Magellan Rx MANAGEMENT℠

MRx Pipeline

April 2018

A view into upcoming specialty and traditional drugs

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INTRODUCTION

Welcome to the *MRx Pipeline*. In its second year of publication, this quarterly report offers clinical insights and competitive intelligence on anticipated drugs in development. Our universal forecast addresses trends applicable across market segments.

Traditional and specialty drugs, agents under the pharmacy and medical benefits, new molecular entities, pertinent new and expanded indications for existing medications, and biosimilars are profiled in the report.

Clinical analyses, financial outlook, and pre-regulatory status are considered as part of the evaluation process. The products housed in the *MRx Pipeline* have been researched in detail and developed in collaboration and in consultation with our internal team of clinical and analytics experts.

Emerging therapeutics continue to grow and influence the clinical and financial landscape. Therefore, Magellan Rx Management has developed a systematic approach to determine the products with significant clinical impact. For the in-depth clinical evaluations, the products' potential to meet an underserved need in the market by becoming the new standard of care and the ability to replace existing therapies were investigated. The extent to which the pipeline drugs could shift market share on a formulary and their impact on disease prevalence were also important considerations.

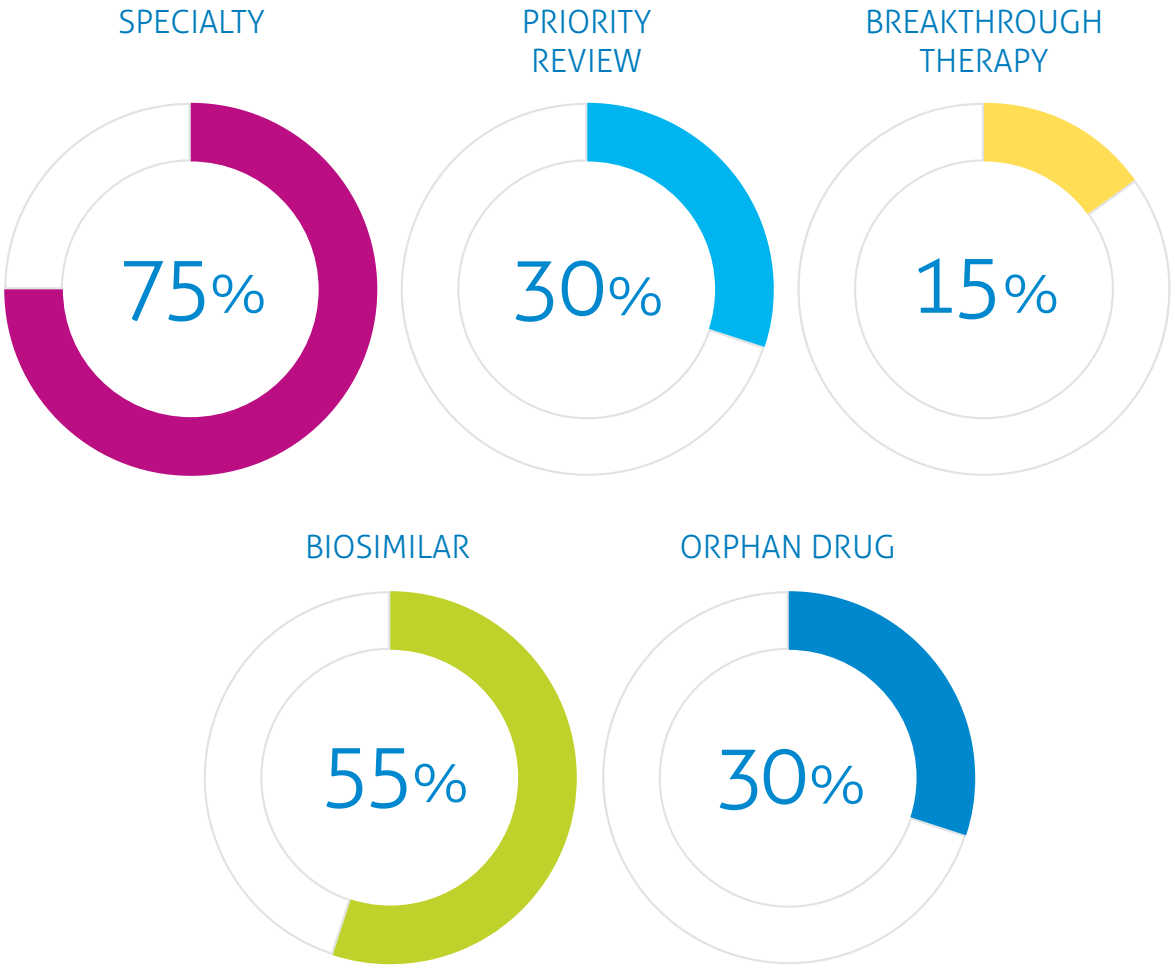
In order to assist payers to assess the potential impact of these pipeline drugs, where available, a financial forecast has been included for select products. Primarily complemented by data from Evaluate™, this pipeline report looks ahead at the 5-year projected total annual US sales through the year 2022. These figures are not specific to a particular commercial or government line of business, rather they look at forecasted US sales. Depending on a variety of factors, such as the therapeutic category, eventual approved FDA indications, population within the plan, and other indices, the financial impact could vary by different lines of business.

In the past few years, game changers such as products in the hepatitis C field have revolutionized standard of care. As we look ahead, a trend toward the approval of specialty medications, including digital therapeutics is expected. Noteworthy pipeline trends to watch in the upcoming quarters include the development of complex therapies, therapeutic options for rare hereditary diseases, oncology, immunology, hemophilia, Alzheimer's disease, and migraine prophylaxis, growth of biosimilars, and new treatment modalities using gene therapy.

The drug pipeline ecosphere will continue to evolve as it faces challenges and successes. Novel agents that apply innovation to show positive results, without compromising patient safety and access, offer true therapeutic advances and hold the promise to alter the treatment paradigm.

Pipeline Deep Dive

Objective evidence-based methodology was used to identify the Deep Dive drugs in the upcoming quarters. This section features a clinical overview and explores the potential place in therapy for these agents. Moreover, it addresses their FDA approval timeline and 5-year financial forecast.



★ Specialty drug names appear in magenta throughout the publication.

Blood Modifier

Thrombopoetin receptor agonists (TBO-RA)

BACKGROUND

Thrombocytopenia, defined as platelet count < 150 x 10^9/L, is often seen in patients with chronic liver disease (CLD). Thrombocytopenia is caused, in part, by decreased thrombopoietin (TBO) production by the impaired liver, leading to decreased platelet production and maturation. Increased platelet destruction and splenic sequestration are also contributing factors.

Avatrombopag and lusutrombopag are second-generation oral TBO-RAs that stimulate platelet production by targeting the megakaryocyte c-Mpl receptor.

avatrombopag *oral*

Dova

PROPOSED INDICATIONS

Thrombocytopenia in patients with CLD prior to a scheduled procedure

CLINICAL OVERVIEW

The ADAPT-1 (n=231) and ADAPT-2 (n=204) double-blind, pivotal trials evaluated the efficacy and safety of avatrombopag in adults with CLD and thrombocytopenia who were scheduled to undergo an elective invasive procedure with anticipated need for a platelet transfusion for procedure-related bleeding. Patients were stratified based on platelet count (cohort 1: platelets < 40 x 10^9/L; cohort 2: platelets 40 to < 50 x 10^9/L). Across all study arms, as compared with placebo, avatrombopag was associated with a significantly greater proportion of patients who did not require a platelet transfusion or bleeding rescue therapy up to 7 days following the elective procedure (ADAPT 1: cohort 1, 66% versus 23%, cohort 2, 88% versus 38%; ADAPT 2: cohort 1, 69% versus 35%, cohort 2, 88% versus 33%, respectively; p≤0.0006 for all). Common treatment-related adverse effects were typically mild to moderate in severity and similar for avatrombopag and placebo; they included pyrexia, abdominal pain, nausea, and headache.

Avatrombopag was studied as oral doses of 60 mg once daily in cohort 1 (lower baseline platelet count) and 40 mg once daily in cohort 2 (higher baseline platelet count). Avatrombopag and placebo were given daily for 5 days. The elective procedure was scheduled 5 to 8 days after the last dose.

FDA APPROVAL TIMELINE

May 21, 2018

✓ Priority review

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$29	$136	$180	$216	$254

The forecast is a projection of total US sales per year.

lusutrombopag *oral*

Shionogi

PROPOSED INDICATIONS

Thrombocytopenia in patients with CLD prior to a scheduled procedure

CLINICAL OVERVIEW

The phase 3, double-blind, L-PLUS-2 trial evaluated lusutrombopag in 215 adults with CLD (Child-Pugh A or B) and thrombocytopenia (platelets < 50 x 10^9/L) who were scheduled to undergo an elective invasive procedure that was likely to require administration of platelets. A significantly greater percentage of patients treated with lusutrombopag did not require platelet transfusion prior to their procedure or rescue therapy for bleeding up to 7 days after the procedure compared to patients who received placebo (65% versus 29%, respectively). Three non-clinically significant portal vein thrombosis (PVT) events were reported with lusutrombopag versus 2 events with placebo, all of which resolved with treatment. Bleeding-related adverse events were reported in 3 patients treated with lusutrombopag and 6 patients with placebo.

Lusutrombopag was studied as 3 mg orally once daily for up to 7 days. Platelet count was measured on days 5, 6, and 7 to prevent exceeding platelet target. Elective procedures were scheduled between days 9 and 14.

FDA APPROVAL TIMELINE

August 26, 2018

✓ Fast track ✓ Priority review

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$3	$17	$36	$56	$75

The forecast is a projection of total US sales per year.

PLACE IN THERAPY

It is estimated that 3.9 million Americans are living with CLD. Approximately 6% of CLD patients without cirrhosis and up to 84% with cirrhosis/fibrosis will develop thrombocytopenia. CLD patients with thrombocytopenia may require platelet transfusions to prevent bleeding during or after an invasive procedure (e.g., liver biopsy, colonoscopy, dental procedure). If approved, avatrombopag and lusutrombopag will be the first agents to provide an alternative to platelet transfusion prior to an elective procedure in patients with CLD-related thrombocytopenia.

Additionally, Dova plans to seek approval for avatrombopag for the treatment of idiopathic thrombocytopenia (ITP) in the second half of 2018. It may compete with the commercially available oral TBO-RAs, eltrombopag (Promacta®) and romiplostim (Nplate™), in the ITP space.

galcanezumab *sc*

Eli Lilly

PROPOSED INDICATIONS

Migraine prevention

CLINICAL OVERVIEW

Galcanezumab is a monoclonal antibody that inhibits calcitonin gene-related peptide (CGRP), which is released during a migraine attack and transmits sensory stimulus to the brain.

Two 6-month, double-blind, phase 3 trials, EVOLVE-1 and EVOLVE-2, evaluated safety and efficacy of galcanezumab in 1,773 adults with episodic migraine (EM) who experienced 4 to 14 migraine headaches per month at baseline (mean, 9.1). In both studies, galcanezumab was associated with a significantly greater decrease in average number of migraine days per month compared to placebo (galcanezumab: -3.6 and -4 days; placebo: -1.85 and -2.15 days). In addition, in the respective studies, roughly 57% and 62% of patients treated with galcanezumab experienced at least a 50% reduction in monthly migraine days compared to 36% and 39% of patients treated with placebo.

The double-blind, phase 3 REGAIN trial evaluated galcanezumab in 1,113 adults with chronic migraine (CM). CM was defined as ≥ 15 headache days per month, of which ≥ 8 were considered migraine (mean, 19.4 days). Over 3 months, galcanezumab led to a significant reduction in headache days per month compared to placebo (-4.6 to -4.8 days versus -2.7 days, respectively). About 27% of patients treated with galcanezumab experienced ≥ 50% reduction in headache days per month compared to about 15% of patients treated with placebo.

In all 3 trials, galcanezumab was studied as 2 monthly SC dosing regimens; an initial dose of 240 mg was followed monthly by either 120 mg or 240 mg. Similar reductions in migraine days were seen with both doses in patients with EM and CM, beginning at 1 month of therapy.

PLACE IN THERAPY

More than 37 million Americans, predominantly women, suffer from migraine headaches. Attacks can be debilitating, with pain lasting hours to days. Studies suggest that 38% to 50% of migraine sufferers are candidates for preventive therapy with agents such as select anticonvulsants, antihypertensives, short-term triptans (for menstrual migraines), antidepressants, and onabotulinumtoxinA (Botox®) injection (for chronic migraine only). However, side effects and failure to completely eliminate migraine attacks lead to low adherence.

Galcanezumab is expected to be the third CGRP inhibitor to be approved in the US, following erenumab (anticipated May 2018) and fremanezumab (anticipated June 2018). All 3 agents have the potential for SC self-administration and will offer a new mechanism in preventing migraine attacks. CGRP inhibitors will likely be used as second-line therapy following trial and failure of oral agents, most of which are available in generic formulations. Furthermore, new modalities for migraine relief under investigation include the first self-administered, non-invasive vagus nerve stimulator device, Gammacore®, which was FDA approved in December 2017 for cluster headaches. Galcanezumab and fremanezumab are also in Fast track development for cluster headaches.

