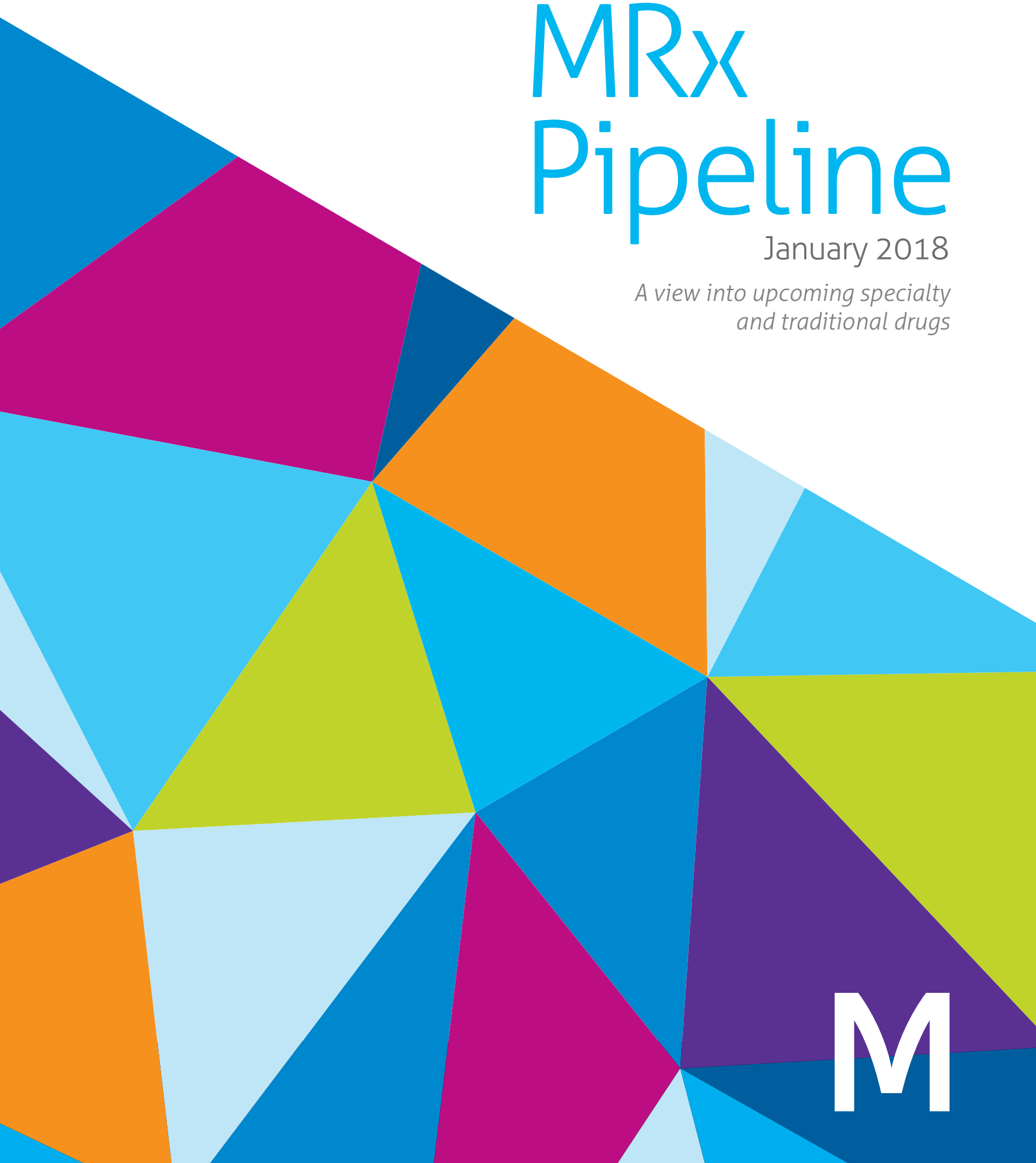
Magellan Rx MANAGEMENT℠

MRx Pipeline

January 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. 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 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.

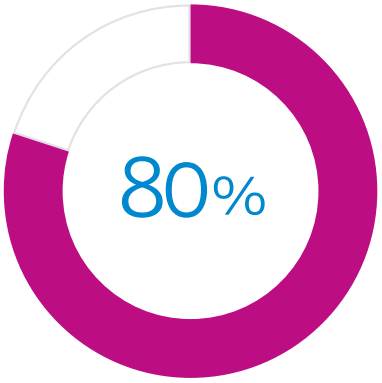
The FDA approved a record number of drugs in 2017, reaching a 21-year high with 46 novel approvals. As the Agency more than doubled approvals compared to 2016, they also reached milestones not captured in the novel approvals count. In 2017, two chimeric antigen receptor T cell (CAR-T) therapies and the first ever gene therapy for an inherited retinal condition secured approvals, representing a historic advancement for patients and medicine. In the past few years, game changers such as products in the hepatitis C and immunotherapy fields have blazed the pipeline trail. As we look ahead, a continued key trend toward the approval of specialty medications is expected. Noteworthy pipeline trends to watch in the upcoming quarters include the development of complex therapies, rare diseases, oncology, immunology, Alzheimer's disease, migraine prophylaxis, neurology, ophthalmology, women's health, and growth of biosimilars.

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.

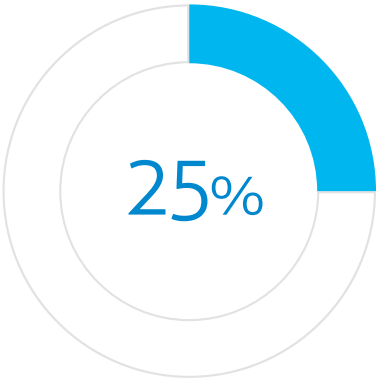
Pipeline Deep Dive

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.

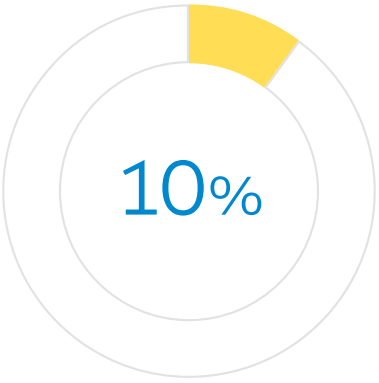
SPECIALTY



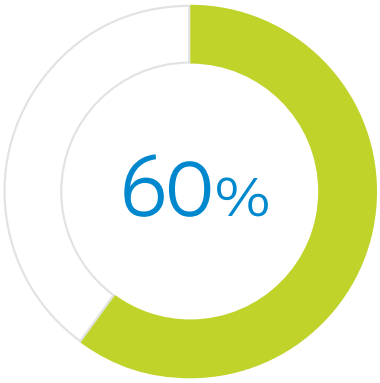
PRIORITY REVIEW



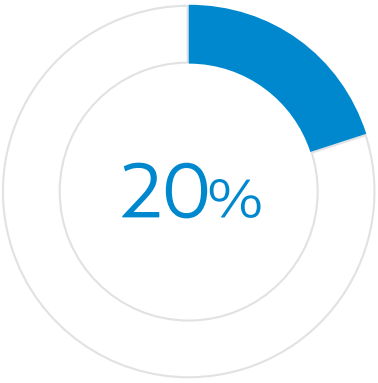
BREAKTHROUGH THERAPY



BIOSIMILAR



ORPHAN DRUG



★ Specialty drug names appear in magenta throughout the publication.

