiesterase-5 (PDE-5) inhibitor	Erectile dysfunction	PO	CRL	2020	Yes	No
ND-0612L	levodopa/ carbidopa	NeuroDerm	dopamine precursor/ dopa-decarboxylase inhibitor	Parkinson's disease (PD)	SC	InTrial	2020	Yes	No
BGF-MDI (PT-010)	budesonide/ glycopyrronium/ formoterol	AstraZeneca	corticosteroid/ long-acting muscarinic receptor antagonist (LAMA)/ long-acting beta 2 adrenergic receptor agonist (LABA)	Chronic obstructive pulmonary diseaser (COPD)/ Asthma	INH	InTrial	2020	No	No
Tivopath (AV-951, KRN-951, ASP-4130)	tivozanib	Aveo/ Astellas/ Kyowa Hakko Kirin	VEGF inhibitor	Renal cell cancer	PO	InTrial	2020	Yes	No
DS-200	DS-200	Eton	undisclosed	Ophthalmological disease	SC	InTrial	2020	unknown	No
QMF-149	indacaterol maleate/ mometasone furoate	Novartis/ Merck	long-acting beta 2 agonist/ corticosteroid	Asthma	INH	InTrial	2020	No	No
BHV-0223	riluzole	Biohaven	glutamate release inhibitor	Amyotrophic lateral sclerosis (ALS)	SL/ Transmucosal	CRL	2020	No	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
MNK-812	oxycodone	Mallinckrodt	opioid agonist	Pain	PO	CRL	2020	No	No
CPP-1X/ sulindac (DFMO)	eflornithine/ sulindac	Cancer Prevention Pharma/ Zeria	ornithine decarboxylase inhibitor/ non-steroidal anti-inflammatory drug (NSAID)	Familial adenomatous polyposis (FAP)/ Colorectal cancer	PO	InTrial	2020	Yes	Yes
GZ-402666 (NeoGAA)	neo-recombinant human acid alpha glucosidase	Sanofi	enzyme therapy	Pompe disease	IV	InTrial	2020	Yes	No
Numbrino	cocaine HCl	Lannett	anesthetic	Anesthesia	TOP	CRL	2020	No	No
cannabidiol	cannabidiol	Insys Therapeutics	cannabinoid product	Seizures/ Prader-Willi	PO	InTrial	Late 2020	Yes	No
skQ1	visomitin	Mitotech	plastoquinone derivative	Dry eyes	OP	InTrial	Late 2020	Yes	No
tanezumab	tanezumab	Pfizer/ Eli Lilly	neurotrophic tyrosine kinase receptor type 1 (TrkA) antagonist (monoclonal antibody)	Osteoarthritis/ Pain	IV/SC	InTrial	Late 2020	Yes	No
BMN-111	vosoritide (vasoritide)	BioMarin/ Chugai	C-type natriuretic peptide (CNP) analog	Achondroplasia	SC	InTrial	Late 2020	Yes	Yes
NS-2 (ALDX-1E1, ALDX-1E2, ADX-102)	reproxalap	Aldeyra Therapeutics	aldehyde antagonist	Uveitis/ Allergic conjunctivitis/ Dry eyes	OP	InTrial	Late 2020	No	No
azacitidine	azacitidine	Celgene	DNA methylation inhibitor	Acute myeloid leukemia (AML)/ Myelodysplastic syndromes	PO	InTrial	Late 2020	Yes	Yes