FDA APPROVAL TIMELINE

September 2018

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$6	$15	$185	$270	$334

The forecast is a projection of total US sales per year.

BACKGROUND

Hereditary transthyretin (TTR) amyloidosis (hATTR) is a rare, autosomal dominant genetic disorder characterized by mutations in the TTR gene that causes the liver to produce abnormal TTR protein. The abnormal TTR protein misfolds into amyloid fibrils that deposit in tissues throughout the body, most notably in the nerves and heart. Amyloid deposits accumulate slowly over many years and may lead to organ failure. Age of onset and severity of disease depend on the specific genetic mutation, of which over 100 different TTR mutations have been identified. The most prominent TTR mutations found in the US are V30M, which typically presents as familial amyloid polyneuropathy (FAP), and V122I, usually seen in familial amyloid cardiomyopathy (FAC). Onset occurs at about 30 to 50 years of age for FAP and typically after age 60 years for FAC. Life expectancy from the onset of FAP symptoms is 5 to 15 years and is about 3 to 5 years from the time of diagnosis of FAC. The presenting signs and symptoms in patients with hATTR are fairly nonspecific and are often attributed to more common diseases affecting the heart (e.g., heart failure, diastolic dysfunction, arrhythmias) and peripheral and autonomic nervous systems (e.g., upper or lower limb neuropathy, autonomic dysfunction). Moreover, some patients who inherit a TTR gene mutation may never develop symptoms. Therefore, genetic testing of healthy individuals cannot predict whether a person will develop FAP and/or FAC.

inotersen *sc*

Ionis/ Akcea

PROPOSED INDICATIONS

Hereditary TTR (hATTR) amyloidosis

CLINICAL OVERVIEW

Inotersen, an antisense oligoneucleotide, is a single-stranded RNA fragment that targets messenger RNA (mRNA) to block protein translation and inhibit production of mutant and normal TTR.

In the double-blind, placebo-controlled, phase 3 NEURO-TTR study, inotersen's impact on neurological dysfunction and QOL was evaluated in 172 adults with stage 1 and 2 hATTR polyneuropathy (FAP). At 15 months, inotersen led to significant improvements in QOL and activities of daily living, as measured by the Norfolk Quality of Life-Diabetic Neuropathy questionnaire (QOL-DN; difference from placebo, -11.7 points). Also, the modified Neuropathy Impairment Score plus 7 (mNIS+7) showed significantly less disease progression with inotersen (difference from placebo, -19.7 points). TTR reductions by more than 50% and 75% were reported in nearly 90% and 50% of patients treated with inotersen, respectively. Key safety concerns included thrombocytopenia and renal events, which were managed through blood and urine laboratory monitoring. The extension phase demonstrated durability of effect for up to 27 months. While NEURO-TTR was powered to evaluate inotersen's affect on FAP, benefit of therapy was also observed in patients with significant cardiac disease based on decreases in left ventricular mass (LVM) and posterior wall thickness.

Inotersen was administered as 300 mg SC once weekly in phase 3 trials.

FDA APPROVAL TIMELINE

July 6, 2018

✓ Fast track ✓ Orphan drug ✓ Priority review

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$24	$103	$173	$232	$365

The forecast is a projection of total US sales per year.

patisiran *IV*

Alnylam/ Arbutus/ Ionis/ Sanofi

PROPOSED INDICATIONS

Hereditary TTR (hATTR) amyloidosis

CLINICAL OVERVIEW

RNA interference (RNAi) is a naturally occurring process in cells that uses small interfering RNA (siRNA) molecules to regulate gene expression. Patisiran is made of nanoparticles of siRNA that bind to specific mRNA to inhibit production of mutant and nonmutant forms of TTR protein. Patisiran may also facilitate the clearance of TTR amyloid deposits in peripheral tissues and potentially restore their function.

A significant improvement in neuropathy and QOL was demonstrated with patisiran in the 18-month APOLLO study in 225 patients with FAP. Compared to placebo, patisiran resulted in a mean change in mNIS+7 of -34 points and Norfolk QOL-DN of -21 points. Most adverse effects were mild to moderate in severity and included infusion-related reactions and peripheral edema. Deaths reported during the study were consistent with the natural history of the condition. Durability of response (≥ 36 months) and neuropathy stabilization were demonstrated in open-label extensions of phase 2 and phase 3 trials.

A subgroup analysis of 126 patients with hATTR and cardiomyopathy reported 29% of patisiran-treated patients compared to 4% of placebo-treated patients experienced > 2 mm reduction in left ventricular wall thickness at 18 months. Patisiran also increased 10-meter walking time by 0.35 m/s versus placebo.

Patisiran was studied at a dose of 0.3 mg/kg administered via IV infusion once every 3 weeks.

FDA APPROVAL TIMELINE

August 11, 2018

✓ Breakthrough therapy ✓ Fast track ✓ Orphan drug ✓ Priority review

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$24	$149	$306	$492	$624

The forecast is a projection of total US sales per year.

PLACE IN THERAPY

The incidence of hATTR varies widely by geographic region and ethnic group. Prevalence is estimated as 1 in 100,000 Americans of European descent. The V122I mutation that results in FAC is most often detected in elderly African American men with prevalence of about 3% to 4%; it is virtually undetected in Caucasians.

Currently, there are no FDA-approved pharmacological options to treat hATTR. Furthermore, standard treatments for CV disease such as beta-blockers, angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), diuretics, or digoxin could worsen symptoms of FAC. Liver transplantation, ideally in early disease stages, removes the source of variant TTR; however, accumulation of nonvariant TTR can still occur. Oral TTR stabilizers may provide benefit for hTTR and includes off-label use of the NSAID diflunisal. The oral TTR stabilizer tafamidis is in phase 3 trials in the US and is approved in Europe and Japan.

If approved, inotersen and patisiran may provide an alternative to organ transplant. Since inotersen is administered SC, it has the potential to be self-administered. Patisiran is administered IV, possibly requiring administration by a clinician. Although both agents bind to target mRNA to inhibit TTR production, long-term final data on whether either agent will be disease-stabilizing versus disease-modifying will be of interest.

lanadelumab *sc*

Shire

PROPOSED INDICATIONS

Hereditary angioedema (HAE) prophylaxis

CLINICAL OVERVIEW

HAE is a rare genetic condition characterized by recurrent episodes of subcutaneous (SC) or submucosal edema of the GI tract, limbs, face, and upper respiratory tract. Patients with HAE have deficient (Type I) or dysfunctional (Type II) C1 esterase inhibitor (C1-INH), a protein that blocks the activity of plasma kallikrein. During HAE attacks, unregulated activity of plasma kallikrein results in excessive production of bradykinin, a vasodilator responsible for localized swelling and inflammation. Most HAE episodes are self-limiting and resolve in 2 to 4 days. However, abdominal edema may lead to nausea, vomiting, and severe pain. Life-threatening swelling of the throat or larynx can also occur. HAE symptoms typically begin in early childhood and persist throughout life. Frequency of attacks can vary greatly. Minor trauma and stress can lead to an attack; however, attacks can occur without any apparent trigger.

Lanadelumab is a monoclonal antibody that binds to and inhibits plasma kallikrein.

The phase 3, double-blind, HELP trial evaluated the efficacy and safety of lanadelumab in 125 patients ≥ 12 years of age with Type I or II HAE. At 26 weeks, lanadelumab demonstrated consistent reductions in monthly HAE attack rates compared to placebo, regardless of baseline rates. Lanadelumab produced reductions in monthly HAE attacks by 76% with a dose of 150 mg every 4 weeks, 73% with 300 mg every 4 weeks, and 87% with 300 mg every 2 weeks compared to placebo. The most commonly reported treatment-related adverse effect with lanadelumab was injection site reactions. No serious adverse events were reported.

PLACE IN THERAPY

HAE affects between 1 in 10,000 to 50,000 people in the US. Management consists of treatment of acute attacks, short-term prophylaxis in situations that may precipitate an attack, and long-term prophylaxis if attacks are frequent. Agents approved in the US employ various mechanisms to manage HAE. Products that replace the missing or dysfunctional C1-INH include plasma derived C1-INH (Berinert®, Cinryze®, Haegarda®) and recombinant C1-INH (Ruconest®). The kallikrein inhibitor escallantide (Kalbitor®) and bradykinin receptor antagonist icatibant (Firazyr®) are also available for HAE. Treatments for acute attacks include Berinert (IV), Ruconest (IV), Firazyr (SC), and Kalibitor (IV). Cinryze (IV) and Haegarda (SC) are administered every 3 or 4 days for routine prophylaxis of HAE attacks. All approved products, except Kalibitor, can be self-administered.

Lanadelumab is a monoclonal antibody that targets kallikrein to prevent HAE attacks. Its long elimination half-life (14 days) allows for every 2 to 4 week dosing. It was also studied as self-administered low volume (1-2 mL) SC injections. Both factors may reduce treatment burden compared to other prophylactic agents. In addition, an SC formulation of Cinryze, dosed twice weekly, is in phase 3 clinical trials for HAE. Finally, phase 3 trials are ongoing for Biocryst's second-generation oral plasma kallikrein inhibitor.

FDA APPROVAL TIMELINE

August 26, 2018

✓ Breakthrough therapy ✓ Fast track ✓ Orphan drug ✓ Priority review

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$54	$284	$508	$731	$940

The forecast is a projection of total US sales per year.

Oncology

larotrectinib *oral*

Loxo Oncology

PROPOSED INDICATIONS

Solid tumors with neurotrophic tyrosine receptor kinase (NTRK) gene fusion

CLINICAL OVERVIEW

Larotrectinib is a selective inhibitor of tropomyosin receptor kinases (TRK), a type of receptor tyrosine kinase.

Phase 2 trials (NAVIGATE and SCOUT) evaluated treatment of larotrectinib in a total of 55 patients with NTRK fusion-positive cancers, including salivary, sarcoma, infantile fibrosarcoma, lung, thyroid, colon, melanoma, cholangio, and GI stromal tumor. NAVIGATE was conducted in adults, while SCOUT enrolled patients 4 months to 21 years of age. Fusions included NTRK1, NTRK2, and NTRK3. According to an independent review committee, the ORR with larotrectinib was 75% across adult and pediatric patients. After 1 year, 71% of responses were ongoing, with 55% of patients remaining progression-free. At a median follow-up of 9.4 months, 86% of responders (38 of 44 patients) were still on treatment or had undergone curative surgery. The first patient treated remained in response and on therapy at 27 months. Most common treatment-related adverse effects were fatigue, dizziness, and nausea. Primary (n=6) and/or acquired (n=10) resistance was reported. In patients with acquired resistance, larotrectinib was continued with sustained clinical benefit.

The study dose of larotrectinib was 100 mg orally twice daily.

PLACE IN THERAPY

TRK receptors are widely expressed in the nervous system and at non-neuronal sites, including lung, bone, and pancreas, and occur across a wide array of tumor types. It is estimated that each year 1,500 to 5,000 cancer patients in the US may bear TRK fusion-cancers and may be appropriate for TRK-directed therapy.

The discovery of oncogenic mutations and development of drugs to inhibit specific genetic abnormalities is transforming the treatment approach for many cancers. Larotrectinib demonstrated significant response and durability in treating NTRK-positive solid tumors. If approved, larotrectinib will be the first targeted therapy for NTKR mutations and its use will be driven by the presence of NKTR gene fusion and not by tumor type or location. Loxo Oncology has partnered with Illumina to develop a companion diagnostic test to detect NTRK-positive tumors. Entrectinib, another TRK inhibitor, is in phase 2 investigation; its FDA submission for treatment of solid tumors is anticipated in 2018.

FDA APPROVAL TIMELINE

Quarter 4, 2018

✓ Breakthrough therapy ✓ Orphan drug ✓ Rare pediatric disease product

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$33	$102	$223	$365	$497

The forecast is a projection of total US sales per year.

Endocrine

migalastat *oral*

Amicus

PROPOSED INDICATIONS

Fabry disease in patients with amenable mutations

CLINICAL OVERVIEW

After Gaucher disease, Fabry disease is the second most prevalent lysosomal storage disorder. As a rare, X-linked storage disorder, Fabry disease is characterized by the accumulation of the fatty compound globotriaosylceramide in the skin, kidneys, heart, brain, and nervous system. The condition is caused by a genetic mutation in the *GLA* gene that is responsible for the production of alpha-galactosidase A (α-GAL A), an enzyme that normally breaks down globotriaosylceramide (GL-3). Classic forms of the disease are caused by complete absence of α-GAL A activity and onset occurs in childhood. Clinical presentation includes chronic neuropathic pain, GI disturbances, progressive renal impairment, cardiomyopathy, myocardial infarctions, and stroke. A more common milder form of the disease may be seen if activity of α-GAL A is not completely absent; onset appears later in life and affects only the heart or kidneys. Patients with either type have a decreased life expectancy (males, 58 years; females, 75 years) and QOL.