Magellan Rx MANAGEMENT℠

Cardiovascular

andexanet alfa (Andexxa) *IV*

Portola

PROPOSED INDICATIONS

Reversal of factor Xa inhibitor anticoagulation. While andexanet alfa is being developed as a universal reversal agent to factor Xa anticoagulants, Portola is seeking initial approval for reversal of apixaban and rivaroxaban in patients experiencing an uncontrolled or life-threatening bleed.

CLINICAL OVERVIEW

Anticoagulants, used to prevent and/or treat thromboembolism, are associated with an inherent risk of bleeding that could be serious and life-threatening. Andexanet alfa is a universal anticoagulant reversal agent that targets direct and indirect factor Xa inhibitors, including apixaban (Eliquis®), betrixaban (Bevyxxa®, also by Portola), edoxaban (Savaysa®), rivaroxaban (Xarelto®), and enoxaparin (Lovenox®).

Clinical trials in healthy adult volunteers demonstrated the safe and successful reversal of apixaban and rivaroxaban anticoagulation by andexanet alfa, given as an IV bolus with or without a subsequent 2-hour IV infusion. Reversal of the anticoagulant effect occurred within 2 to 5 minutes after the bolus dose. Unbound factor Xa inhibitor levels returned to placebo levels within 1 to 3 hours after the completion of the bolus or infusion doses, depending on the anticoagulant. Similar extent of anticoagulant reversal was observed in a phase 4 study in apixaban- and rivaroxaban-treated patients with acute major bleed.

Doses studies of andexanet alfa included 400 mg and 800 mg bolus, with or without a subsequent 2-hour IV infusion (4 or 8 mg/min).

PLACE IN THERAPY

For some patients, the use of factor Xa inhibitors is preferred over warfarin, in part because they do not require blood work monitoring to verify anticoagulant effect. However, as with warfarin, factor Xa inhibitors are associated with an increased risk of bleeding. In an analysis of private and public insurance claims data from a recent 12-month period, there were over 50,000 hospital admissions in the US due to bleeding in patients receiving apixaban or rivaroxaban. While there are agents available to reverse the anticoagulant effects of warfarin (antidote: vitamin k) and the thrombin inhibitor, dabigatran etexilate (Pradaxa®; antidote: Praxbind®), there is currently no antidote for factor Xa inhibitors in emergency situations. Effective reversal of the anticoagulant effect could further enhance patient safety and increase prescriber and patient confidence in factor Xa inhibitor products. Andexanet alfa will be administered in a medical setting. Clinical studies are ongoing for the use of andexanet alfa for the reversal of betrixaban, edoxaban, and enoxaparin.

FDA APPROVAL TIMELINE

May 4, 2018

This is Portola's second FDA submission for andexanet alfa. After an accelerated review in August 2016, the FDA issued a CRL that primarily addressed the manufacturing process and requested additional information related to edoxaban and enoxaparin.

✓ Breakthrough therapy ✓ Orphan drug

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$ 73	$ 148	$ 230	$ 349	$ 482

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

Oncology

apalutamide *oral*

Janssen

PROPOSED INDICATIONS

Non-metastatic, castration-resistant prostate cancer (nmCRPC)

CLINICAL OVERVIEW

Apalutamide is a next-generation oral androgen receptor (AR) antagonist. It inhibits the action of testosterone in prostate cancer (PC) cells and prevents androgen from binding to the AR.

A single-arm, phase 2 study enrolled 51 men with nmCRPC at high risk for progression (prostate-specific antigen [PSA] ≥ 8 ng/mL or PSA doubling time ≤ 10 months). Median age was 71 years. After 12 weeks of apalutamide therapy, the median change in PSA from baseline was -85% (based on Prostate Cancer Working Group 2 [PCWG2] criteria). A reduction in PSA of ≥ 50% was reported in 89% of patients. At 28 months of follow-up, the median time to PSA progression was 24 months and the metastatic-free survival (MFS) was not reached. The most commonly reported adverse effects were grade 1/2 fatigue, diarrhea, and nausea. While the risk of seizures has been identified with AR antagonists, no seizures were reported in this study with apalutamide. The results of this trial shaped the design of the pivotal phase 3 SPARTAN study evaluating MFS with apalutamide in men with nmCRPC; SPARTAN will support the application to the FDA of apalutamide in this setting. Interim data of SPARTAN are anticipated in February 2018.

The study dose of apalutamide in the phase 2 trial was 240 mg per day.

PLACE IN THERAPY

PC is most often diagnosed in men ages 55 to 74 years. In 2017, it was estimated that PC was diagnosed in over 161,000 men and accounted for approximately 26,730 deaths in the US. The 5-year survival rate is 100% for the majority of cases, which consist of localized and regional disease at diagnosis; however, for the 5% of cases with metastatic disease, 5-year survival drops to 29%. Androgen deprivation therapy (ADT), via surgical and/or drug therapy (leuprolide, degarelix), is the basis of PC treatment. Men who are at high risk for metastasis are typically treated with surgery or radiation combined with ADT. If response to ADT ceases (e.g., castration-resistant), continued ADT with the addition of an antiandrogen or androgen synthesis inhibitor is recommended.

While drugs, such as ADTs, are approved for advanced PC, safe and effective treatment to delay or prevent the development of metastatic disease in nmCRPC is an important unmet medical need. If approved, oral apalutamide will be the first therapy indicated for the treatment of nmCRPC. It is predicted that apalutamide may absorb marketshare from drugs indicated for metastatic CRPC (mCRPC) that are prescribed off-label for nmCRPC (e.g., abiraterone [Zytiga®], enzalutamide [Xtandi®], cabazitaxel [Jevtana®], docetaxel, and sipuleucel-T [Provenge®]). Initial approval of oral apalutamide will most likely be for nmCRCP, but expanded indications for mCRPC and in hormone/castration-sensitive PC are anticipated by 2022. Likewise, enzalutamide is expected to receive approval for nmCRPC in 2020.

FDA APPROVAL TIMELINE

April 2018

✓ Priority review

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$ 53	$ 182	$ 306	$ 473	$ 639

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

Neurology

cannabidiol (Epidiolex) *oral*

GW

PROPOSED INDICATIONS

Dravet syndrome and Lennox-Gastaut syndrome (LGS)

Epidiolex is an oral liquid formulation of a highly purified extract of plant-derived cannabidiol (CBD). It lacks the psychoactivity of tetrahydrocannabinol (THC).

CLINICAL OVERVIEW

A 14-week, phase 3 trial in 120 patients (aged 2 to 18 years) with uncontolled Dravet syndrome added CBD (20 mg/ kg/day) or placebo to standard antiepileptic drugs (AEDs). Patients given CBD had a significantly greater median reduction in convulsive seizures (39%) compared to placebo (13%). While more patients treated with CBD compared to placebo achieved ≥ 50% reduction in seizure frequency (43% versus 27%) or were seizure-free (5% versus 0%), both endpoints fell short of statistical significance (p=0.08 for each). CBD also had no impact on frequency of nonconvulsive seizures.