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	InTrial	Late 2020	No	No
QAW-039 (NVP-QAW-039)	fevipiprant	Novartis	chemoattractant receptor-homologous molecule (CRTH2) antagonist	Asthma/ Atopic dermatitis	PO	InTrial	Late 2020	Yes	No
Molgradex	molgramostim	Savara	granulocyte macrophage-colony stimulating factor	Pulmonary alveolar proteinosis (PAP)	INH	InTrial	Late 2020	Yes	Yes
Translarna	ataluren	PTC Therapeutics	gene transcription modulator	Duchenne muscular dystrophy/ Mucopolysaccharidosis (MPS)	PO	CRL	Late 2020	Yes	Yes
BIVV-009 (TNT-009)	sutimlimab	Sanofi	complement C1s subcomponent inhibitor	Cold agglutnin disease	IV	InTrial	Late 2020	Yes	Yes
RG-3477 (ACT-128800)	ponesimod	Johnson & Johnson	sphingosine 1 phosphate receptor agonists	Multiple sclerosis	PO	InTrial	Late 2020	Yes	No
Lucassin	terlipressin	Orphan Therapeutics/ Ikaria	V-1 (vasopressin) agonist	Hepato-renal syndrome (HRS)	IV	CRL	Late 2020	Yes	Yes
HuMax-TF ADC	tisotumab vedotin	Genmab/ Seattle Genetics	tissue factor antibody	Solid tumors	Undisclosed	InTrial	Late 2020	Yes	No
RE-024	fosmetpantotenate	Retrophin	phosphopantothenate replacement therapy	Neurodegeneration	IV	InTrial	Late 2020	Yes	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
MK-0594 (VPD-737)	serlopitant	Menlo	NK-1 receptor antagonist	Atopic dermatitis/ Cough	PO	InTrial	Late 2020	Yes	No
Linhaliq	ciprofloxacin	Aradigm/ Grifols	fluoroquinolone	Non-cystic fibrosis bronchiectasis/ Cystic fibrosis	INH	CRL	Late 2020	Yes	Yes
MEDI-551	inebilizumab	AstraZeneca	CD-19 antagonist	Neuromyelitis optica (NMO)	IV	InTrial	Late 2020	Yes	Yes
TSR-042	dostarlimab	AnaptysBio	PD-1 checkpoint inhibitor	Endometrial cancer	IV	InTrial	Late 2020	Yes	No
LY-900014 (URLi)	LY-900014	Eli Lilly	insulins	Diabetes mellitus	SC	InTrial	Late 2020	No	No
SHP-621	budesonide	Shire	corticosteroid	Eosinophilic esophagitis	PO	InTrial	Late 2020	Yes	Yes
iclaprim	iclaprim	Motif Bio	tetrahydrofolate dehydrogenase inhibitor	Bacterial infections	IV	CRL	Late 2020	Yes	Yes
GFT-505	elafibranor	Genfit	selective peroxisome proliferator-activated receptor (PPAR) modulator	Non-alcoholic steatohepatitis (NASH)/ Primary biliary cirrhosis	PO	InTrial	Late 2020	No	No
BIM-22493 (RM-493)	setmelanotide	Rhythm/ Camurus/ Ipsen	melanocortin 4 receptor (MC4R) agonist	Obesity/ Bardet-Biedl syndrome	SC	InTrial	Late 2020	Yes	Yes
SCY-078 (MK-3118)	ibrexafungerp	Scynexis/ R-Pharm JSC/ Merck	glucan synthase inhibitors	Fungal infections	IV/PO	InTrial	Late 2020	No	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
2021 Possible launch date									
Furoscix	furosemide	scPharmaceuticals	diuretic	Heart failure	SC	CRL	1Q2021	Yes	No
MK-4618 (KRP-114V, RVT-901)	vibegron	Roivant Sciences/ Urovant/ Kissei/ Kyorin/ Merck	selective beta 3 adrenergic receptor agonist	Overactive bladder	PO	InTrial	1Q2021	No	No
ALNG-01 (ALN-G-01)	lumasiran	Alnylam	glycolate oxidase antagonist	Hyperoxaluria	Intranasal	InTrial	1Q2021	Yes	Yes
SDP-037, SDN-037	SDP-037, SDN-037	Sun Pharma Advanced Research Company (SPARC)	Corticosteroid	Ocular inflammation/pain	OP	InTrial	2Q2021	No	No
UCB-4940 (CDP-4940)	bimekizumab	UCB	interleukin-17 (IL-17) receptor inhibitor	Psoriasis(Ps)/ Psoriatic arthritis (PsA)/ Ankylosing spondylitis (AS)/ Rheumatoid arthritis (RA)	IV	InTrial	1H2021	Yes	No