Migalastat is a small molecule chaperone therapy that binds to and stabilizes the α-GAL A enzyme to restore its activity, thereby reducing the buildup of GL-3.

Safety and efficacy of migalastat were evaluated in male and female patients with Fabry disease in the 24-month FACETS and 18-month ATTRACT trials. FACETS included 67 enzyme replacement therapy (ERT)-naive patients, while ATTRACT included 57 ERT-experienced patients. Among the respective trials, 50 and 53 patients had amenable mutations. FACETS reported a significant reduction in interstitial GL-3 and plasma globotriaosylsphingosine (lyso-Gb3) at 6 months. In ATTRACT, plasma lyso-Gb3 levels remained low and stable following the switch from ERT to migalastat in patients with amenable mutations at study end. Changes in lyso-Gb3 were not consistent among patients with non-amenable mutations. In both studies, renal function remained stable among patients with amenable mutations. In ATTRACT, left ventricular mass index (LVMi) was significantly reduced by 6.6 g/m^2 after switching to migalastat, while no significant change occurred in patients who remained on ERT. Renal function and LVMi remained stable at 30 months. Renal, CV, or cerebrovascular events occurred significantly less often with migalastat compared to ERT (29% versus 44%, respectively). Migalastat was generally well tolerated.

Migalastat was studied in oral doses of 150 mg every other day. ERT consisted of agalsidase administered IV according to the product labeling.

PLACE IN THERAPY

About 3,000 Americans are diagnosed with Fabry disease, and males are more often affected. The current standard of care is life-long ERT with agalsidase beta (Fabrazyme®) given IV every 2 weeks. Migalastat is a first-in-class oral chaperone agent. It is approved outside the US, and the National Institute for Health and Care Excellence (NICE) supports it as an option for treating Fabry disease. Phase 3 data for Protalix's IV administered ERT pegunigalsidase alfa are expected in 2018.

FDA APPROVAL TIMELINE

August 13, 2018

✓ Fast track ✓ Orphan drug ✓ Priority review

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$0	$15	$24	$106	$145

The forecast is a projection of total US sales per year.

volanesorsen *SC*

Akcea

PROPOSED INDICATIONS

Familial chylomicronemia syndrome (FCS)

CLINICAL OVERVIEW

FCS is a rare genetic disorder characterized by severe chylomicronemia and hypertriglyceridemia (triglycerides [TG] ≥ 1,500 mg/dL), as well as recurrent pancreatitis. FCS is also known as lipoprotein lipase deficiency, Fredrickson type 1, hyperlipoproteinemia, and familial hyperlipidemia. People with FCS are deficient in functioning lipoprotein lipase (LPL), an enzyme that is responsible for breaking down chylomicrons and TG. The condition leads to abnormal fat stores around and within organs. Patients can experience daily abdominal pain and are at increased risk for CV complications, hepatic impairment, and pancreatitis.

Volanesorsen is an antisense drug that blocks the hepatic production of apolipoprotein C-III (apoC-III), a potent inhibitor of LPL; thus, volanesorsen may lead to an increased clearance of TGs.

The phase 3 APPROACH study evaluated volanesorsen in 66 patients with FCS who agreed to a fat-restricted (≤ 20 g/day) diet during the study. Mean baseline TG was 2,209 mg/dL. At week 13, volanesorsen treatment resulted in a mean 77% reduction in TG, compared to 18% for placebo. Also, TG < 750 mg/dL and TG < 500 mg/dL were achieved in 77% and 50% of volanesorsen-treated patients, repectively, versus 9.7% and zero placebo-treated patients. The response was sustained through 52 weeks. The most common adverse effect with volanesorsen was injection site reactions. Similar results were seen in the 26-week COMPASS trial in patients with FCS (n=7). In APPROACH and COMPASS, thrombocytopenia led to discontinuation in 5 patients; platelet count subsequently recovered in all 5 patients. In a phase 2 trial, large dose-dependent increases (mean, 118%) in LDL-C were reported in a cohort of patients with FCS (n=11) who received volanesorsen 300 mg monotherapy; smaller increases (mean, 21%) were seen when volanesorsen was given with fibrates (n=10). In comparison, mean LDL-C increased by almost 11% with placebo in the phase 2 study.

Volanesorsen was administered SC at a dose of 300 mg once weekly.

PLACE IN THERAPY

It is estimated that FCS occurs in 1 in 1,000,000 people. Currently, no effective therapies are available for FCS. Patients with FCS are managed by restricting fat intake to < 10-25 g/day and also limiting consumption of carbohydrates and alcohol. Traditional hyperlipidemia treatments such as statins, fibrates, and niacin are not effective in FCS because these agents depend, at least in part, on functional LPL enzyme. While lomitapide (Juxtapid®) and mipomersen (Kynamro®) lower apolipoprotein B (apo B) and are indicated for homozygous familial hypercholesterolemia (HoFH), data for their effectiveness for FCS is lacking. Volanesorsen has demonstrated significant reductions in TG in phase 3 trials; however, phase 2 trials reported an increase in LDL-C, which may lead to cautious use of the medication. No additional drugs are in late-stage trials that target apoC-III for dyslipidemia. Volanesorsen is also in phase 3 trials for familial partial lipodystrophy (FPL); results are expected in 2019. Further, Akcea is planning to conduct a phase 3 CV outcome study for volanesorsen.

FDA APPROVAL TIMELINE

August 30, 2018

✓ Orphan drug

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$11	$63	$119	$172	$214

The forecast is a projection of total US sales per year.

Biosimilar Overview

CLINICAL OVERVIEW

Biosimilars are very different from generic drugs in that they are not exact duplicates of their reference biologic product. The FDA approval process for biosimilars is designed to ensure that the biosimilar product is highly similar to the reference product without having any meaningful clinical differences.

Many controversies surround biosimilars. The FDA has issued final and draft guidances, but regulatory hurdles remain. In February 2017, the Agency issued final guidance on the nonproprietary naming of biologic products, which also applies to biosimilars. The biological products must bear a core name, followed by a distinguishing 4-letter, lowercase, hyphenated suffix that is devoid of meaning. The FDA is still considering how to implement the nomenclature for previously-approved biosimilar products. The international nonproprietary name (INN) impacts interchangeability as it affects the pharmacists' ability to substitute an interchangeable biosimilar for the reference product. Although the Agency has not released its final guidance on interchangeability, several states have already enacted biosimilar substitution legislation.

Biosimilars are expected to receive full extrapolation for the eligible indications of the reference products without requiring additional trials. Nevertheless, as each biosimilar comes to market, it will likely need to be considered individually.

Insulins are historically regulated by the FDA as small molecules. Since the reference products are not deemed biologics by the FDA, any generics are technically branded competitors and are not considered biosimilars under the FDA's definition. In practice, however, *follow-on* insulins are regarded to be complex molecules and considered in the biosimilar space.

PLACE IN THERAPY

The patents of several biologic drugs are set to expire in the next few years, opening up the US market for biosimilar entry; however, patent litigation can result in significant delays before an FDA-approved biosimilar can launch. In June 2017, the US Supreme Court issued 2 rulings: (1) allowing a biosimilar manufacturer to provide launch notice of commercial marketing to the originator manufacturer before or after FDA approval of the biosimilar product; and (2) eliminating any federal requirement for disclosure, also known as the "patent dance"; however, some states may mandate disclosure. These decisions may bring biosimilars to the market sooner and potentially create price competition in the market place.

To date, a total of 9 biosimilars have received FDA approval. Of these, only 3 have entered the market.

APPROVED BIOSIMILARS				
Brand Name (Nonproprietary name)	**Manufacturer**	**Approval Date**	**Commercially Available**	**Originator Product (Manufacturer)**
Zarxio® (filgrastim-sndz)	Sandoz	March 2015	✓	Neupogen® (Amgen)
Inflectra® (infliximab-dyyb)	Pfizer/ Celltrion	April 2016	✓	Remicade® (Janssen)
Erelzi™ (etanercept-szzs)	Sandoz	August 2016	-	Enbrel® (Amgen)
Amjevita™ (adalimumab-atta)	Amgen	September 2016	-	Humira® (Abbvie)
Renflexis™ (infliximab-abda)	Merck	May 2017	✓	Remicade (Janssen)
Cyltezo® (adalimumab-adbm)	Boehringer Ingelheim	August 2017	-	Humira (Abbvie)
Mvasi™ (bevacizumab-awwb)	Amgen	September 2017	-	Avastin® (Genentech)
Ixifi™ (infliximab-qbtx)*	Pfizer	December 2017	-	Remicade (Janssen)
Ogivri™ (trastuzumab-dkst)	Mylan	December 2017	-	Herceptin® (Genentech)

* Pfizer already has Inflectra on the market and has not announced plans to launch Ixifi.

Also available are Eli Lilly's Basaglar® insulin glargine, a follow-on agent to Sanofi's Lantus®, and Sanofi's Admelog® insulin lispro, approved as a follow-on product to Eli Lilly's Humalog®.

A host of factors will contribute to market acceptability and the potential success of biosimilars. Payers, pharmacies, prescribers, and patients each play a role in market adoption of biosimilars.

The global biologic market is projected to exceed $390 billion by 2020. An IMS Health analysis expects biosimilars to save the US and Europe's top 5 markets up to $110 billion by 2020. It is estimated that, in the US, biosimilars will cost 15% to 35% less than the originator product. The potential cost savings, however, can vary based on the market segment, where brand contracts can play a role. A 2017 report by the RAND Corporation estimates a $54 billion cost savings from biosimilars between 2017 and 2026. A 2017 analysis by the Moran Company projects biosimilars can save the government an estimated $11.4 billion by 2027, but it would require the Centers for Medicare and Medicaid Services (CMS) to revise its reimbursement policy for biosimilars. In November 2017, CMS revised its reimbursement policy. The CMS will begin issuing a unique Healthcare Common Procedure Coding System (HCPCS) code (commonly referred to as J-codes) to each individual biosimilar. Under this new rule, Medicare Part B will separately code and pay for biosimilars and no longer group them into a common payment code with originator agents.

Biosimilar products may provide an opportunity to increase access to important biologic therapies that could increase survival and/or quality of life for many patients with diseases difficult to treat, while also reducing costs.

Blood modifier
adalimumab (GP2017) *SC*

Novartis/ Sandoz

GP2017 is a biosimilar to Abbvie's Humira, a tumor necrosis factor alpha (TNFα) blocker indicated for the treatment of autoimmune disorders including rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), ankylosing spondylitis (AS), plaque psoriasis (PSO), psoriatic arthritis (PsA), Crohn's disease (CD) in adults and children, ulcerative colitis (UC), and for hidradenitis suppurativa (HS) and non-infectious uveitis.

FDA APPROVAL TIMELINE
November 16, 2018

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$13,947	$15,398	$16,766	$18,049	$18,401

The forecast is a projection of total US sales per year for the *branded product*.

Blood modifier
filgrastim *IV, SC*

Adello, Apotex, and Pfizer are seeking biosimilars to Amgen's Neupogen®, a leukocyte growth factor indicated for use in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs; following induction or consolidation chemotherapy for acute myeloid leukemia (AML); with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation; to mobilize autologous hematopoietic progenitor cells for collection by leukapheresis; in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia; and acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome [HSARS]).

FDA APPROVAL TIMELINE
Adello
April to May 2018

Pfizer (Nivestim)
September 2018

Apotex (Grastofil)
Pending

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$287	$239	$211	$190	$172

The forecast is a projection of total US sales per year for the *branded product*.

Diabetes
insulin glargine *SC*

Basalog and Lusduna Nexvue are follow-on insulins to Sanofi's Lantus, a long-acting insulin indicated for the treatment of T1DM and T2DM.

FDA APPROVAL TIMELINE

Mylan/ Biocon (Basalog)
July 2018

Merck (Lusduna Nexvue)
Pending

- Lusduna Nexvue has met all required regulatory standards for follow-on insulins, including clinical and nonclinical safety, efficacy, and quality, but litigation claiming patent infringement invoked an automatic stay on final FDA approval for up to 30 months, or a court decision in favor of Merck, whichever occurs sooner.

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$2,203	$1,780	$1,411	$1,123	$959

The forecast is a projection of total US sales per year for the *branded product*.

Blood modifier
pegfilgrastim *SC*

Lapelga and Myl-1401H are biosimilars to Amgen's Neulasta®, a leukocyte growth factor indicated for use in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs and patients acutely exposed to myelosuppressive doses of radiation (HSARS).

FDA APPROVAL TIMELINE

Mylan/Biocon (Myl-1401H)
June 4, 2018

Apotex (Lapelga)
Pending

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$3,738	$3,212	$2,756	$2,430	$2,148

The forecast is a projection of total US sales per year for the *branded product*.