Another 14-week, phase 3 trial enrolled 225 patients with treatment-resistant LGS, aged 2 to 55 years (mean, 16 years), with an average of 85 drop (tonic and atonic) seizures per month. At 14 weeks, the addition of daily CBD to current treatment significantly reduced the frequency of drop seizures with daily doses of 10 mg/kg and 20mg/kg (37% and 42% reduction, respectively) compared with add-on placebo (17% reduction). Significantly more patients achieved ≥ 50% reduction in seizures with either dose of CBD (36% to 40%) versus placebo (15%).

CBD-associated adverse effects included GI symptoms, somnolence, lethargy, and decreased appetite.

PLACE IN THERAPY

Dravet syndrome is an early-onset encephalopathic epilepsy associated with a high mortality rate. It is reported in approximately 1 out of 15,700 individuals in the US. Dravet syndrome is characterized by frequent prolonged seizures and developmental delays. There is currently no medication approved in the US to treat Dravet syndrome. LGS is characterized by drop seizures and impaired intellectual development. LGS accounts for 2% to 5% of childhood seizure disorders and persists into adulthood. Onset is typically between ages 3 to 5 years. Partial response is seen with currently available AEDs. If approved, CBD will provide an important treatment option for Dravet syndrome and LGS, devastating seizure disorders with no or few good treatment options.

CBD is 1 of many compounds found in the cannabis plant. According to the DEA, it falls within the Controlled Substance Act definition of marijuana. The WHO indicates that, while CBD can be converted to THC under experimental conditions, it does not appear to have significant psychoactive effects. Drug interactions between CBD and prescribed medications have been reported. Further, the WHO states that CBD does not lead to abuse or dependence or cause harm. Although, they do not recommend CBD for medical use at this time, they do recognize its value in the setting of seizure disorders.

FDA APPROVAL TIMELINE

June 27, 2018

✓ Fast track ✓ Orphan drug ✓ Priority review ✓ Rare pediatric disease

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$ 7	$ 57	$ 98	$ 134	$ 157

The forecast is a projection of total US sales per year for LGS. Sales data for Dravet syndrome are not currently available.

elagolix *oral*

Abbvie

PROPOSED INDICATIONS

Endometriosis with associated pain

CLINICAL OVERVIEW

Endometriosis is an estrogen-dependent condition in which endometrial tissue forms outside the uterus and leads to chronic pelvic pain and infertility. Elagolix is an oral gonadotropin-releasing hormone (GnRH) antagonist. It reduces estrogen production, resulting in shrinking of endometrial lesions.

Efficacy of elagolix was evaluated in 2 similar double-blind trials (Elaris Endometriosis [EM] I and II) in nearly 1,700 premenopausal women, 18 to 49 years of age, with confirmed endometriosis and moderate to severe endometriosis-related pain. In both trials at 3 months, significant dose-dependant responses were seen with elagolix compared to placebo, based on reduction in pain and a decreased or stable use of rescue analgesics. In EM-I and EM-II, response rates with elagolix 150 mg once daily were 46.4% and 43.4% for dysmenorrhea and 50.4% and 49.8% for nonmenstrual pelvic pain, respectively; with elagolix 200 mg twice daily, response rates were 75.8% and 72.4% for dysmenorrhea and 54.5% and 57.8% for nonmenstrual pelvic pain, respectively; compared with placebo, which were 19.6% and 22.7% for dysmenorrhea, respectively, and 36.5% in both trials for nonmenstrual pelvic pain. Effects of elagolix were maintained for 6 months and in extension trials for 12 months. Dose-dependent effects, such as hot flushes, elevated serum lipids, and decreased bone mineral density (BMD), occurred. At 6 months, more women treated with elagolix had lumbar spine Z-scores ≤ −1.5; and the proportion of women was greater with the higher dose of elagolix (3.3% and 4.9%) compared with the lower dose (1.1% and 0.6%) and with placebo (0.4% and 0%).

In a 24-week study, elagolix (150 mg/day) demonstrated a similar reduction in endometriosis-associated pain and a similar minimal impact on BMD compared to SC depot medroxyprogesterone acetate.

PLACE IN THERAPY

It is estimated up to 10% of females aged 15 to 49 years are affected by endometriosis. Initial treatments include NSAIDs and continuous hormonal birth control. Progestins, androgens, aromatase inhibitors, and injectable GnRH agonists are alternatives. Existing therapies may interfere with contraception and/or may be associated with unwanted hypoestrogenic adverse effects, such as reduced BMD. While GnRH agonists reduce pain in over 80% of cases, they may cause flare of endometriosis pain in the days following the dose, which is typically mitigated with concurrent hormonal therapy. Surgery to remove scar tissue may relieve pain and improve fertility; however, symptoms often recur within 1 year.

Elagolix will be the first FDA-approved oral treatment option for premenopausal women with endometriosis. Unlike other therapies, elagolix does not completely suppress ovulation or cause hormonal flare of endometriosis-related pain. Data also suggests that it has an antiproliferative effect and may reduce endometrial thickness. Phase 3 trials of elagolix for the management of uterine fibroids are ongoing. The oral GnRH antagonist relugolix is also in phase 3 trials for endometriosis.

FDA APPROVAL TIMELINE

May 6, 2018

✓ Priority review

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$ 38	$ 140	$ 297	$ 418	$ 509

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

fremanezumab *sc*

Teva

PROPOSED INDICATIONS

Migraine prevention

CLINICAL OVERVIEW

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

The phase 3 HALO clinical trial program evaluated fremanezumab for the preventive treatment of episodic migraine (EM) and chronic migraine (CM; headache ≥ 15 days/month and migraine on ≥ 8 days/month). Patients received 12 weeks of treatment and were evaluated 4 weeks after the last dose.

In the EM study, 875 patients received quarterly (675 mg) or monthly (225 mg) doses of SC fremanezumab or placebo. Baseline average monthly migraine days (MMD) in each group were 8.9, 9.2, and 9.1 days, respectively. Patients given fremanezumab saw a significant reduction in average MMD compared to placebo (-3.4, -3.7, and -2.2 days, respectively). Fremanezumab led to more patients achieving ≥ 50% reduction in average MMD compared to placebo (44.4%, 47.7%, and 27.9%, respectively).

In the CM study, 1,130 patients received either 1 dose of fremanezumab 675 mg (quarterly regimen), fremanezumab 675 mg followed by monthly 225 mg (monthly regimen), or placebo. Average baseline MMD was 13.2, 12.8, and 13.3, respectively. A significant change in average MMD in each fremanezumab group was reported compared to placebo (-4.3, -4.6, and -2.5 days, respectively). Fremanezumab also resulted in ≥ 50% reduction in average MMD in significantly more patients than placebo (38%, 41%, and 18%, respectively). Common adverse effects with fremanezumab included injection site reactions.

PLACE IN THERAPY

Over 37 million Americans suffer from migraine attacks, the majority of whom are women. Migraines can be painful, debilitating, contribute to absenteeism, and reduce quality of life. Studies suggest that 38% to 50% of migraineurs are candidates for preventive therapy. Select anticonvulsants, antihypertensives, short-term triptans (for menstrual migraines), antidepressants, and onabotulinumtoxinA (Botox®) injection (for CM only) may be effective for migraine prevention. However, side effects and failure to completely eliminate migraine attacks have resulted in low adherence (estimated 20% at 1 year).