RGN-259 (GBT-201; RGN-352)	thymosin beta 4	RegeneRx	actin regulating peptide	Neurotrophic keratitis (NK)/ Dry eyes	OP	InTrial	1H2021	No	Yes
WVE-210201	WVE-210201	Wave Life Sciences	oligonucleotide	Duchenne muscular dystrophy (DMD)	IV	InTrial	1H2021	Yes	Yes
ACER-001	sodium phenylbutyrate	Acer Therapeutics	BCKDC kinase inhibitor	Maple Syrup Urine Disease	PO	InTrial	1H2021	No	Yes
AXS-05	dextromethorphan/ bupropion	Axsome	N-methyl-D-aspartate (NMDA) antagonist/ antidepressant	Treatment-resistant depression/ Alzheimer's disease	PO	InTrial	1H2021	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
ACP-001	TransCon Growth Hormone	Ascendis	growth hormone prodrug	Short stature/ Growth hormone deficiency	SC	InTrial	1H2021	Yes	No
CCX-168	avacopan	ChemoCentryx/ Galencia	C5a receptor (C5aR) antagonist	Vasculitis/ Glomerulopathy	PO	InTrial	1H2021	Yes	Yes
GSK-2894512 (WBI-1001)	tapinarof	GSK/ Celestial/ Roivant Sciences/ Welichem Biotech	therapeutic aryl hydrocarbon receptor modulating agent (TAMA)	Atopic dermatitis (AD)/ Psoriasis	TOP	InTrial	1H2021	Yes	No
TadFin	tadalafil and finasteride	Veru	phosphodiesterase type 5 inhibitor /5-alpha-reductase inhibitor	Benign prostatic hyperplasia (BPH)	PO	InTrial	Mid-2021	No	No
EBV-CTL (ATA-129)	tabelecleucel	Atara Biotherapeutics/ Memorial Sloan-Kettering Cancer Center	cell therapy	Lymphoproliferative disorder	IV	InTrial	Mid-2021	Yes	Yes
RSV-F (ResVax)	respiratory syncytial virus vaccine	Novavax	vaccine	Respiratory syncytial virus (RSV) infection	IM	InTrial	Mid-2021	Yes	No
Recorlev	levoketoconazole	Strongbridge Biopharma	azole antifungal	Cushing's syndrome	PO	InTrial	3Q2021	No	Yes
PDP-716	brimonidine	Sun Pharma Advanced Research Company (SPARC)	alpha-2 agonist	Glaucoma	OP	InTrial	3Q2021	No	No
Otividex	dexamethasone sustained-release	Otonomy	corticosteroid	Meniere's disease	Intratympanic	InTrial	2H2021	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
VBP-15	vamorolone	Santhera	corticosteroid	Duchenne muscular dystrophy (DMD)	PO	InTrial	2H2021	Yes	Yes
PL-56	budesonide	Calliditas/ Kyowa Hakko Kirin	corticosteroid	Nephropathy	PO	InTrial	2H2021	No	No
TWIN (S6G5T-1; S6G5T-3)	benzoyl peroxide/ tretinoin	Sol-Gel Technologies	retinoid	Acne vulgaris	TOP	InTrial	2H2021	No	No
177Lu-PSMA-617	Lutetium	Endocyte	Radiopharmaceutical	Prostate cancer	IV	InTrial	2H2021	Yes	No
LN-145	lifileucel	Iovance Biotherapeutics	tumor infiltrating lymphocyte	Cervical Cancer	IV	InTrial	2H2021	Yes	No
GS-010	GS-010	GenSight Biologics	gene therapy	Optic neuropathy	Intraocular	InTrial	2H2021	Yes	Yes
AMAG-423	digoxin immune fab (DIF)	AMAG/ Velo	digitalis-like factor antagonist	Preeclampsia	IV	InTrial	2H2021	Yes	Yes
SPN-810	molindone	Supernus	atypical antipsychotic	Attention deficit hyperactivity disorder (ADHD)	PO	InTrial	2H2021	No	No
R-1658 (RG-1658, JTT-705, RO-4607381)	dalcetrapib	DalCor/ Japan Tobacco/ Roche	cholesteryl ester transfer protein inhibitor	Acute coronary syndrome (ACS)	PO	InTrial	2021	Yes	No
Korsuva	difelikefalin	Cara Therapeutics/ Vifor/ Fresenius	opioid receptor agonist	Pruritus/ Pain/ Osteoarthritis	IV/PO	InTrial	2021	No	No
OTL-101	ADA-transduced autologous stem cell therapy	Orchard Therapeutics	gene therapy	Adenosine deaminase (ADA)-deficient severe combined immunodeficiency (SCID)	Undisclosed	InTrial	2021	Yes	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