Oncology
rituximab *IV*

Novartis/ Sandoz

Rixathon is a biosimilar to Genentech's Rituxan®, a CD20-directed cytolytic antibody indicated for the treatment of non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), RA, and antineutrophil cytoplasmic antibodies-associated vasculitis.

FDA APPROVAL TIMELINE
April to May 2018

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$4,032	$3,108	$2,450	$2,036	$1,733

The forecast is a projection of total US sales per year for the *branded product*.

Oncology
trastuzumab *IV*

ABP980 and SB3 are biosimilars to Genentech's Herceptin, a HER2/neu receptor antagonist indicated for the treatment of HER2-positive breast cancer and HER2-positive metastatic gastric or gastroesophageal junction adenocarcinoma.

FDA APPROVAL TIMELINE
Amgen (ABP980)
May 28, 2018

Merck/ Samsung Bioepis (SB3)
October 20, 2018

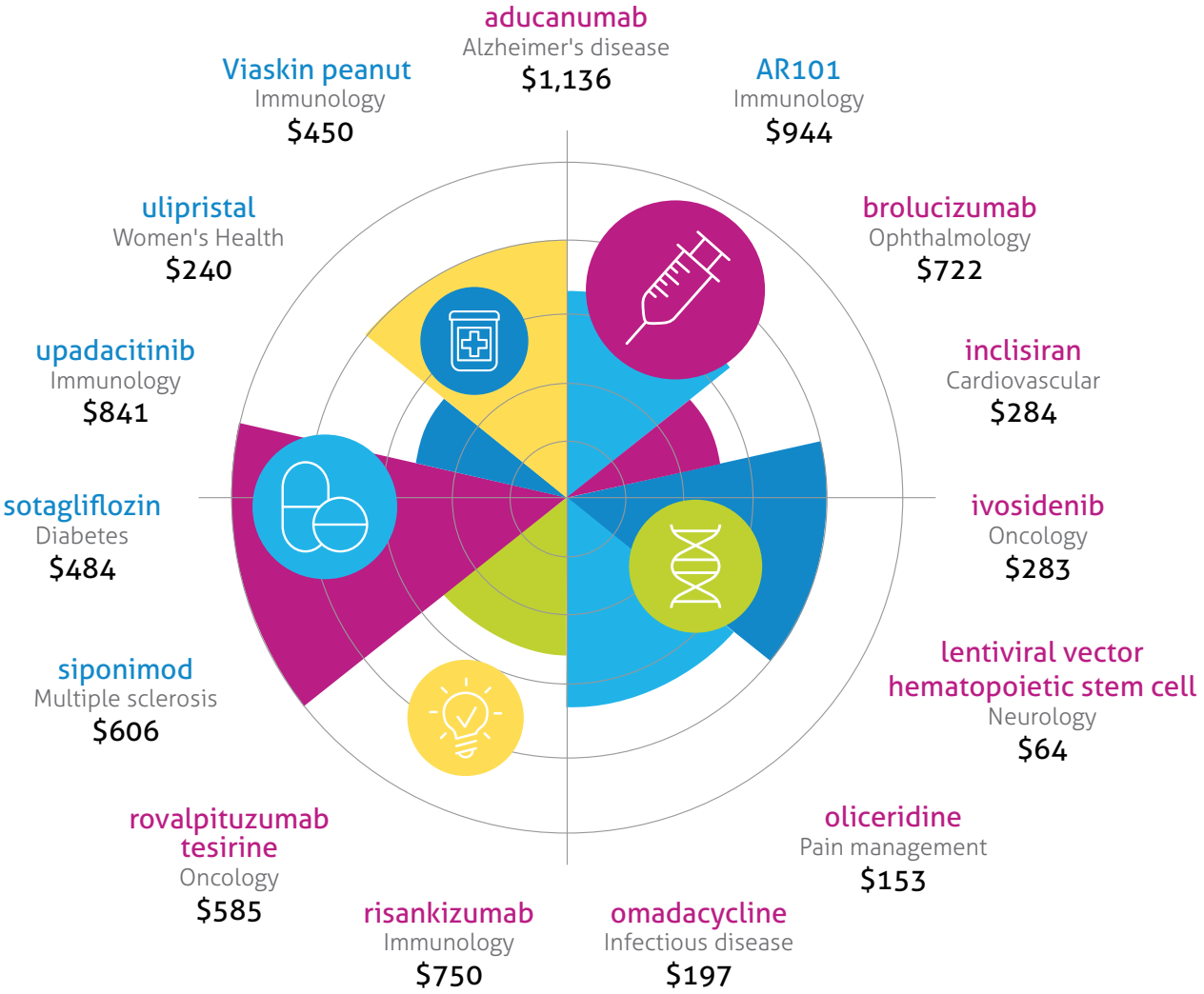
FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$2,814	$2,474	$1,918	$1,508	$1,285

The forecast is a projection of total US sales per year for the *branded product*.

Keep on Your Radar

Notable agents that are further from approval have been identified in this unique watch list. These are products with the potential for significant clinical and financial impact. Their development status is being tracked on the MRx Pipeline radar. These pipeline products, their respective class or proposed indication, as well as an estimated financial forecast for the year 2022, are displayed. The financials are projected total annual US sales, reported in *millions.*



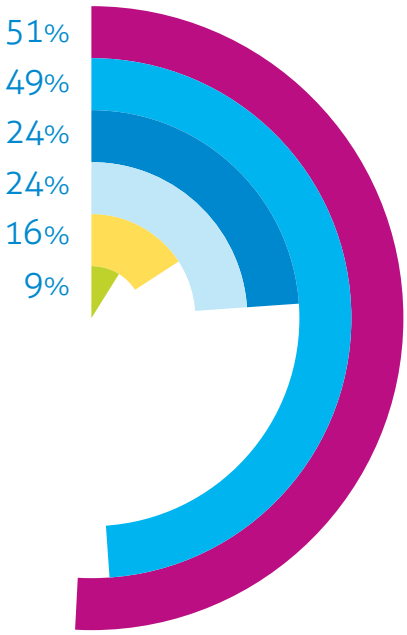
★ Specialty drug names appear in magenta throughout the publication.

Magellan Rx MANAGEMENT

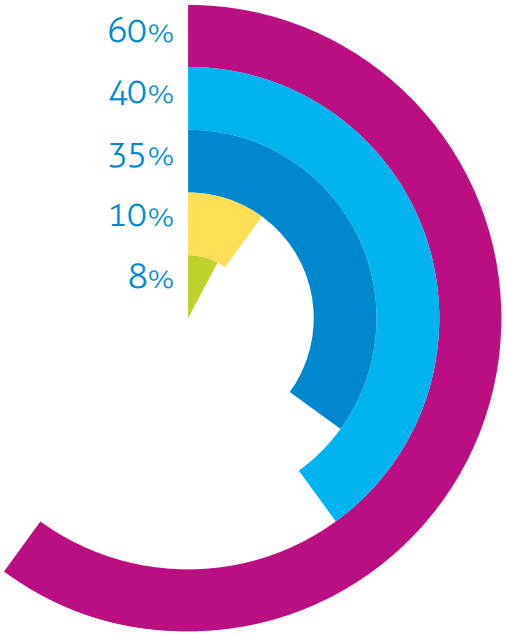
Pipeline Drug List

The pipeline drug list is an aerial outline of drugs with anticipated FDA approval through 2019. It is not intended to be a comprehensive inventory of all drugs in the pipeline; emphasis is placed on drugs in high-impact categories. Investigational drugs with a Complete Response Letter (CRL) and those that have been withdrawn from development are also noted.

APPLICATION SUBMITTED TO THE FDA



IN PHASE 3 TRIALS



Specialty | Traditional | Orphan drug | Priority review | Breakthrough therapy | Biosimilar

★ Specialty drug names appear in magenta throughout the publication.

PIPELINE DRUG LIST

★ Specialty drug names appear in magenta throughout the publication.

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
dabrafenib (Tafinlar®)	Novartis	Melanoma (stage III BRAF V600+ or V600K+ after resection)	Oral	Submitted - sNDA; Breakthrough therapy; Priority review	Q2, 2018
rizatriptan film	Redhill	Migraine treatment	SL	Submitted - 505(b)(2) NDA	Q2, 2018
sodium zirconium cyclosilicate	AstraZeneca	Hyperkalemia	Oral	Submitted - NDA	Q2, 2018
trametinib (Mekinist®)	Novartis	Melanoma (stage III BRAF V600+ or V600K+ after resection)	Oral	Submitted - sNDA; Breakthrough therapy; Priority review	Q2, 2018
filgrastim (biosimilar to Amgen's Neupogen)	Adello	Neutropenia/ leukopenia	IV, SC	Submitted - BLA	Apr-May 2018
rituximab (biosimilar to Genentech's Rituxan)	Novartis/ Sandoz	RA; CLL; NHL (indolent); Antineutrophil cytoplasmic antibodies associated vasculitis	IV	Submitted - BLA	Apr-May 2018
lubiprostone (Amitiza®)	Sucampo	Chronic constipation (pediatrics)	Oral	Submitted - sNDA	04/27/2018
solifenacin (Vesicare®)	Astellas	Overactive bladder (in combination with mirabegron)	Oral	Submitted - sNDA	04/30/2018
tisagenlecleucel-T (Kymriah®)	Novartis	DLBCL (stem cell transplant ineligible)	IV	Submitted - sBLA; Breakthrough therapy; Orphan drug; Priority review	04/30/2018
andexanet alfa	Portola	Anticoagulant reversal	IV	Submitted - NDA; Breakthrough therapy; Orphan drug	05/04/2018
testosterone undecanoate	Lipocine	Hypogonadism	Oral	Submitted - 505(b)(2) NDA	05/08/2018
polyethylene glycol (low volume)	Valeant	Colon cleansing	Oral	Submitted - NDA	05/13/2018
erenumab	Amgen	Migraine prevention	SC	Submitted - BLA	05/17/2018
avatrombopag	Dova	Thrombocytopenia associated with chronic liver disease	Oral	Submitted - NDA; Priority review	05/21/2018
fluticasone furoate (Arnuity® Ellipta®)	GlaxoSmithKline	Asthma (ages 5-11 years)	Inhaled	Submitted - sNDA	05/24/2018
certolizumab (Cimzia®)	UCB	PSO	SC	Submitted - sBLA	05/25/2018
lenvatinib (Lenvima®)	Eisai	Hepatocellular carcinoma (1st-line)	Oral	Submitted - sNDA; Orphan drug	05/25/2018
meloxicam (nanocrystal)	Recro	Postsurgical pain	IM, IV	Submitted - 505(b)(2) NDA	05/25/2018

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
pegvaliase	Biomarin	Phenylketonuria	SC	Submitted - BLA; Orphan drug; Priority review	05/25/2018
lofexidine	US Worldmeds	Substance use disorder	Oral	Submitted - NDA; Fast track; Priority review	05/26/2018
denosumab (Prolia®)	Amgen	Glucocorticoid-induced osteoporosis	SC	Submitted - sBLA	05/28/2018
trastuzumab (biosimilar to Genentech's Herceptin)	Amgen	Breast cancer (HER2+); Gastric/ gastroesophageal cancer (HER2+)	IV	Submitted - BLA	05/28/2018
17-beta estradiol	TherapeuticsMD	Vaginal atrophy	Intravaginal	Submitted - 505(b)(2) NDA	05/29/2018
celecoxib/ amlodipine besylate	Kitov	Osteoarthritis pain + HTN	Oral	Submitted - 505(b)(2) NDA	05/31/2018
fingolimod (Gilenya®)	Novartis	MS (relapsing, pediatrics)	Oral	Submitted - sNDA; Breakthrough therapy; Fast track	H2, 2018
baricitinib	Eli Lilly	RA	Oral	Submitted - NDA	June 2018
moxidectin	Medicines Development for Global Health	Onchocerciasis	Oral	Submitted - NDA; Priority review	June 2018
rituximab (Rituxan)	Genentech	Pemphigus vulgaris	IV	Submitted - sBLA; Breakthrough therapy; Orphan drug; Priority review	June 2018
tofacitinib (Xeljanz®/ Xeljanz XR®)	Pfizer	UC	Oral	Submitted - sNDA	June 2018
mogamulizumab	Kyowa Hakko Kirin	Cutaneous T cell lymphoma	IV	Submitted - BLA; Breakthrough therapy; Orphan drug; Priority review	06/04/2018
pegfilgrastim (biosimilar to Amgen's Neulasta)	Mylan/ Biocon	Neutropenia / leukopenia	SC	Submitted - BLA	06/04/2018
rivaroxaban 2.5 mg (Xarelto®) twice daily	Janssen	Coronary artery disease; Peripheral artery disease	Oral	Submitted - sNDA; Fast track	06/11/2018
fremanezumab	Teva	Migraine prevention	IV, SC	Submitted - BLA; Fast track; Priority review	06/15/2018
halobetasol propionate/ tazarotene	Valeant	PSO	Topical	Submitted - NDA	06/18/2018
tafenoquine	60 Degrees	Malaria (prevention)	Oral	Submitted - NDA; Fast track; Priority review	06/18/2018
C1-esterase inhibitor, plasma-derived (Cinryze®)	Shire	Hereditary angioedema (aged ≥ 6 years)	IV	Submitted - sNDA	06/20/2018
furosemide pump	scPharmaceuticals	Congestive heart failure/ cardiomyopathies	SC	Submitted - 505(b)(2) NDA	06/23/2018