Following SC erenumab (May 2018), SC fremanezumab is expected to be the second CGRP inhibiting agent approved in the US. The SC-administered agents have the potential to be self-injected and may offer a new approach to prevent migraine. Two additional CGRP inhibitors, SC galcanezumab and IV eptinezumab may bring additional competition to this category within the next few years. CGRP inhibitors will likely be used as second-line therapy following trial and failure of oral agents, most of which are available in relatively inexpensive generic formulations. Furthermore, new modalities for migraine relief are under investigation include the the first self-administered non-invasive vagus nerve stimulator device, Gammacore®, which was FDA approved in December 2017 for cluster headaches. Fremanezumab and galcanezumab are in Fast track development in the cluster headache arena.

FDA APPROVAL TIMELINE

June 15, 2018

✓ Priority review

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$ 12	$ 112	$ 240	$ 439	$ 640

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

Oncology

lenvatinib (Lenvima®) *oral*

Eisai

PROPOSED INDICATIONS

Hepatocellular carcinoma (HCC), first-line treatment

CLINICAL OVERVIEW

Lenvatinib is a tyrosine kinase inhibitor (TKI). It prevents kinase activities of vascular endothelial growth factor (VEGF) receptors and other tyrosine kinase receptors involved in tumor growth and progression.

Lenvatinib is currently indicated to treat differentiated thyroid cancer and select patients with renal cell cancer (RCC).

REFLECT, the pivotal, phase 3, open-label, trial, demonstrated non-inferiority of lenvatinib compared to sorafenib (Nexavar®) as systemic treatment in 954 treatment-naive patients with unresectable HCC. The median OS, PFS, and time to progression with lenvatinib were 13.6, 7.4, and 8.9 months, respectively, compared to 12.3, 3.7, and 3.7 months, respectively, for sorafenib. In addition, lenvatinib demonstrated a significantly higher ORR of 24% compared to 9% for sorafenib (odds ratio: 3.13). While hypertension, proteinuria, dysphonia, and hypothyroidism occurred more frequently with lenvatinib, palmar-plantar erythrodysesthesia, diarrhea, and alopecia were reported more often with sorafenib. Serious adverse events occurred at a rate of 43% with lenvatinib and 30% with sorafenib. The rate of study discontinuation due to adverse effects was 9% and 7% with lenvatinib and sorafenib, respectively.

Lenvatinib was dosed as 8 mg or 12 mg orally once daily, depending on body weight, until disease progression or unacceptable toxicity.

PLACE IN THERAPY

Each year in the US, approximately 31,000 new cases of liver cancer are diagnosed, and 24,000 deaths occur due to the condition. Common causes are hepatitis B and C virus infections. The majority of patients are diagnosed with advanced disease. This, coupled with the presence of liver impairment, makes management of HCC a challange. Most patients with advanced disease are not eligible for curative surgical resection, tumor ablation, or liver transplant, and are left with a poor prognosis, with an overall 5-year survival of 17.6%.

Currently, the oral kinase inhibitor sorafenib (Nexavar) has a strong presence in the US market as first-line treatment for advanced or metastatic HCC. If approved, lenvatinib will be the only alternative to sorafenib as a first-line agent for advanced/metastatic HCC. Lenvatinib has shown non-inferiority to sorafenib in terms of OS in this setting and has a more desirable side effect profile compared to sorafenib. The oral kinase inhibitor regorafenib (Stivarga®) and the IV programmed death receptor-1 (PD-1) inhibitor nivolumab (Opdivo®) are currently approved for use after failure of sorafenib for HCC; nivolumab is seeking a first-line indication for HCC.

FDA APPROVAL TIMELINE

May 24, 2018

✓ Orphan drug

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$ 105	$ 213	$ 255	$ 306	$ 359

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

Rheumatology

tildrakizumab *sc*

Sun

PROPOSED INDICATIONS

Plaque psoriasis (PSO)

CLINICAL OVERVIEW

Tildrakizumab is a humanized monoclonal antibody that targets interleukin (IL)-23.

The reSURFACE 2 trial evaluated the safety and efficacy of tildrakizumab in 1,090 patients with moderate-to-severe PSO compared to placebo and etanercept. At week 12, a 75% improvement in PSO (measured by the Psoriasis Area Sensitivity Index 75 [PASI 75]) was achieved by 61% and 66% of patients treated with tildrakizumab 100 mg and 200 mg, respectively, 6% with placebo, and 48% with etanercept. In addition, at week 12, Physician's Global Assessment (PGA) of "clear" or "minimal" was reported in 55% and 59% of patients treated with tildrakizumab 100 mg and 200 mg, respectively, 4% with placebo, and 48% with etanercept. Similar findings were seen with tildrakizumab and placebo in the placebo-controlled reSURFACE 1 trial; this study did not include comparison to etanercept. Serious adverse effects were infrequent and similar between the groups. One death was reported with tildrakizumab 100 mg in a patient with alcoholic cardiomyopathy and steatohepatitis; the cause of death was not determined.

Tildrakizumab was studied at doses of 100 mg and 200 mg SC at weeks 0 and 4, then every 12 weeks thereafter.

PLACE IN THERAPY

It is estimated that 7.5 million Americans are living with PSO, with 20% of cases being moderate to severe. Currently, the American Academy of Dermatology (AAD) guidelines (2009) consider the tumor necrosis factor alpha (TNFα) inhibitors, adalimumab (Humira®), etanercept (Enbrel®), and infliximab (Remicade® and biosimilars), and the IL-12/23 inhibitor, ustekinumab (Stelara®), as acceptable options for PSO after failure of topical therapy alone when phototherapy is not available; however, many of the newer agents were not available at the time that this guidance was developed.

Tildrakizumab will join several other biologic agents in the PSO sphere. It will likely compete directly against guselkumab (IL-23; Tremfya®), as well as other IL inhibitors, such as ustekinumab, secukinumab (IL-17A; Cosentyx®), ixekizumab (IL-17A; Taltz®), and brodalumab (IL-17; Siliq®), after failure of TNFα inhibitors. Other factors that may impact market uptake of tildrakizumab include emergence of TNFα inhibitor biosimilars (infliximab-dyyb [Inflectra®] and infliximab-abad [Renflexis™] are currently available in the US), as well as an additional IL-23 inhibitor in late phase development (risankizumab).

FDA APPROVAL TIMELINE

March to April 2018

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$ 1	$ 10	$ 26	$ 44	$ 65

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

Oncology

tisagenlecleucel-T (Kymriah™) *IV*

Novartis

PROPOSED INDICATIONS

Relapsed or refractory diffuse large B cell lymphoma (r/r DLBCL) in adults ineligible for autologous stem cell transplant (ASCT)

Tisagenlecleucel-T is currently indicated for the treatment of patients ≤ 25 years of age with B cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.

CLINICAL OVERVIEW

Tisagenlecleucel-T is a chimeric antigen receptor T cell (CAR-T) immunotherapy that uses a patient's own T cells that have been modified to attack cancerous B cells that express the CD19 protein.