BMS-986089 (RG-6206)	BMS-986089 (RG-6206)	Roche/ Bristol-Myers Squibb	anti-myostatin adnectin	Duchenne muscular dystrophy (DMD)	SC	InTrial	2021	Yes	Yes
AZD-6094 (HMPL-504)	savolitinib (volitinib)	AstraZeneca (Hutchison MediPharma)	c-Met receptor tyrosine kinase inhibitor	Renal cell cancer (RCC)/ Non-small cell lung cancer (NSCLC)	PO	InTrial	2021	Yes	No
CT-100	corticotrophin	Eton	adrenocorticotropic hormone (ACTH)	Rheumatoid arthritis (RA)	INJ	InTrial	2021	No	No
SHP-647 (PF-00547659)	SHP-647 (PF-00547659)	Shire	MAdCAM-1 antagonist	Irritable bowel disease (IBD)/ Crohn's disease (CD)/ Ulcerative colitis (UC)	IV/SC	InTrial	2021	Yes	Yes
ABL-001	asciminib	Novartis	allosteric Bcr-Abl inhibitor	Chronic myelogenous leukemia (CML)	PO	InTrial	2021	Yes	Yes
CMX-001	brincidofovir hexadecyloxypropyl ester	Chimerix	DNA-directed DNA polymerase inhibitor	Adenovirus/ Cytomegalovirus (CMV)/ Smallpox	PO	InTrial	2021	No	Yes
S5G4T-1 (DER-45-EV)	benzoyl peroxide	Sol-Gel Technologies	benzoyl peroxide	Rosacea	TOP	InTrial	2021	No	No
POL-6326	balixafortide	Polyphor	chemokine (CXCR4) antagonist	Transplant/ Breast cancer	IV	InTrial	2021	Yes	No
DS-100	DS-100	Eton	undisclosed	Ophthalmological disease	SC	InTrial	2021	unknown	No
Qizenday	MD-1003	MedDay	biotin	Multiple sclerosis	PO	InTrial	2021	Yes	No
ATI-5923	tecarfarin	ARYx Therapeutics/ Armetheon	vitamin K epoxide reductase enzyme inhibitor	Anticoagulation	PO	InTrial	2021	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
RG-7314 (RO-5285119)	balovaptan	Roche	V1A vasopressin receptor antagonist	Autism spectrum disorder	PO	InTrial	2021	Yes	No
Edsivo	celiprolol HCl	Acer Therapeutics	alpha-2/beta-1 adrenergic agent	vascular Ehlers-Danlos Syndrome (vEDS)	PO	CRL	2021	Yes	Yes
OSE-2101 (IDM-2101, EP-2101)	tedopi	OSE Pharma/ Takeda	vaccine	Non-small cell lung cancer (NSCLC)	SC	InTrial	2021	Yes	Yes
LY-686017	tradipitant	Vanda Pharmaceuticals	neurokinin 1 receptor (NK-1R) antagonist	Motion sickness	PO	InTrial	2021	No	No
IMO-2125	tilsotolimod	Idera	toll-like receptor 9 (TLR-9) agonist	Melanoma	SC/ intratumoral	InTrial	2021	Yes	Yes
gantenerumab	gantenerumab	Roche	beta-amyloid (Abeta) inhibitor	Alzheimer's disease	SC	InTrial	Late 2021	Yes	No
Ultomiris SC	ravulizumab-cwvz	Alexion	C5 complement inhibitor	paroxysmal nocturnal hemoglobinuria (PNH); Hemolytic uremic syndrome (HUS)	SC	InTrial	Late 2021	Yes	Yes
ONS-5010	bevacizumab	Outlook Therapeutics	anti-VEGF antibody	wet age-related macular degeneration	Intravitreal	InTrial	Late 2021	Yes	No
PF-06482077	multivalent group B streptococcus vaccine	Pfizer	vaccine	Bacterial infection	IM	InTrial	Late 2021	Yes	No
CAT-1004	edasalonexent	Catabasis	NF-kB inhibitor	Duchenne muscular dystrophy (DMD)	PO	InTrial	Late 2021	Yes	Yes
Humacyl	human acellular vessel	Humacyte	cellular therapy	End-stage renal disease (ESRD)/ Peripheral artery disease (PAD)	Implant	InTrial	Late 2021	Yes	No
AMT-061	AMT-061	uniQure	gene therapy	Hemophilia B	IV	InTrial	Late 2021	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
PW-4142 (T-111)	nalbuphine ER	Trevi Therapeutics/ Endo	opioid agonist/ antagonist	Prurigo nodularis	PO	InTrial	Late 2021	No	No
NNZ-2566	trofinetide	Neuren	insulin-like growth factor 1 (IGF-1) derivative	Rett syndrome/ Fragile X syndrome/ Brain injury	IV/PO	InTrial	Late 2021	Yes	Yes
GSK-2696274 (OTL-200)	GSK-2696274 (OTL-200)	GlaxoSmithKline	gene therapy	Leukodystrophy	IV	InTrial	Late 2021	Yes	Yes