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
bevacizumab (Avastin®)	Genentech	Ovarian cancer (advanced, 1st-line)	IV	Submitted - sBLA	06/25/2018
plazomicin	Achaogen	Bacteremia; HAP (bacterial); Complicated UTI (bacterial)	IV	Submitted - NDA; Breakthrough therapy; Fast track; Priority review	06/25/2018
cannabidiol	GW	Dravet syndrome; Lennox-Gastaut syndrome	Oral	Submitted - NDA; Fast track; Orphan drug; Priority review; Rare pediatric disease product	06/27/2018
pembrolizumab (Keytruda®)	Merck	Cervical cancer (advanced, progression on/after chemotherapy)	IV	Submitted - sBLA; Priority review	06/28/2018
aripiprazole lauroxil ER (nanocrystal dispersion)	Otsuka	Schizophrenia	Oral	Submitted - NDA	06/29/2018
glycopyrronium tosylate	Dermira	Primary axillary hyperhidrosis	Topical	Submitted - NDA	06/29/2018
binimetinib	Array	Melanoma (BRAF+, advanced, unresectable/ metastatic)	Oral	Submitted - NDA	06/29/2018
encorafenib	Array	Melanoma (BRAF+, advanced, unresectable/ metastatic)	Oral	Submitted - NDA	06/29/2018
enzalutamide (Xtandi®)	Astellas	Prostate cancer (non-metastatic, castration-resistant)	Oral	Submitted - sNDA; Fast track; Priority review	July 2018
insulin glargine (follow-on to Sanofi's Lantus)	Mylan/ Biocon	T1DM; T2DM	SC	Submitted - 505(b)(2) NDA	July 2018
inotersen	Ionis/ Akcea	Hereditary TTR amyloidosis	SC	Submitted - NDA; Fast track; Orphan drug; Priority review	07/06/2018
nivolumab (Opdivo®)	Bristol-Myers Squibb	Colorectal cancer (microsatellite instability-high [MSI-H] or mismatch repair deficient [dMMR] metastatic)	IV	Submitted - sBLA; Breakthrough therapy; Priority review	07/10/2018
cocaine 4% and 10% topical solutions	Lannett	Local anesthesia	Topical	Submitted - 505(b)(2) NDA	07/20/2018
buprenorphine spray	Insys	Acute pain (moderate to severe)	SL	Submitted - 505(b)(2) NDA	07/27/2018
risperidone depot	Indivior	Schizophrenia	SC	Submitted - 505(b)(2) NDA	07/27/2018
tafenoquine	GlaxoSmithKline	Malaria (radical cure)	Oral	Submitted - NDA; Breakthrough therapy; Orphan drug	07/27/2018

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
ultratrace Iobenguane I-131	Progenics	Neuroendocrine tumors	IV	Submitted - NDA; Breakthrough therapy; Fast track; Orphan drug; Priority review	07/30/2018
cyclosporine (nanomicellar)	Sun	Dry eye	Intraocular	Submitted - 505(b)(2) NDA	August 2018
lorlatinib	Pfizer	NSCLC (ALK+)	Oral	Submitted - NDA; Breakthrough therapy; Orphan drug; Priority review	August 2018
ulipristal	Allergan	Uterine fibroids	Oral	Submitted - 505(b)(2) NDA	August 2018
canakinumab (Ilaris®)	Novartis	Atherosclerosis (secondary prevention)	SC	Submitted - sBLA	Aug-Oct 2018
canagliflozin (Invokana®)	Janssen	CV risk reduction in patients with T2DM	Oral	Submitted sNDA	08/02/2018
elagolix	Abbvie	Endometriosis	Oral	Submitted - NDA; Priority review	08/06/2018
oxycodone ER	Pain Therapeutics	Chronic Pain	Oral	Submitted - 505(b)(2) NDA	08/07/2018
tecovirimat	SIGA	Smallpox	IV, Oral	Submitted - NDA; Fast track; Orphan drug; Priority review	08/08/2018
aflibercept (Eylea®) - 12 week dosing	Regeneron	Wet AMD	Intraocular	Submitted - sBLA	08/10/2018
patisiran	Alnylam/ Arbutus/ Ionis/ Sanofi	Hereditary TTR amyloidosis	IV	Submitted - NDA; Breakthrough therapy; Fast track; Orphan drug; Priority review	08/11/2018
migalastat	Amicus	Fabry disease	Oral	Submitted - NDA; Fast track; Orphan drug; Priority review	08/13/2018
ivosidenib	Agios	AML (relapsed/refractory, IDH1 mutation)	Oral	Submitted - NDA; Fast track; Orphan drug; Priority review	08/21/2018
stannsoporfin	Infacare	Hyperbilirubinemia	IM	Submitted - NDA; Fast track	08/22/2018
alirocumab (Praluent®)	Regeneron	Hypercholesterolemia (with apheresis)	SC	Submitted - sBLA	08/24/2018
loteprednol etabonate 1%	Kala	Ocular pain/ inflammation	Ophthalmic	Submitted - 505(b)(2) NDA	08/24/2018

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
lanadelumab	Shire	Hereditary angioedema prophylaxis	SC	Submitted - BLA; Breakthrough therapy; Fast track; Orphan drug; Priority review	08/26/2018
lusutrombopag	Shionogi	Thrombocytopenia associated with chronic liver disease	Oral	Submitted - NDA; Fast track; Priority review	08/26/2018
tretinoin 0.05% lotion	Valeant	Acne	Topical	Submitted - 505(b)(2) NDA	08/27/2018
eravacycline	Tetraphase	Intra-abdominal infections (bacterial)	IV, Oral	Submitted - NDA; Fast track; Priority review	08/28/2018
volanesorsen	Akcea	Familial chylomicronemia syndrome	SC	Submitted - NDA; Orphan drug	08/30/2018
damoctocog alfa pegol	Bayer	Hemophilia A	IV	Submitted - BLA	08/31/2018
dasotraline	Sumitomo Dainippon	ADHD (adults, pediatrics)	Oral	Submitted - NDA	08/31/2018
clobazam oral film	Aquestive	Lennox-Gastaut syndrome	SL	Submitted - 505(b)(2) NDA	September 2018
dacomitinib	Pfizer	NSCLC (first-line, locally advanced, EGFR+)	Oral	Submitted - NDA; Orphan drug; Priority review	September 2018
filgrastim (biosimilar to Amgen's Neupogen)	Pfizer	Neutropenia/ leukopenia	IV, SC	Submitted - BLA	September 2018
galcanezumab	Eli Lilly	Migraine prevention	SC	Submitted - BLA	September 2018
moxetumomab pasudotox	AstraZeneca	Hairy cell leukemia	IV	Submitted - BLA; Priority review	Sep-Oct 2018
epinephrine 0.15 mg (Symjepi®)	Adamis	Anaphylaxis (pediatrics)	SC	Submitted - sNDA	09/03/2018
mepolizumab (Nucala®)	GlaxoSmithKline	COPD (eosinophilic phenotype, maintenance)	IV, SC	Submitted - sBLA	09/07/2018
C1-esterase inhibitor, recombinant (Ruconest®)	Pharming	Hereditary angioedema (routine prophylaxis)	IV	Submitted - sNDA; Fast track; Orphan drug	09/21/2018
daratumumab (Darzalex®)	Janssen	Multiple myeloma (newly diagnosed)	IV	Submitted - sBLA; Orphan drug	09/21/2018
fluticasone furoate/ umeclidinium bromide/ vilanterol (Trelegy® Ellipta®)	GlaxoSmithKline	COPD (expanded maintenance indication)	Inhaled	Submitted - sNDA	09/21/2018
testosterone enanthate auto-injector	Antares	Hypogonadism	SC	Submitted - 505(b)(2) NDA	09/28/2018
larotrectinib	Loxo Oncology	Solid tumors (NTRK gene fusion)	Oral	Submitted - NDA; Breakthrough therapy; Orphan drug; Rare pediatric disease product	Q4, 2018

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
sarecycline	Allergan	Acne	Oral	Submitted - NDA	October 2018
incobotulinumtoxinA (Xeomin®)	Merz	Sialorrhea	IM	Submitted - sBLA	Oct-Nov 2018
nestorone and ethinyl estradiol contraceptive vaginal ring (1-year)	Allergan	Contraception	Intravaginal	Submitted - NDA	Oct-Nov 2018
omadacycline	Paratek	CAP (bacterial); SSSI (bacterial)	IV, Oral	Submitted - NDA; Fast track; Priority review; Qualified infectious disease product	10/02/2018
amisulpride	Acacia	Post-operative nausea/ vomiting	IV	Submitted - NDA	10/05/2018
duvelisib	Verastem	CLL/ SLL; Follicular lymphoma	Oral	Submitted - NDA; Fast track; Orphan drug; Priority review	10/05/2018
halobetasol	Valeant	PSO	Topical	Submitted - 505(b)(2) NDA	10/05/2018
levodopa	Acorda	Parkinson's disease	Inhaled	Submitted - 505(b)(2) NDA	10/05/2018
dupilumab (Dupixent®)	Regeneron	Asthma (severe, uncontrolled)	SC	Submitted - sBLA	10/20/2018
trastuzumab (biosimilar to Genentech's Herceptin)	Merck/ Samsung Bioepis	Breast cancer (HER2+); Gastric/ gastroesophageal cancer (HER2+)	IV	Submitted - BLA	10/20/2018
doravirine	Merck	HIV-1 infection	Oral	Submitted - NDA	10/23/2018
doravirine/ lamivudine/ tenofovir disoproxil fumarate	Merck	HIV-1 infection	Oral	Submitted - NDA	10/23/2018
17-beta estradiol/ progesterone (bio-identical)	TherapeuticsMD	Menopause	Oral	Submitted - 505(b)(2) NDA	10/28/2018
pasireotide diaspartate long-acting (Signifor®)	Novartis	Cushing's disease	IM, SC	Submitted - sNDA	November 2018
oliceridine	Trevena	Acute pain (moderate to severe)	IV	Submitted - NDA; Breakthrough therapy; Fast track	11/02/2018
fluocinolone acetonide (Iluvien®)	Alimera	Uveitis	Intraocular	Submitted - sNDA; Orphan drug	11/05/2018
revefenacin	Theravance	COPD	Inhaled	Submitted - NDA	11/13/2018
adalimumab (biosimilar to Abbvie's Humira)	Novartis/ Sandoz	RA; AS; PSO; PsA; JIA; CD; UC	SC	Submitted - BLA	11/16/2018
solriamfetol	Jazz	Narcolepsy; Sleep Apnea	Oral	Submitted - NDA; Orphan drug	12/20/2018
prucalopride	Shire	Chronic idiopathic constipation	Oral	Submitted - NDA	12/21/2018
calaspargase pegol	Shire	ALL	IV	Submitted - BLA	12/22/2018

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
glycerol phenylbutyrate (Ravicti®)	Horizon	Urea cycle disorders (infants < 2 months of age)	Oral	Submitted - sNDA; Fast track; Orphan drug	12/27/2018
amifampridine	Catalyst	Lambert-Eaton myasthenic syndrome	Oral	Submitted - NDA; Breakthrough therapy; Orphan drug	Q1, 2019
amikacin (liposomal)	Insmed	Nontuberculous Mycobacterial (NTM) lung disease caused by Mycobacterium avium complex	Inhaled	Submitted - NDA; Breakthrough therapy; Fast track; Orphan drug; Qualified infectious disease product	Q1, 2019
brexanolone	Sage	Postpartum depression	IV	Submitted - NDA; Breakthrough therapy	Q1, 2019
perampanel (Fycompa®)	Eisai	Primary generalized tonic-clonic seizures (ages 2-11 years); Partial onset seizures (ages 2-11 years)	Oral	Submitted - sNDA; Orphan drug	Q1, 2019
tacrolimus ER (Envarsus XR®)	Veloxis	Kidney transplant rejection	Oral	Submitted - sNDA; Orphan drug	01/08/2019
cabozantinib (Cabometyx®/ Cometriq®)	Exelixis	HCC (including secondary metastases)	Oral	Submitted - sNDA; Orphan drug	01/15/2019
apomorphine	Sumitomo Dainippon	Parkinson's disease (on-demand treatment of all types of motor OFF episodes)	SL	Submitted - 505(b)(2) NDA; Fast track	01/29/2019
samidorphan/ buprenophine	Alkermes	MDD	Oral	Submitted - NDA; Fast track	01/31/2019
turoctocog alfa pegol	Novo Nordisk	Hemophilia A	IV	Submitted - BLA	02/27/2019
sotagliflozin	Sanofi	T1DM	Oral	Submitted - NDA	03/25/2019
bremelanotide	AMAG	Female sexual arousal disorder	SC	Submitted - NDA	03/26/2019
emapalumab	Novimmune	Hemophagocytic lymphohistiocytosis	IV	Submitted - BLA; Breakthrough therapy; Orphan drug	03/29/2019
siponimod	Novartis	MS (secondary progressive)	Oral	Submitted - NDA	April 2019
sumatriptan	Dr. Reddy's	Migraine treatment	Intranasal	Submitted - 505(b)(2) NDA	04/02/2019
filgrastim (biosimilar to Amgen's Neupogen)	Apotex	Neutropenia/ leukopenia	IV, SC	Submitted - BLA	Pending
insulin glargine (follow-on to Sanofi's Lantus)	Merck	T1DM; T2DM	SC	Submitted - 505(b)(2) NDA	Pending
pegfilgrastim (biosimilar to Amgen's Neulasta)	Apotex	Neutropenia/ leukopenia	SC	Submitted - BLA	Pending