The open-label, phase 2 JULIET trial included patients with r/rDLBCL after receiving ≥ 2 lines of chemotherapy, who either failed or were not eligible for ASCT. Patients' T cells were collected, re-engineered with CAR, and allowed to expand. Patients were given lymphodepleting chemotherapy 1 to 4 days prior to administration of a single IV infusion of tisagenlecleucel-T. A total of 99 patients received tisagenlecleucel-T. Among 81 infused patients with at least 3 months of follow-up or earlier discontinuation, ORR was 53.1%, with 39.5% of patients attaining a complete response (CR) and 13.6% achieving a partial response. Median duration of response and OS were not reached. Tisagenlecleucel-T was detected in peripheral blood for up to 367 days in patients who responded. Cytokine release syndrome (CRS) and grade 3/4 neurologic adverse events occurred in 58% and 12% of patients who received the tisagenlecleucel-T infusion, respectively. Tocilizumab was required to manage CRS in 15% of patients. Three patients died within 30 days of infusion due to disease progression; no deaths related to tisagenlecleucel-T were reported.

PLACE IN THERAPY

It is estimated that over 72,000 Americans were diagnosed with non-Hodgkin's lymphoma (NHL) in 2017. DLBCL accounts for about one-third of all NHL cases. DLBCL is typically aggressive, but is often responsive to intensive chemotherapy; ASCT is recommended in patients who fail to achieve CR with chemotherapy. For patients who are refractory to or who relapse after chemotherapy or stem cell transplant, there remain few options.

Tisagenlecleucel-T was FDA approved in August 2017 to treat select patients with ALL. If the proposed indication of r/rDLBCL is approved, it will join axicabtagene ciloleucel (Yescarta™) as the second CAR-T therapy approved for ALL. Juno Therapeutics, Cellular Biomedicine Group, and Novartis/Blu Bird also have CAR-T products in clinical studies to treat DLBCL. CAR-T therapy may prove to be a valuable means for salvage therapy for r/rDLBCL, with less mid-to-long-term toxicity compared to ASCT, despite the initial acute toxicity. However, long-term safety and durability are yet to be confirmed.

FDA APPROVAL TIMELINE

April 30, 2018

✓ Breakthrough therapy ✓ Orphan drug ✓ Priority review

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$ 126	$ 222	$ 387	$ 523	$ 594

The forecast is a projection of total US sales per year for ALL. Sales data for DLBLC are not currently available.

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	-	Avastrin® (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 referrered 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 may 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 (CD), and also for hidradenitis suppurativa (HS) and non-infectious uveitis.

FDA APPROVAL TIMELINE
November 16, 2018

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$ 13,923	$ 15,240	$ 16,485	$ 17,629	$ 17,735

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

Blood modifier
filgrastim *IV, SC*

Adello and Apotex 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 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 in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS]).

FDA APPROVAL TIMELINE
Adello
April to May 2018

Apotex (Grastofil)
Pending

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$ 281	$ 234	$ 200	$ 180	$ 162

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 type 1 and type 2 diabetes mellitus.

FDA APPROVAL TIMELINE

Biocon/Mylan (Basalog)
July 2018

Merck (Lusduna Nexvue)
Pending

- Lusduna Nexvue has met all required regulatory standards for follow-on insulins of 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 comes sooner.

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$ 2,170	$ 1,759	$ 1,391	$ 1,113	$ 937

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

Blood modifier
pegfilgrastim (Lapelga) *SC*

Apotex

Lapelga is a biosimilar 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

Pending

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$ 3,854	$ 3,301	$ 2,822	$ 2,463	$ 2,166

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

Oncology
rituximab *IV*

Rixathon and Truxima are biosimilars 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

Celltrion/ Teva (Truxima)
February to March 2018

Novartis/ Sandoz (Rixathon)
April to May 2018

FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$ 3,547	$ 2,888	$ 2,225	$ 1,813	$ 1,541

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

Oncology
trastuzumab *injectable*

ABP980, Herzuma, PF-05280014, 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

Celltrion/ Teva (Herzuma)
March to April 2018

Pfizer (PF-05280014)
April 2018

Amgen (ABP980)
May 28, 2018

Merck/ Samsung Bioepis (SB3)
October 2018

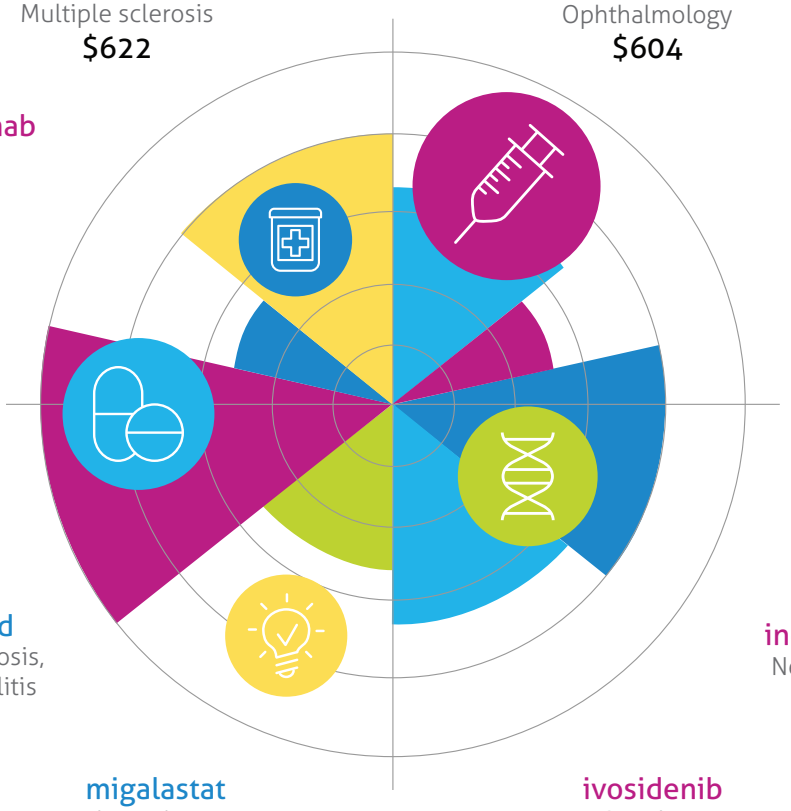
FINANCIAL FORECAST (reported in millions)