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

Key pending indication forecast

OptumRx key pending indication forecast

Brand name	Generic name	Company	Drug class	Therapeutic use	Proposed new indication	Route of administration	Estimated approval date
Tecentriq	atezolizumab	Genentech	PD-L1 monoclonal antibody	Non-small cell lung cancer (NSCLC)	In combination with Abraxane (albumin-bound paclitaxel; nab-paclitaxel) and carboplatin for the initial (first-line) treatment of people with metastatic non-squamous non-small cell lung cancer (NSCLC) who do not have EGFR or ALK genomic tumour aberrations	IV	9/2/2019
Ofev	nintedanib	Boehringer Ingelheim	tyrosine kinase inhibitor	Systemic sclerosis	Treatment of systemic sclerosis associated with interstitial lung disease	PO	9/7/2019
Nucala	mepolizumab	GlaxoSmithKline	IL-5 antagonist monoclonal antibody	Eosinophilic asthma	Add-on treatment for severe eosinophilic asthma in pediatric patients aged six to 11 years	SC	9/19/2019
Pifeltro	doravirine	Merck	non-nucleoside reverse transcriptase inhibitor (NNRTI)	HIV infection	Use in people living with HIV-1 who are switching from a stable antiretroviral regimen and whose virus is suppressed (HIV-1 RNA < 50 copies/mL)	PO	9/20/2019
Delstrigo	doravirine/ lamivudine/ tenofovir disoproxil fumarate	Merck	non-nucleoside reverse transcriptase inhibitor (NNRTI)/ nucleoside reverse transcriptase inhibitor (NRTI)/ NRTI	HIV infection	Use in people living with HIV-1 who are switching from a stable antiretroviral regimen and whose virus is suppressed (HIV-1 RNA < 50 copies/mL)	PO	9/20/2019

Brand name	Generic name	Company	Drug class	Therapeutic use	Proposed new indication	Route of administration	Estimated approval date
Invokana	canagliflozin	Janssen	sodium-dependent glucose transporter 2 (SGLT-2) inhibitor	Diabetes mellitus	To reduce the risk of end-stage kidney disease (ESKD), the doubling of serum creatinine, which is a key predictor of ESKD, and renal or cardiovascular death in adults with type 2 diabetes and chronic kidney disease	PO	9/22/2019
Darzalex	daratumumab	Janssen	CD 38 molecule agonist	Multiple myeloma	in combination with bortezomib, thalidomide and dexamethasone (VTd) for newly diagnosed patients with multiple myeloma who are eligible for autologous stem cell transplant (ASCT)	IV	9/26/2019
Xarelto	rivaroxaban	Janssen	factor Xa inhibitor	Anticoagulation	Prevention of venous thromboembolism (VTE), or blood clots, in medically ill patients.	PO	10/14/2019
Nplate	romiplostim	Amgen	thrombopoietin receptor agonist	Immune thrombocytopenia (ITP)	Treatment of adult patients with immune thrombocytopenia (ITP) who have had ITP for 12 months or less and an insufficient response to corticosteroids, immunoglobulins or splenectomy	SC	10/15/2019
Eylea	aflibercept	Regeneron	vascular endothelial growth factor-A (VEGF-A) inhibitor/ placental growth factor (PlGF) inhibitor	Macular degeneration	Prefilled-syringe formulation	INJ	10/15/2019

Brand name	Generic name	Company	Drug class	Therapeutic use	Proposed new indication	Route of administration	Estimated approval date
Zilretta	triamcinolone acetonide	Flexion Therapeutics	corticosteroids	Osteoarthritis	Label update: Repeat administration of Zilretta for treatment of osteoarthritis (OA) knee pain was safe and well tolerated with no deleterious impact on cartilage or joint structure observed through X-ray analysis.	Intra-articular	10/17/2019
Ultomiris	ravulizumab-cwvz	Alexion	C5 complement inhibitor	Hemolytic uremic syndrome (HUS)	Treatment of atypical hemolytic uremic syndrome	IV	10/19/2019
Stelara	ustekinumab	Janssen	human interleukin-12 and -23 antagonist	Ulcerative colitis	Treatment of ulcerative colitis (UC)	SC	10/20/2019
Baxdela	delafloxacin	Melinta Therapeutics	fluoroquinolone	Community Acquired Pneumonia (CAP)	Treatment of adult patients with community acquired pneumonia (CAP)	PO/IV	10/24/2019
Zejula	niraparib	Tesaro	poly (ADP-ribose) polymerase (PARP) inhibitor	Ovarian cancer	Treatment of advanced ovarian, fallopian tube, or primary peritoneal cancer patients who have been treated with three or more prior chemotherapy regimens and whose cancer	PO	10/24/2019
Erleada	apalutamide	Janssen	androgen receptor antagonist	Prostate cancer	Treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).	PO	10/26/2019
Belviq XR	lorcaserin	Arena/Eisai	5-HT-2C receptor agonist	Obesity	Label update: to include long-term efficacy and safety data and remove the limitation of use related to the effect of Belviq on CV morbidity and mortality	PO	10/31/2019
Botox	onabotulinumtoxinA	Allergan	botulinum toxin analog	Lower spasticity	Treatment of pediatric patients (2 years of age and older) with lower limb spasticity	IM	11/1/2019