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
abatacept (Orencia®)	Bristol-Myers Squibb	Dermatomyositis; Lupus neprhitis; Sjogren's syndrome	IV, SC	Phase 3 - sBLA; Orphan drug	TBD
acalabrutinib (Calquence®)	AstraZeneca	CLL/ SLL	Oral	Phase 3 - sNDA; Orphan drug	TBD
aclidinium/ formoterol	Circassia	COPD	Inhaled	Phase 3 - NDA	TBD
adalimumab (biosimilar to Abbvie's Humira)	Coherus	RA; AS; PSO; PsA; JIA; CD; UC	SC	Phase 3 - BLA	TBD
adalimumab (biosimilar to Abbvie's Humira)	Fresenius	RA; AS; PSO; PsA; JIA; CD; UC	SC	Phase 3 - BLA	TBD
adalimumab (biosimilar to Abbvie's Humira)	Kyowa Hakko Kirin	RA; AS; PSO; PsA; JIA; CD; UC	SC	Phase 3 - BLA	TBD
adalimumab (biosimilar to Abbvie's Humira)	Momenta	RA; AS; PSO; PsA; JIA; CD; UC	SC	Phase 3 - BLA	TBD
adalimumab (biosimilar to Abbvie's Humira)	Mylan/ Biocon	RA; AS; PSO; PsA; JIA; CD; UC	SC	Phase 3 - BLA	TBD
adalimumab (biosimilar to Abbvie's Humira)	Pfizer	RA; AS; PSO; PsA; JIA; CD; UC	SC	Phase 3 - BLA	TBD
adalimumab (biosimilar to Abbvie's Humira)	Samsung Bioepis/ Merck	RA; AS; PSO; PsA; JIA; CD; UC	SC	Phase 3 - BLA	TBD
aducanumab	Biogen	Alzheimer's disease	IV	Phase 3 - BLA; Fast track	TBD
afamelanotide	Clinuvel	Porphyria	Intradermal	Phase 3 - NDA; Fast track; Orphan drug	TBD
aldoxorubicin	Nantworks	Sarcoma	IV	Phase 3 - NDA; Orphan drug	TBD
alicaforsen	Atlantic Healthcare	UC	Rectal	Phase 3 - NDA; Fast track; Orphan drug	TBD
alirocumab (Praluent)	Regeneron	Homozygous familial hypercholesterolemia; CV risk reduction	SC	Phase 3 - sBLA; Orphan drug	TBD
allogenic expanded adipose-derived stem cells	Tigenix	CD (fistulizing)	IV	Phase 3 - BLA; Orphan drug	TBD
allopregnanolone	SAGE	MDD	IV	Phase 3 - NDA; Breakthrough therapy	TBD
alpelisib	Novartis	Breast cancer	Oral	Phase 3 - NDA	TBD
amifampridine	Catalyst	Myasthenia gravis; Congenital myasthenic syndrome	Oral	Phase 3 - NDA; Orphan drug	TBD
amikacin (liposomal)	Insmed	CF	Inhaled	Phase 3 - NDA; Orphan drug	TBD
amrubicin	Celgene	SCLC	IV	Phase 3 - NDA; Fast track; Orphan drug	TBD
andecaliximab	Gilead	Gastric cancer	IV	Phase 3 - BLA; Orphan drug	TBD
anifrolumab	AstraZeneca	SLE	IV	Phase 3 - BLA; Fast track	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
anlotinib	Advenchen	Sarcoma	Oral	Phase 3 - NDA; Orphan drug	TBD
annabidiol	GW	Infantile spasms	Oral	Phase 3 - NDA; Orphan drug	TBD
anti-digoxin antibody	AMAG	Eclampsia/pre-eclampsia	IV	Phase 3 - BLA; Fast track; Orphan drug	TBD
apremilast (Otezla®)	Celgene	Axial spondyloarthtitis; Behçet syndrome	Oral	Phase 3 - sNDA; Orphan drug	TBD
AR101	Aimmune	Peanut allergy	Oral	Phase 3 - BLA; Breakthrough therapy; Fast track	TBD
astodrimer sodium	Starpharma	Bacterial vaginosis	Intravaginal	Phase 3 - NDA; Fast track; Qualified infectious disease product	TBD
atezolizumab (Tecentriq®)	Roche	Breast cancer; Melanoma; Prostate cancer; SCLC	IV	Phase 3 - sBLA; Orphan drug	TBD
avacopan	Chemocentryx	Antineutrophil cytoplasmic antibodies associated vasculitis	Oral	Phase 3 - NDA; Orphan drug	TBD
avatrombopag	Dova	ITP	Oral	Phase 3 - NDA	TBD
avelumab (Bavencio®)	Merck	NSCLC; RCC; Ovarian cancer; DBLCL; SCCHN; Gastric cancer	IV	Phase 3 - sBLA; Breakthrough therapy	TBD
AVXS-101	Avexis	Spinal muscular atrophy	IV	Phase 3 - BLA; Breakthrough therapy; Fast track; Orphan drug	TBD
axalimogene filolisbac	Advaxis	Cervical cancer	IV	Phase 3 - BLA; Fast track; Orphan drug	TBD
baclofen/ naltrexone/ sorbitol	Pharnext	Charcot-Marie-Tooth disease	Oral	Phase 3 - NDA; Orphan drug	TBD
baloxavir marboxil	Roche	Influenza	Oral	Phase 3 - NDA	TBD
baricitinib	Eli Lilly	Atopic dermatitis	Oral	Phase 3 - NDA	TBD
bempedoic acid	Esperion	Dyslipidemia	Oral	Phase 3 - NDA	TBD
bempedoic acid/ ezetimibe	Esperion	Dyslipidemia	Oral	Phase 3 - NDA	TBD
benralizumab (Fasenra®)	AstraZeneca	COPD; Nasal polyposis	SC	Phase 3 - sBLA	TBD
bevacizumab (biosimilar to Genentech's Avastin)	Boehringer Ingelheim	CRC; NSCLC; Ovarian/ fallopian tube/ peritoneal cancer; Glioblastoma; RCC	IV	Phase 3 - BLA	TBD
bevacizumab (biosimilar to Genentech's Avastin)	Kyowa Hakko Kirin	CRC; NSCLC; Ovarian/ fallopian tube/ peritoneal cancer; Glioblastoma; RCC	IV	Phase 3 - BLA	TBD
bevacizumab (biosimilar to Genentech's Avastin)	Mylan/ Biocon	CRC; NSCLC; Ovarian/ fallopian tube/ peritoneal cancer; Glioblastoma; RCC	IV	Phase 3 - BLA	TBD
bevacizumab (biosimilar to Genentech's Avastin)	Pfizer	CRC; NSCLC; Ovarian/ fallopian tube/ peritoneal cancer; Glioblastoma; RCC	IV	Phase 3 - BLA	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
brexpiprazole (Rexulti®)	Otsuka	Alzheimer's disease; Bipolar disease	Oral	Phase 3 - sNDA; Fast track	TBD
brincidofovir	Chimerix	Adenovirus infection; Cytomegalovirus infection	Oral	Phase 3 - NDA; Fast track	TBD
brolucizumab	Novartis	Wet AMD; Diabetic macular edema	Intraocular	Phase 3 - BLA	TBD
budesonide/ formoterol	AstraZeneca	COPD	Inhaled	Phase 3 - NDA	TBD
budesonide/ glycopyrronium/ formoterol	AstraZeneca	COPD	Inhaled	Phase 3 - NDA	TBD
bupivacaine collagen matrix implant	Innocoll	Postsurgical pain	Implant	Phase 3 - NDA	TBD
C1-esterase inhibitor (Cinryze®)	Shire	Hereditary angioedema (aged ≥ 6 years)	SC	Phase 3 - sBLA	TBD
canagliflozin (Invokana®)	Janssen	Diabetic nephropathy	Oral	Phase 3 - sNDA	TBD
cannabidiol (synthetic oral solution)	Insys	Infantile spasms	Oral	Phase 3 - NDA	TBD
caplacizumab	Ablynx	Thrombotic thrombocytopenic purpura	IV	Phase 3 - BLA; Fast track; Orphan drug	TBD
capsaicin	Centrexion	Osteoarthritis pain of the knee	Intra-articular	Phase 3 - NDA; Fast track	TBD
carotuximab	Tracon	Sarcoma	IV	Phase 3 - BLA; Orphan drug	TBD
cediranib	AstraZeneca	Ovarian cancer; Biliary cancer	Oral	Phase 3 - NDA; Orphan drug	TBD
cefiderocol	Shionogi	HAP (bacterial)	IV	Phase 3 - NDA	TBD
celiprolol	Acer	Vascular Ehlers-Danlos syndrome	Oral	Phase 3 - NDA; Orphan drug	TBD
cemiplimab	Regeneron	NSCLC; Cervical cancer	IV	Phase 3 - BLA	TBD
cetirizine	Pfizer	Urticaria	IV	Phase 3 - 505(b)(2) NDA	TBD
citrulline	Asklepion	Acute respiratory distress syndrome; PAH	IV	Phase 3 - NDA; Orphan drug	TBD
cortexolone 17a-propionate	Cassiopea	Acne	Topical	Phase 3 - NDA	TBD
CTP-modified human growth hormone long-acting	Opko	Growth hormone deficiency	SC	Phase 3 - BLA; Orphan drug	TBD
cyclobenzaprine	Tonix	Post-traumatic stress disorder	Oral, SL	Phase 3 - NDA; Breakthrough therapy	TBD
dapagliflozin (Farxiga®)	AstraZeneca	T1DM; Renal and CV outcomes in patients with CKD	Oral	Phase 3 - sNDA	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
daprodustat	GlaxoSmithKline	Anemia due to CKD (dialysis dependent & independent)	Oral	Phase 3 - NDA	TBD
darleukin	Philogen	Melanoma	IV	Phase 3 - BLA	TBD
darunavir/ emtricitabine/ tenofovir alafenamide/ cobicistat	Janssen	HIV-1 infection	Oral	Phase 3 - NDA	TBD
dasiprotimut-T	Accentia	NHL (indolent)	SC	Phase 3 - BLA; Fast track; Orphan drug	TBD
dehydrated human amnion-chorion membrane	Mimedx	Achilles tendonitis; Plantar fasciitis	Injection	Phase 3 - BLA	TBD
denileukin diftitox (Ontak®)	Dr. Reddy's	Peripheral T cell lymphoma	IV	Phase 3 - sBLA	TBD
derazantinib	Arqule	Biliary tract cancer	Oral	Phase 3 - NDA; Orphan drug	TBD
dexamethasone	Eyegate	Uveitis	Intraocular	Phase 3 - NDA	TBD
dexamethasone, sustained-release	Otonomy	Meniere's disease	Intratympanic	Phase 3 - NDA; Fast track	TBD
dianhydrogalactitol	Delmar	Glioblastoma (recurrent)	IV	Phase 3 - NDA; Fast track; Orphan drug	TBD
difelikefalin	Cara	Pruritus related to CKD; Post surgical pain	IV, Oral	Phase 3 - NDA; Breakthrough therapy	TBD
dinutuximab beta	EUSA	Neuroblastoma	SC	Phase 3 - BLA; Orphan drug	TBD
docosahexaenoic acid	Sancilio	Sickle cell anemia	Oral	Phase 3 - NDA; Orphan drug	TBD
dolutegravir/ lamivudine	GlaxoSmithKline	HIV-1 infection	Oral	Phase 3 - NDA	TBD
donor lymphocytes depleted alloreactive T cells	Kiadis	AML	IV	Phase 3 - BLA	TBD
dupilumab (Dupixent)	Regeneron	Nasal polyposis	SC	Phase 3 - sBLA	TBD
durvalumab (Imfinzi®)	AstraZeneca	HCC (including secondary metastasis); SCCHN; SCLC	IV	Phase 3 - sBLA; Fast track	TBD
dusquetide	Soligenix	Mucositis	IV	Phase 3 - NDA; Fast track	TBD
eculizumab (Soliris®)	Alexion	Neuromyelitis optica (Devic's syndrome); Delayed graft function	IV	Phase 3 - sBLA; Orphan drug	TBD
eflapegrastim	Spectrum	Neutropenia/ leukopenia	SC	Phase 3 - NDA	TBD
elafibranor	Genfit	Non-alcoholic steatohepatitis	Oral	Phase 3 - NDA; Fast track	TBD
elagolix	Abbvie	Uterine fibroids	Oral	Phase 3 - NDA	TBD
EP-2101 cancer vaccine	OSE Immuno	NSCLC	SC	Phase 3 - NDA; Orphan drug	TBD
epoetin alfa (biosimilar to Janssen's Procrit®)	Novartis	Anemia due to CKD (dialysis dependent)	IV, SC	Phase 3 - BLA	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
epratuzumab	Immunomedics	ALL	IV	Phase 3 - BLA; Orphan drug	TBD
eptinezumab	Alder	Cluster headache	SC	Phase 3 - BLA	TBD
erdosteine	Alitair	COPD	Oral	Phase 3 - NDA	TBD
esketamine	Janssen	MDD	Intranasal	Phase 3 - NDA; Breakthrough therapy; Fast track	TBD
etanercept (biosimilar to Amgen's Enbrel)	Coherus	RA; JIA; AS; PSO; PsA	SC	Phase 3 - BLA	TBD
etanercept (biosimilar to Amgen's Enbrel)	Merck/ Samsung Bioepis	RA; JIA; AS; PSO; PsA	SC	Phase 3 - BLA	TBD
etrolizumab	Roche	CD; UC	IV, SC	Phase 3 - BLA; Orphan drug	TBD
fenfluramine (low-dose)	Zogenix	Dravet syndrome; Lennox-Gastaut syndrome	Oral	Phase 3 - NDA; Breakthrough therapy; Fast track; Orphan drug	TBD
ferric maltol	Shield	Anemia due to CKD (dialysis dependent & independent)	Oral	Phase 3 - NDA	TBD
fevipiprant	Novartis	Asthma (severe, uncontrolled)	Oral	Phase 3 - NDA	TBD
filgotinib	Gilead	RA; CD; UC	Oral	Phase 3 - NDA	TBD
fluticasone furoate/ umeclidinium bromide/ vilanterol (Trelegy® Ellipta®)	GlaxoSmithKline	Asthma	Inhaled	Phase 3 - sNDA	TBD
formoterol fumarate	AstraZeneca	COPD	Inhaled	Phase 3 - NDA	TBD
fosfomycin	Zavante	Complicated UTI	IV	Phase 3 - NDA; Fast track	TBD
fosmetpantotenate	Retrophin	Pantothenate kinase-associated neurodegeneration	IV	Phase 3 - NDA; Fast track; Orphan drug	TBD
fostemsavir	GlaxoSmithKline	HIV-1 infection	Oral	Phase 3 - NDA; Breakthrough therapy; Fast track	TBD
fremanezumab	Teva	Cluster headache prevention	SC	Phase 3 - BLA; Fast track	TBD
fusidic acid	Cempra	SSSI (bacterial); Bone and Joint Infections (Antibacterial)	Oral	Phase 3 - NDA; Orphan drug	TBD
galcanezumab	Eli Lilly	Cluster headache	SC	Phase 3 - BLA; Fast track	TBD
gefapixant	Merck	Chronic cough	Oral	Phase 3 - NDA	TBD
givosiran	Alnylam	Porphyria	SC	Phase 3 - NDA; Breakthrough therapy; Orphan drug	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
glycopyrrolate hydrofluoroalkane (metered dose inhaler)	AstraZeneca	COPD	Inhaled	Phase 3 - NDA	TBD
glycopyrronium bromide (Seebri™ Neohaler®)	Sumitomo Dainippon	Asthma	Inhaled	Phase 3 - sNDA	TBD
golodirsen	Sarepta	Duchenne muscular dystrophy	IV	Phase 3 - NDA	TBD
grazoprevir/ elbasvir (Zepatier®)	Merck	HCV infection (with CKD)	Oral	Phase 3 - sNDA; Breakthrough therapy	TBD
GS010	Gensight	Leber's hereditary optic neuropathy	Intraocular	Phase 3 - BLA; Orphan drug	TBD
human plasminogen	Kedrion	Ligneous conjunctivitis	Ophthalmic	Phase 3 - BLA; Orphan drug	TBD
ibritumomab tiuxetan	Spectrum	DLBCL	IV	Phase 3 - BLA	TBD
iclaprim	Motif Bio	SSSI (bacterial); HAP	IV	Phase 3 - NDA; Fast track	TBD
icosapent ethyl (Vascepa®)	Amarin	Major CV event risk reduction	Oral	Phase 3 - sNDA	TBD
idasanutlin	Roche	AML	Oral	Phase 3 - NDA	TBD
idebenone	Santhera	Duchenne muscular dystrophy	Oral	Phase 3 - NDA; Fast track; Orphan drug	TBD
inclisiran	The Medicines Company	Dyslipidemia	SC	Phase 3 - NDA; Orphan drug	TBD