2018	2019	2020	2021	2022
$ 2,595	$ 2,376	$ 1,880	$ 1,523	$ 1,314

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.*



aducanumab
Alzheimer's disease
$1,142

siponimod
Multiple sclerosis
$622

brolucizumab
Ophthalmology
$604

rovalpituzumab tesirine
Oncology
$971

epacadostat
Oncology
$301

risperidone depot
Neurology
$131

galcanezumab
Migraine, Cluster headache
$508

patisiran
Neurology
$665

inclisiran
Cardiovascular
$474

ozanimod
Multiple sclerosis, Ulcerative colitis
$896

inotersen
Neurology
$339

migalastat
Fabry's disease
$145

ivosidenib
Oncology
$313

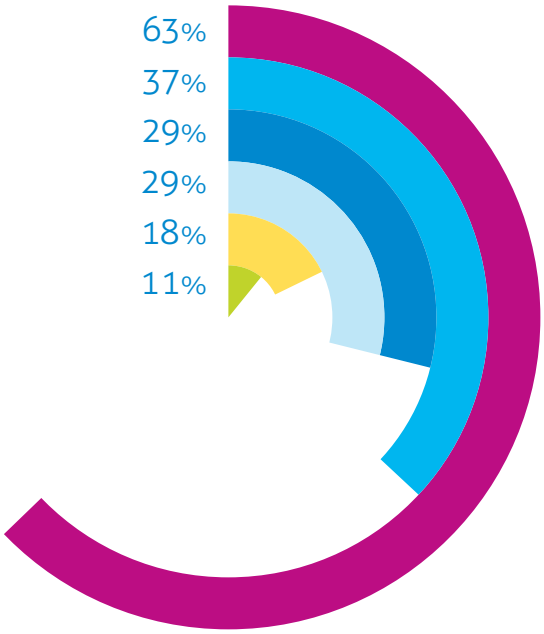
lentiviral vector hematopoietic stem cell
Neurology
$35

★ Specialty drug names appear in magenta throughout the publication.

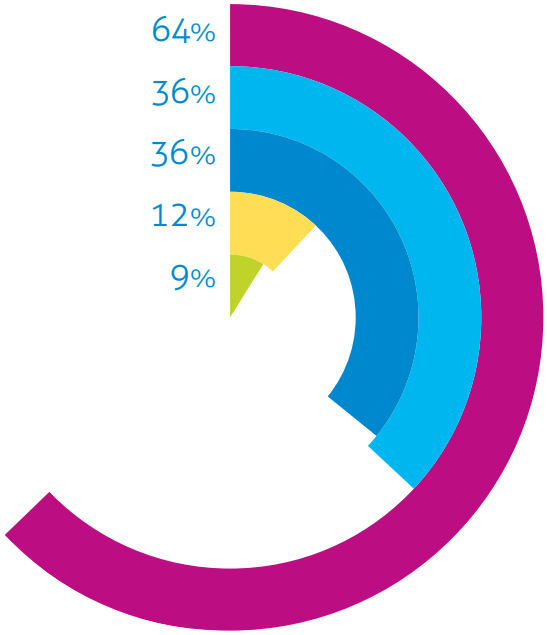
Pipeline Drug List

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.

Magellan Rx MANAGEMENT℠

PIPELINE DRUG LIST

★ Specialty drug names appear in magenta throughout the publication.

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
ceftazidime/ avibactam (Avycaz®)	Allergan	HAP	IV	Submitted - 505(b)(2) sNDA; Fast track; Priority review	Q1, 2018
testosterone undecanoate	Clarus	Hypogonadism	Oral	Submitted - NDA	Q1, 2018
rizatriptan film	Intelgenx	Migraine treatment	SL	Submitted - 505(b)(2) NDA	H1, 2018
buprenorphine depot	Apple Tree	Substance use disorder	SC	Submitted - 505(b)(2) NDA; Fast track; Priority review	01/19/2018
plecanatide (Trulance®)	Synergy	IBS with constipation	Oral	Submitted - sNDA	01/24/2018
ciprofloxacin (liposomal, dual-release)	Grifols	Bronchiectasis (non-CF-related)	Inhaled	Submitted - NDA; Fast track; Orphan drug; Priority review; Qualified infectious disease product	01/26/2018
lutetium Lu 177 dotatate	Advanced Accelerator Applications	Neuroendocrine tumors	IV	Submitted - NDA; Fast track; Orphan drug	01/26/2018
durvalumab (Imfinzi™)	AstraZeneca	NSCLC	IV	Submitted - sBLA; Breakthrough therapy; Fast track; Priority review	Feb-Mar 2018
lurasidone (Latuda®)	Sumitomo Dainippon	Bipolar disorder (ages 10-17 years)	Oral	Submitted - sNDA	Feb-Mar 2018
rituximab (biosimilar to Genentech's Rituxan)	Celltrion/ Teva	RA; CLL/ SLL; NHL (indolent); Antineutrophil cytoplasmic antibodies associated vasculitis	IV	Submitted - BLA	Feb-Mar 2018
ferumoxytol (Feraheme®)	AMAG	Anemia (iron-deficiency)	IV	Submitted - sNDA; Priority review	02/02/2018
bictegravir/ emtricitabine/ tenofovir alafenamide	Gilead	HIV-1 infection	Oral	Submitted - NDA; Orphan drug; Priority review	02/12/2018
polyethylene glycol (low volume)	Valeant	Colon cleansing	Oral	Submitted - NDA	02/13/2018
hydroxyprogesterone caproate (Makena® auto-injector)	AMAG	Preterm birth	SC	Submitted - sNDA; Orphan drug	02/14/2018
tezacaftor/ ivacaftor	Vertex	CF (*F508del* mutation)	Oral	Submitted - NDA; Breakthrough therapy; Orphan drug; Priority review	02/28/2018
tildrakizumab	Sun	PSO	SC	Submitted - BLA	Mar-Apr 2018
trastuzumab (biosimilar to Genentech's Herceptin)	Celltrion/ Teva	Breast cancer; Gastric/ gastroesophageal cancer	IV	Submitted - BLA	Mar-Apr 2018

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
immune globulin 20%, human (Hizentra®)	CSL	Chronic inflammatory demyelinating polyneuropathy	SC	Submitted - sBLA; Orphan drug	Mar-May 2018
ulipristal acetate	Allergan	Uterine fibroids	Oral	Submitted - 505(b)(2) NDA	Mar-May 2018
ciprofloxacin (Otiprio®)	Ostonomy	Acute otitis media externa	Intratympanic	Submitted - sNDA	03/02/2018
abiraterone acetate (ultramicrosize tablet)	Churchill	Prostate cancer	Oral	Submitted - 505(b)(2) NDA	03/19/2018
blinatumomab (Blincyto®)	Amgen	ALL (1st-line or relapsed B cell precursor with minimal residual disease)	IV	Submitted - sBLA; Breakthrough therapy; Orphan drug; Priority review	03/29/2018
baricitinib	Eli Lilly	RA	Oral	Submitted - NDA	Q2, 2018
dabrafenib (Tafinlar®)	Novartis	Melanoma (BRAF V600+)	Oral	Submitted - sNDA; Breakthrough therapy; Priority review	Q2, 2018
trametinib (Mekinist®)	Novartis	Melanoma (BRAF V600+)	Oral	Submitted - sNDA; Breakthrough therapy; Priority review	Q2, 2018
apalutamide	Janssen	Prostate cancer (nmCRPC)	Oral	Submitted - NDA; Priority review	April 2018
trastuzumab (biosimilar to Genentech's Herceptin)	Pfizer	Breast cancer; Gastric/ gastroesophageal cancer	IV	Submitted - BLA	April 2018
filgrastim (biosimilar for Amgen's Neupogen)	Adello	Neutropenia/ leukopenia	IV, SC	Submitted - BLA	Apr-May, 2018
netupitant/ palonosetron (Akynzeo®)	Helsinn	Chemotherapy induced nausea and vomiting (highly emetogenic)	IV	Submitted - sNDA	Apr-May 2018
osimertinib (Tagrisso®)	AstraZeneca	NSCLC (1st-line, EGFR+)	Oral	Submitted - sNDA; Breakthrough therapy; Priority review	Apr-May 2018
rituximab (biosimilar to Genentech's Rituxan)	Novartis/ Sandoz	RA; CLL/ SLL; NHL (indolent); Antineutrophil cytoplasmic antibodies associated vasculitis	IV	Submitted - BLA	Apr-May 2018
ibalizumab	Theratechnologies	HIV-1 infection (multidrug resistant)	IM, IV, SC	Submitted - BLA; Breakthrough therapy; Fast track; Orphan drug; Priority review	04/03/2018
pembrolizumab (Keytruda®)	Merck	Mediastinal B cell lymphoma (relapsed after ≥ 2 prior lines of therapy)	IV	Submitted - sBLA; Breakthrough therapy; Priority review	04/03/2018