Brand name	Generic name	Company	Drug class	Therapeutic use	Proposed new indication	Route of administration	Estimated approval date
Xofluza	baloxavir	Genentech/ Shionogi	polymerase acidic (PA) endonuclease inhibitor	Influenza	Treatment of influenza in individuals at high-risk for influenza-related complications 12 years of age or older	PO	11/4/2019
Farxiga	dapagliflozin	AstraZeneca	sodium glucose cotransporter-2 (SGLT-2) inhibitor	Diabetes mellitus	Addition of cardiovascular outcomes trial data for Farxiga for type 2 diabetes.	PO	12/1/2019
Rituxan	rituximab	Roche/ Genentech	CD-20 antagonist	Granulomatosis with polyangiitis (GPA) and microscopic polyangiitis	In combination with glucocorticoids, for the treatment of granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) in children two years of age and older	IV	12/11/2019
Vascepa	icosapent ethyl	Amarin	ethyl ester of eicosapentaenoic acid	Hyperlipidemia	Adjunct to diet in the treatment of adults with high triglycerides (≥ 200 mg/dL and < 500 mg/dL) and mixed dyslipidemia	PO	12/28/2019
Fiasp	insulin aspart	Novo Nordisk	insulins	Diabetes mellitus	To improve glycemic control in children and adolescents with type 1 diabetes	SC	1/1/2020
Ozempic	semaglutide	Novo Nordisk	glucagon-like peptide-1 (GLP-1) receptor agonist	Cardiovascular risk reduction	Cardiovascular risk reduction in adults with type 2 diabetes	SC	1/20/2020

Brand name	Generic name	Company	Drug class	Therapeutic use	Proposed new indication	Route of administration	Estimated approval date
Keytruda	pembrolizumab	Merck	anti-PD-1 inhibitor	Melanoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, gastric cancer, hepatocellular carcinoma and Merkel cell carcinoma	Updated dosing frequency: every-six-weeks (Q6W) dosing schedule option.	IV	2/18/2020
luspatercept	luspatercept	Celgene	modified type II activin receptor recombinant fusion protein	Myelodysplastic syndromes (MDS)	Treatment of adult patients with very low to intermediate risk myelodysplastic syndromes (MDS)-associated anemia who have ring sideroblasts and require red blood cell (RBC) transfusions	SC	4/4/2020
Otezla	apremilast	Celgene	phosphodieasterase 4 inhibitor	Scalp psoriasis	Treatment of moderate to severe scalp psoriasis	PO	4/15/2020
Nerlynx	neratinib	Puma Biotechnology	irreversible pan-ErbB receptor tyrosine kinase inhibitor	Breast cancer	In combination with capecitabine for the treatment of patients with HER2-positive metastatic breast cancer who have failed two or more prior lines of HER2-directed treatment (third-line disease)	PO	5/1/2020
Xtandi	enzalutamide	Astellas/ Pfizer	androgen receptor inhibitor	Prostate cancer	Treatment of metastatic hormone-sensitive prostate cancer (mHSPC)	PO	5/30/2020

Brand name	Generic name	Company	Drug class	Therapeutic use	Proposed new indication	Route of administration	Estimated approval date
Orilissa	elagolix	AbbVie	gonadotropin-releasing hormone (GnRH) receptor antagonist	Uterine fibroids	Management of heavy menstrual bleeding (HMB) associated with uterine fibroids in women	PO	6/5/2020

IM = intramuscular, IV = intravenous, OPH = ophthalmic, PO = oral, SC = subcutaneous

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