indacaterol/ glycopyrronium bromide/ mometasone furoate	Novartis	Asthma	Inhaled	Phase 3 - NDA	TBD
indacaterol/ mometasone furoate	Novartis	Asthma	Inhaled	Phase 3 - NDA	TBD
inebilizumab	AstraZeneca	Neuromyelitis optica (Devic's syndrome)	IV	Phase 3 - BLA; Orphan drug	TBD
infliximab (biosimilar to Janssen's Remicade)	Amgen	RA; AS; PSO; PsA; CD; UC	IV	Phase 3 - BLA	TBD
insulin glargine (follow-on to Sanofi's Lantus)	Gan & Lee	T2DM	SC	Phase 3 - NDA	TBD
interferon-beta 1a	Faron	Acute respiratory failure; Acute lung injury, Acute respiratory distress syndrome	IV	Phase 3 - BLA; Fast track	TBD
isatuximab	Sanofi	Multiple myeloma	IV	Phase 3 - BLA; Orphan drug	TBD
istradefylline	Kyowa Hakko Kirin	Parkinson's disease	Oral	Phase 3 - NDA	TBD
ivosidenib	Agios	Biliary tract cancer	Oral	Phase 3 - NDA; Fast track; Orphan drug	TBD
ixekizumab (Taltz®)	Eli Lilly	Axial spondyloarthritis	SC	Phase 3 - sBLA	TBD
lasmiditan	Eli Lilly	Migraine treatment	Oral	Phase 3 - NDA	TBD
lefamulin	Nabriva	CAP (bacterial)	IV, Oral	Phase 3 - NDA; Fast track	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
lemborexant	Eisai	Insomnia	Oral	Phase 3 - NDA	TBD
lentiviral beta-globin gene transfer	Bluebird bio	Anemia	IV	Phase 3 - BLA; Breakthrough therapy; Fast track; Orphan drug	TBD
lentiviral vector hematopoietic stem cell	Bluebird bio	Adrenomyeloneuropathy (Adrenoleukodystrophy)	N/A	Phase 3 - BLA; Orphan drug	TBD
leuprolide mesylate	Foresee	Prostate cancer	SC	Phase 3 - NDA	TBD
levodopa/ carbidopa (patch pump)	Mitsubishi Tanabe	Parkinson's disease	SC	Phase 3 - NDA	TBD
levoketoconazole	Strongbridge	Cushing's syndrome	Oral	Phase 3 - NDA; Orphan drug	TBD
lumateperone	Intracellular Therapies	Schizophrenia; Bipolar disorder; Alzheimer's disease	Oral	Phase 3 - NDA; Fast track	TBD
luspatercept	Acceleron	Anemia; Myelodysplastic syndrome	SC	Phase 3 - BLA; Fast track; Orphan drug	TBD
margetuximab	Macrogenics	Breast cancer	IV	Phase 3 - BLA; Fast track	TBD
masitinib mesylate	AB Science	Alzheimer's disease; ALS; Asthma (severe, uncontrolled); Gastrointestinal stromal tumor; Mastocytosis; Pancreatic cancer; CRC, Prostate cancer; Multiple myeloma; Melanoma; Ovarian cancer; MS	Oral	Phase 3 - NDA	TBD
meningitis B vaccine	GlaxoSmithKline	Invasive meningococcal disease prevention (ages 2-10 years)	IM	Phase 3 - BLA; Breakthrough therapy	TBD
mepolizumab (Nucala)	GlaxoSmithKline	Nasal polyposis	SC	Phase 3 - sBLA	TBD
meropenem/ vaborbactam (Vabomere®)	The Medicines Company	HAP; Septicemia/ bacteremia	IV	Phase 3 - sNDA	TBD
metachromatic leukodystrophy gene therapy	GlaxoSmithKline	Metachromatic leukodystrophy	IV	Phase 3 - BLA	TBD
metoclopramide spray	Evoke	Diabetic gastroparesis	Intranasal	Phase 3 - NDA	TBD
microbiota suspension	Rebiotix	*Clostridium difficile*-associated diarrhea/ infection	Rectal	Phase 3 - BLA; Breakthrough therapy; Fast track; Orphan drug	TBD
midazolam spray	Upsher-Smith	Seizure disorder	Intranasal	Phase 3 - NDA; Fast track; Orphan drug	TBD
minocycline	Foamix	Rosacea	Topical	Phase 3 - NDA	TBD
mirvetuximab soravtansine	Immunogen	Ovarian cancer	IV	Phase 3 - BLA; Orphan drug	TBD
molgramostim	Savara	Pulmonary alveolar proteinosis	Inhaled	Phase 3 - BLA; Orphan drug	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
monomethyl fumarate prodrug	Alkermes	MS	Oral	Phase 3 - NDA	TBD
nalbuphine ER	Trevi	Uremic pruritus	Oral	Phase 3 - NDA	TBD
netarsudil/ latanoprost	Aerie	Glaucoma/ ocular hypertension	Ophthalmic	Phase 3 - NDA	TBD
nitric oxide	Mallinckrodt	Bronchopulmonary dysplasia	Inhaled	Phase 3 - NDA	TBD
nivolumab (Opdivo®)	Bristol-Myers Squibb	Brain cancer; Esophageal cancer; Gastric cancer; Mesothelioma; Multiple myeloma; SCLC	IV	Phase 3 - sBLA; Orphan drug	TBD
NKTR-181	Nektar	Chronic pain	Oral	Phase 3 - NDA; Fast track	TBD
nolasiban	Obseva	Reproductive disorder	Oral	Phase 3 - NDA	TBD
ofranergene obadenovec	VBL	Ovarian cancer	IV	Phase 3 - BLA	TBD
olaparib (Lynparza®)	AstraZeneca	Breast cancer (1st-line); Pancreatic cancer; Prostate cancer	Oral	Phase 3 - sNDA; Breakthrough therapy	TBD
olipudase alfa	Sanofi	Niemann-Pick disease	IV	Phase 3 - BLA; Breakthrough therapy; Orphan drug	TBD
omalizumab (Xolair®)	Roche	Nasal polyposis	SC	Phase 3 - sBLA	TBD
opicapone	Neurocrine Biosciences	Parkinson's disease	Oral	Phase 3 - NDA	TBD
osilodrostat	Novartis	Cushing's syndrome	Oral	Phase 3 - NDA; Orphan drug	TBD
ozanimod	Celgene	MS; CD; UC	Oral	Phase 3 - NDA	TBD
pegilodecakin	ARMO	Pancreatic cancer	SC	Phase 3 - NDA; Fast track; Orphan drug	TBD
pegunigalsidase alfa	Protalix	Fabry disease	IV	Phase 3 - BLA; Fast track	TBD
pembrolizumab (Keytruda)	Merck	Breast cancer; Esophageal cancer; HCC (including secondary metastasis); RCC; SCLC	IV	Phase 3 - sBLA; Breakthrough therapy	TBD
pertuzumab (Perjeta®)	Roche	Ovarian cancer	IV	Phase 3 - sBLA	TBD
pexidartinib	Daiichi Sankyo	Pigmented villonodular synovitis	Oral	Phase 3 - NDA; Breakthrough therapy; Orphan drug	TBD
pimodivir	Janssen	Influenza	Oral	Phase 3 - NDA; Fast track	TBD
plinabulin	Beyondspring	Neutropenia/ leukopenia	IV	Phase 3 - NDA	TBD
quizartinib	Daiichi Sankyo	AML	Oral	Phase 3 - NDA; Orphan drug	TBD
ramucirumab (Cyramza®)	Eli Lilly	HCC (including secondary metastasis); Bladder cancer	IV	Phase 3 - sBLA; Orphan drug	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
ranibizumab (biosimilar to Genentech's Lucentis®)	Santo	Wet AMD	Intraocular	Phase 3 - BLA	TBD
ranibizumab (Lucentis)	Roche	Cystoid Macular Edema; Myopic Macular Degeneration; Retinopathy of prematurity	Intraocular	Phase 3 - sBLA	TBD
ravulizumab	Alexion	Paroxysmal nocturnal hemoglobinuria; Hemolytic uremic syndrome	IV	Phase 3 - NDA; Orphan drug	TBD
relugolix	Myovant	Endometriosis; Prostate cancer; Uterine fibroids	Oral	Phase 3 - NDA	TBD
remestemcel-L	Mesoblast	Graft versus host disease	IV	Phase 3 - BLA; Fast track; Orphan drug	TBD
reparixin	Dompé	Transplant rejection	IV	Phase 3 - NDA; Orphan drug	TBD
reproxalap	Aldeyra	Congenital ichthyosis	Topical	Phase 3 - NDA; Orphan drug	TBD
rifabutin/ amoxicillin/ pantoprazole	Redhill	*H. pylori* Infection	Oral	Phase 3 - NDA; Fast track	TBD
rifamycin	Cosmo	Traveler's diarrhea	Oral	Phase 3 - NDA; Fast track; Qualified infectious disease product	TBD
rimegepant	Portage Biotech	Migraine treatment	Oral	Phase 3 - NDA	TBD
risankizumab	Abbvie	PSO; CD	SC	Phase 3 - BLA	TBD
risperidone	Apple Tree	Schizophrenia	SC implant	Phase 3 - NDA	TBD
rituximab (biosimilar to Genentech's Rituxan)	Amgen	RA; CLL; NHL (indolent); Antineutrophil cytoplasmic antibodies associated vasculitis	IV	Phase 3 - BLA	TBD
rituximab (biosimilar to Genentech's Rituxan)	Pfizer	RA; CLL; NHL (indolent); Antineutrophil cytoplasmic antibodies associated vasculitis	IV	Phase 3 - BLA	TBD
rivipansel	Pfizer	Sickle cell anemia	IV	Phase 3 - NDA; Fast track; Orphan drug	TBD
rivoceranib	LSK Biopartners	Gastric cancer	Oral	Phase 3 - NDA; Orphan drug	TBD
ropeginterferon alfa-2b	Pharmaessentia	Polycythemia vera	SC	Phase 3 - BLA; Orphan drug	TBD
rosiptor	Aquinox	Interstitial cystitis	Oral	Phase 3 - NDA	TBD
rovalpituzumab tesirine	Abbvie	SCLC	IV	Phase 3 - BLA; Orphan drug	TBD
roxadustat	AstraZeneca	Anemia due to CKD (dialysis dependent); Anemia (chemotherapy-induced)	Oral	Phase 3 - NDA	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
sactuzumab govitecan	Immunomedics	Breast cancer	IV	Phase 3 - BLA; Breakthrough therapy; Fast track	TBD
sacubitril/ valsartan (Entresto®)	Novartis	Heart failure (preserved ejection fraction)	Oral	Phase 3 - sNDA	TBD
satralizumab	Roche	Neuromyelitis optica (Devic's syndrome)	SC	Phase 3 - BLA; Orphan drug	TBD
seladelpar	Cymabay	Primary biliary cirrhosis	Oral	Phase 3 - NDA; Orphan drug	TBD
selinexor	Karyopharm	Multiple myeloma	Oral	Phase 3 - NDA; Fast track; Orphan drug	TBD
selumetinib	AstraZeneca	Thyroid cancer	Oral	Phase 3 - NDA; Orphan drug	TBD
semaglutide	Novo Nordisk	T2DM	Oral	Phase 3 - NDA	TBD
seviprotimut	Polynoma	Melanoma	Intradermal	Phase 3 - BLA	TBD
sodium oxybate (low sodium)	Jazz	Narcolepsy	Oral	Phase 3 - NDA	TBD
sodium oxybate (once nightly dosing)	Avadel	Narcolepsy	Oral	Phase 3 - NDA; Orphan drug	TBD
sodium oxybate (Xyrem®)	Jazz	Narcolepsy-related cataplexy (pediatrics)	Oral	Phase 3 - sNDA	TBD
sodium thiosulfate	Fennec	Hearing loss (chemotherapy-induced)	IV	Phase 3 - NDA; Breakthrough therapy; Fast track; Orphan drug	TBD
somavaratan	Versartis	Growth hormone deficiency	SC	Phase 3 - BLA; Orphan drug	TBD
sotagliflozin	Sanofi	T2DM	Oral	Phase 3 - NDA	TBD
sparsentan	Retrophin	Focal segmental glomerulosclerosis	Oral	Phase 3 - NDA; Orphan drug	TBD
tadalafil (versafilm)	Intelgenx	Erectile dysfunction	Oral	Phase 3 - NDA	TBD
tafamidis meglumine	Pfizer	Transthyretin amyloid cardiomyopathy	Oral	Phase 3 - NDA; Fast track; Orphan drug	TBD
taselisib	Roche	Breast cancer	Oral	Phase 3 - NDA	TBD
tasimelteon (Hetlioz®)	Vanda	Insomnia due to jet lag; Smith-Magenis syndrome	Oral	Phase 3 - sNDA	TBD
tecarfarin	Armetheon	Anticoagulation	Oral	Phase 3 - NDA	TBD
tenapanor	Ardelyx	IBS; Hyperphosphatemia	Oral	Phase 3 - NDA	TBD
teriparatide recombinant human (biosimilar to Eli Lilly's Forteo®)	Pfenex	Osteoporosis/ osteopenia	SC	Phase 3 - BLA	TBD
terlipressin	Mallinckrodt	Hepatorenal syndrome	IV	Phase 3 - NDA; Fast track; Orphan drug	TBD
tezepelumab	AstraZeneca	Asthma (severe, uncontrolled)	SC	Phase 3 - BLA	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
tocilizumab (Actemra®)	Roche	Scleroderma	SC	Phase 3 - sBLA; Breakthrough therapy	TBD
tralokinumab	AstraZeneca	Atopic dermatitis	SC	Phase 3 - BLA	TBD
treprostinil	Steadymed	PAH	SC	Phase 3 - NDA; Orphan drug	TBD
triamcinolone acetonide	Clearside	Uveitis	Intraocular	Phase 3 - NDA	TBD
trigriluzole	Portage	Spinocerebellar ataxia; Obsessive compulsive disorder	Oral	Phase 3 - NDA; Fast track; Orphan drug	TBD
ublituximab	TG	CLL/ SLL; MS	IV	Phase 3 - BLA; Orphan drug	TBD
ublituximab/ umbralisib	TG	CLL/ SLL	IV + Oral	Phase 3 - BLA/NDA; Orphan drug	TBD
ubrogepant	Allergan	Migraine treatment	Oral	Phase 3 - NDA	TBD
udenafil	Allergan	Erectile dysfunction	Oral	Phase 3 - NDA	TBD
upadacitinib	Abbvie	RA; CD	Oral	Phase 3 - NDA	TBD
ursodeoxycholic Acid	Retrophin	Primary biliary cholangitis	Oral	Phase 3 - NDA	TBD
vadadustat	Akebia	Anemia due to CKD (dialysis dependent & independent)	Oral	Phase 3 - NDA	TBD
valoctocogene roxaparvovec	Biomarin	Hemophilia A	IV	Phase 3 - BLA; Breakthrough therapy; Orphan drug	TBD
varicella-zoster vaccine (inactivated)	Merck	Herpes zoster prevention	SC	Phase 3 - BLA	TBD
viaskin peanut	DBV	Peanut allergy	Transdermal	Phase 3 - BLA; Breakthrough therapy; Fast track	TBD
vilanterol trifenatate	GlaxoSmithKline	Asthma; COPD	Inhaled	Phase 3 - NDA	TBD
vilaprisan	Bayer	Uterine fibroids	Oral	Phase 3 - NDA	TBD
vocimagene amiretrorepvec	Tocagen	Brain cancer	Intratumoral	Phase 3 - BLA; Breakthrough therapy; Fast track	TBD
voclosporin	ILJIN	Lupus nephritis	Oral	Phase 3 - NDA; Fast track	TBD
von Willebrand factor (human, concentrate)	LFB Group	von Willebrand disease	IV	Phase 3 - BLA; Orphan drug	TBD
vonapanitase	Proteon	End-stage renal disease	IV	Phase 3 - BLA; Breakthrough therapy; Fast track; Orphan drug	TBD
vosoritide	Biomarin	Achondroplasia	SC	Phase 3 - NDA; Orphan drug	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
voxelotor	Global Blood	Sickle cell anemia	Oral	Phase 3 - NDA; Breakthrough therapy; Fast track; Orphan drug	TBD
VX-659	Vertex	CF (one F508del mutation and one minimal function mutation) - in combination with tezacaftor and ivacaftor	Oral	Phase 3 - NDA	TBD
zolmitriptan (microneedle patch)	Zosano	Migraine treatment	Transdermal	Phase 3 - NDA	TBD