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
rucaparib (Rubraca®)	Clovis Oncology	Ovarian cancer (maintenance)	IV, Oral	Submitted - sNDA; Breakthrough therapy; Orphan drug; Priority review	04/06/2018
plasminogen (human)	Prometic Life	Hypoplasminogenemia	IV	Submitted - BLA; Fast track; Orphan drug; Priority reivew; Rare pediatric disease	04/14/2018
burosumab	Ultragenyx	X-linked hypophosphatemia	IV, SC	Submitted - BLA; Breakthrough therapy; Fast track; Orphan drug; Priority review	04/17/2018
fostamatinib disodium	Rigel	Immune thrombocytopenic purpura	Oral	Submitted - NDA; Orphan drug	04/17/2018
promethazine IR/ hydrocodone/ acetaminophen	Charleston	Acute pain (moderate to severe)	Oral	Submitted - NDA	04/17/2018
solifenacin (Vesicare®)	Astellas	Overactive bladder (in combination with mirabegron)	Oral	Submitted - sNDA	04/28/2018
tisagenlecleucel-T (Kymriah®)	Novartis	DLBCL (stem cell transplant ineligible)	IV	Submitted - sBLA; Breakthrough therapy; Orphan drug; Priority review	04/30/2018
ultratrace Iobenguane I-131	Progenics	Neuroendocrine tumors	IV	Submitted - NDA; Breakthrough therapy; Fast track; Orphan drug; Priority review	04/30/2018
brentuximab vedotin (Adcetris®)	Seattle Genetics	Classic Hodgkin's lymphoma (1st-line, advanced)	IV	Submitted - sBLA; Breakthrough therapy; Fast track; Orphan drug; Priority review	05/01/2018
andexanet alfa	Portola	Anticoagulant reversal	IV	Submitted - NDA; Breakthrough therapy; Orphan drug	05/04/2018
elagolix	Abbvie	Endometriosis	Oral	Submitted - NDA; Priority review	05/06/2018
testosterone undecanoate	Lipocine	Hypogonadism	Oral	Submitted - 505(b)(2) NDA	05/08/2018
erenumab	Amgen	Migraine prevention	SC	Submitted - BLA	05/17/2018
avatrombopag	Dova	Thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure	Oral	Submitted - NDA; Priority review	05/21/2018
fluticasone furoate (Arnuity® Ellipta®)	GlaxoSmithKline	Asthma (ages 5-11 years)	Inhaled	Submitted - sNDA	05/24/2018

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
lenvatinib (Lenvima®)	Eisai	HCC (1st-line)	Oral	Submitted - sNDA; Orphan drug	05/24/2018
certolizumab (Cimzia®)	UCB	PSO	SC	Submitted - sBLA	05/25/2018
meloxicam (nanocrystal)	Recro	Postsurgical Pain	IM, IV	Submitted - 505(b)(2) NDA	05/25/2018
pegvaliase	Biomarin	Phenylketonuria	SC	Submitted - BLA; Orphan drug; Priority review	05/25/2018
denosumab (Prolia®)	Amgen	Glucocorticoid-induced osteoporosis	SC	Submitted - sBLA	05/28/2018
trastuzumab (biosimilar to Genentech's Herceptin)	Amgen	Breast cancer; Gastric/ gastroesophageal cancer	IV	Submitted - BLA	05/28/2018
celecoxib/ amlodipine besylate	Kitov	Osteoarthritis pain + HTN	Oral	Submitted - 505(b)(2) NDA	05/31/2018
moxidectin	Medicines Development for Global Health	Onchocerciasis	Oral	Submitted - NDA; Priority review	June 2018
tofacitinib (Xeljanz®/ Xeljanz XR®)	Pfizer	UC	Oral	Submitted - sNDA	June 2018
mogamulizumab	Amgen	Cutaneous T cell lymphoma	IV	Submitted - BLA; Breakthrough therapy; Orphan drug; Priority review	06/04/2018
rivaroxaban 2.5 mg (Xarelto®) twice daily	Janssen	Coronary artery disease; Peripheral arterial disease	Oral	Submitted - sNDA; Fast track	06/11/2018
fremanezumab	Teva	Migraine prevention	SC	Submitted - BLA; Priority review	06/15/2018
halobetasol propionate/ tazarotene	Valeant	PSO	Topical	Submitted - NDA	06/18/2018
furosemide pump	scPharmaceuticals	Congestive heart failure/ cardiomyopathies	SC	Submitted - 505(b)(2) NDA	06/23/2018
bevacizumab (Avastin®)	Genentech	Ovarian cancer (advanced, 1st-line)	IV	Submitted - sBLA	06/25/2018
plazomicin	Achaogen	Complicated UTI (Enterobacteriaceae); Bacteremia (Enterobacteriaceae)	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	06/27/2018
aripiprazole lauroxil ER (nanocrystal dispersion)	Otsuka	Schizophrenia	Oral	Submitted - 505(b)(2) NDA	06/30/2018
binimetinib	Array	Melanoma (BRAF mutation)	Oral	Submitted - NDA	06/30/2018
encorafenib	Array	Melanoma (BRAF mutation)	Oral	Submitted - NDA	06/30/2018
galcanezumab	Eli Lilly	Migraine prevention	SC	Submitted - BLA	Q3, 2018

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
insulin glargine (follow-on to Sanofi's Lantus)	Biocon/ Mylan	T1DM; T2DM	SC	Submitted - 505(b)(2) NDA	July 2018
inotersen	Ionis	Familial amyloid polyneuropathy	SC	Submitted - NDA; Fast track; Orphan drug; Priority review	07/06/2018
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; Priority review	07/27/2018
dupilumab (Dupixent®)	Regeneron	Asthma (severe, uncontrolled); Nasal polyposis	SC	Phase 3 - sBLA	Aug-Oct, 2018
cyclosporine (nanomicellar)	Sun	Dry eye	Intraocular	Submitted - 505(b)(2) NDA	08/01/2018
aflibercept (Eylea®) - 12 week dosing	Regeneron	Wet AMD	Intraocular	Submitted - sBLA	08/11/2018
volanesorsen	Akcea	Dyslipidemia	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
eravacycline	Tetraphase	Intra-abdominal infections (bacterial)	IV, Oral	Submitted - NDA; Fast track; Priority review	08/31/2018
stannsoporfin	Infacare	Hyperbilirubinemia	IM	Submitted - NDA; Fast track; Priority review	09/04/2018
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 (transplant ineligible)	IV	Submitted - sBLA; Breakthrough therapy; Fast track; Orphan drug	09/21/2018
fluticasone furoate/ umeclidinium bromide/ vilanterol (Trelegy® Ellipta®)	GlaxoSmithKline	COPD (expanded maintenance indication)	Inhaled	Submitted - sNDA	09/23/2018
epinephrine 0.15 mg (Symjepi®)	Adamis	Anaphylaxis (pediatrics)	SC	Submitted - sNDA	09/29/2018
ivosidenib	Agios	AML (relapsed/refractory, IDH1 mutation)	Oral	Submitted - NDA; Fast track; Orphan drug	Q4, 2018