Complete Response Letter (CRL) / Withdrawn Drugs

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
azeliragon	VTV	Alzheimer's disease	Oral	Withdrawn	N/A
buprenorphine depot	Apple Tree	Substance use disorder	SC	CRL	TBD
ciprofloxacin (liposomal, dual-release)	Grifols	Bronchiectasis (non-CF-related)	Inhaled	CRL	TBD
liprotamase	Anthera	Exocrine pancreatic insufficiency	Oral	Withdrawn	N/A
olumacostat glasaretil	Dermira	Acne	Topical	Withdrawn	N/A
rituximab (biosimilar to Genentech's Rituxan®)	Celltrion/ Teva	RA; CLL; NHL (indolent); Antineutrophil cytoplasmic antibodies associated vasculitis	IV	CRL	TBD
trastuzumab (biosimilar to Genentech's Herceptin)	Celltrion/ Teva	Breast cancer (HER2+); Gastric/ gastroesophageal cancer (HER2+)	IV	CRL	TBD
trastuzumab (biosimilar to Genentech's Herceptin)	Pfizer	Breast cancer (HER2+); Gastric/ gastroesophageal cancer (HER2+)	IV	CRL	TBD

GLOSSARY

ADHD Attention Deficit Hyperactivity Disorder

ALL Acute Lymphoblastic Leukemia

AMD Age-related Macular Degeneration

AML Acute Myeloid Leukemia

ANDA Abbreviated New Drug Application

AS Ankylosing Spondylitis

BED Binge Eating Disorder

BLA Biologics License Application

BsUFA Biosimilar User Fee Act

CAP Community Acquired Pneumonia

CD Crohn's Disease

CDC Centers for Disease Control and Prevention

CF Cystic Fibrosis

CHF Congestive Heart Failure

CKD Chronic Kidney Disease

CLL Chronic Lymphocytic Leukemia

COPD Chronic Obstructive Pulmonary Disease

CRC Colorectal Cancer

CRL Complete Response Letter

CV Cardiovascular

CVD Cardiovascular Disease

DEA Drug Enforcement Administration

DLBCL Diffuse Large B Cell Lymphoma

FDA Food and Drug Administration

ER Extended-release

GI Gastrointestinal

GLP-1 Glucagon-like peptide-1

H Half

HAP Hospital Acquired Pneumonia

HCC Hepatocellular Carcinoma

HCP Healthcare Professional

HCV Hepatitis C Virus

HIT Heparin Induced Thrombocytopenia

HTN Hypertension

HR Hazard Ratio

IBS Irritable Bowel Syndrome

IM Intramuscular

IV Intravenous

JIA Juvenile Idiopathic Arthritis

LDL-C Low-Density Lipoprotein Cholesterol

MDD Major Depressive Disorder

MS Multiple Sclerosis

N/A Not Applicable

NDA New Drug Application

NHL Non-Hodgkin Lymphoma

NSAID Non-Steroidal Anti-Inflammatory Drug

NSCLC Non-Small Cell Lung Cancer

ORR Objective/Overall Response Rate

OS Overall Survival

PAH Pulmonary arterial hypertension

PFS Progression-Free Survival

PCI Percutaneous Coronary Intervention

PDUFA Prescription Drug User Fee Application

PsA Psoriatic Arthritis

PSO Plaque Psoriasis

PTCA Percutaneous Transluminal Coronary Angioplasty

Q Quarter

QOL Quality of Life

RA Rheumatoid Arthritis

RCC Renal Cell Carcinoma

SL Sublingual

sBLA supplemental Biologics License Application

SC Subcutaneous

SCCHN Squamous Cell Cancer of the Head and Neck

SCLC Small Cell Lung Cancer

SLE Systemic Lupus Erythematosus

SLL Small Lymphocytic Lymphoma

sNDA supplemental New Drug Application

SSSI Skin and Skin Structure Infection

T1DM Type 1 Diabetes Mellitus

T2DM Type 2 Diabetes Mellitus

TBD To Be Determined

UA Unstable Angina

UC Ulcerative Colitis

US United States

UTI Urinary Tract Infection

WHO World Health Organization

XR Extended-release

Magellan Rx MANAGEMENT

Industry-leading research into the most complex areas of healthcare