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
patisiran	Alnylam	Familial amyloid polyneuropathy	IV	Submitted - NDA; Breakthrough therapy; Fast track; Orphan drug	Q4, 2018
tecovirimat	SIGA	Smallpox	IV, Oral	Submitted - NDA; Fast track; Orphan drug	Q4, 2018
sarecycline	Allergan	Acne	Oral	Submitted - NDA	October 2018
trastuzumab (biosimilar to Genentech's Herceptin)	Merck/ Samsung Bioepis	Breast cancer; Gastric/ gastroesophageal cancer	IV	Submitted - BLA	October 2018
nestorone and ethinyl estradiol contraceptive vaginal ring (1-year)	Allergan	Contraception	Intravaginal	Submitted - NDA	Oct-Nov 2018
amisulpride	Acacia	Post-operative nausea/ vomiting	IV	Submitted - NDA	10/05/2018
levodopa	Acorda	Parkinson's disease	Inhaled	Submitted - 505(b)(2) NDA	10/07/2018
tafenoquine	60 Degrees	Malaria prevention	Oral	Submitted - NDA	10/18/2018
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
oliceridine	Trevena	Acute pain (moderate to severe)	IV	Submitted - NDA; Breakthrough therapy; Fast track	11/02/2018
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
migalastat	Amicus	Fabry's disease	Oral	Submitted - NDA; Fast track; Orphan drug	12/14/2018
solriamfetol	Jazz	Narcolepsy; Sleep apnea	Oral	Submitted - NDA; Orphan drug	12/20/2018
dengue vaccine	Sanofi	Dengue fever	SC	Submitted - BLA; Fast track	Pending
eptacog beta	LFB Group	Hemophilia A and B	IV	Submitted - BLA	Pending
filgrastim (biosimilar for Amgen's Neupogen)	Apotex	Neutropenia/ leukopenia	IV, SC	Submitted - BLA	Pending
fluocinolone acetonide (Iluvien®)	Alimera	Uveitis	Intraocular	Submitted - sNDA; Orphan drug	Pending
HIV vaccine	Immune Response	HIV-1 infection treatment	IM	Submitted - BLA; Orphan drug	Pending
insulin glargine (follow-on to Sanofi's Lantus)	Merck	T1DM; T2DM	SC	Submitted - 505(b)(2) NDA	Pending
ivabradine (Corlanor®)	Amgen	Congestive heart failure/ cardiomyopathies (pediatrics)	Oral	Submitted - sNDA; Fast track	Pending

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
pegfilgrastim (biosimilar for Amgen's Neulasta)	Apotex	Neutropenia/ leukopenia	SC	Submitted - BLA	Pending
acalabrutinib (Calquence®)	AstraZeneca	CLL/ SLL	Oral	Phase 3 - sNDA; Orphan drug	TBD
aclidinium/ formoterol	Fresenius	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)	Merck/ Samsung Bioepis	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	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
adenoviral mediated interferon a2b (recombinant)	FKD Therapies	Bladder cancer	Intravesical	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
alferminogene tadenovec	Gene Biotherapeutics	Angina	Percutaneous catheter injection	Phase 3 - BLA; Fast track	TBD
alicaforsen sodium	Atlantic Healthcare	UC	Rectal	Phase 3 - NDA; Fast track; Orphan drug	TBD
alirocumab (Praluent®)	Regeneron	Hypercholesterolemia (with apheresis)	SC	Phase 3 - sBLA	TBD
allopregnanolone	SAGE	MDD	IV	Phase 3 - NDA; Breakthrough therapy	TBD
alpelisib	Novartis	Breast cancer	Oral	Phase 3 - NDA	TBD
amantadine ER	Osmotica	Levodopa-induced dyskinesia	Oral	Phase 3 - 505(b)(2) NDA; Orphan drug	TBD
amifampridine (Firdapse®)	Catalyst	Lambert-Eaton myasthenic syndrome; Myasthenia gravis	Oral	Phase 3 - sNDA; Breakthrough therapy; Orphan drug	TBD
amikacin (liposomal)	Insmed	CF; Respiratory tract infections (bacterial)	Inhaled	Phase 3 - NDA; Breakthrough therapy; Fast track; Orphan drug	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
amrubicin	Celgene	Small cell lung cancer	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
anlotinib	Advenchen	Sarcoma	Oral	Phase 3 - NDA; Orphan drug	TBD
apatinib mesylate	LSK Biopartners	Gastric cancer	Oral	Phase 3 - NDA; Orphan drug	TBD
apomorphine	Sumitomo Dainippon	Parkinson's disease	SL	Phase 3 - 505(b)(2) NDA; Fast track	TBD
apremilast (Otezla®)	Celgene	Behçet syndrome	Oral	Phase 3 - sNDA; Orphan drug	TBD
astodrimer sodium	Starpharma	Bacterial vaginosis	Intravaginal	Phase 3 - NDA; Fast track; Qualified infectious disease product	TBD
atezolizumab (Tecentriq®)	Roche	Melanoma; Small cell lung cancer; Breast cancer; Ovarian cancer; RCC; Prostate cancer	IV	Phase 3 - sBLA; Orphan drug	TBD
avacopan	Chemocentryx	Antineutrophil cytoplasmic antibodies associated vasculitis	Oral	Phase 3 - NDA; Orphan drug	TBD
avatrombopag	Dova	Immune thrombocytopenic purpura	Oral	Phase 3 - NDA	TBD
avelumab (Bavencio®)	Merck	NSCLC; RCC; Ovarian cancer; Gastric cancer; DLBCL; SCCHN	IV	Phase 3 - sBLA	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
azeliragon	VTV	Alzheimer's disease	Oral	Phase 3 - NDA; Fast track	TBD
baclofen/ naltrexone/ sorbitol	Pharnext	Charcot-Marie-Tooth disease	Oral	Phase 3 - NDA; Orphan drug	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	SC	Phase 3 - sBLA	TBD
bevacizumab (biosimilar to Genentech's Avastin)	Biocon	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
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)	Centrus	CRC; NSCLC; Ovarian/ fallopian tube/ peritoneal cancer; Glioblastoma; RCC	IV	Phase 3 - BLA	TBD
bevacizumab (biosimilar to Genentech's Avastin)	International Biotechnology Center Generium	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
bremelanotide	AMAG	Female sexual arousal disorder	SC	Phase 3 - NDA	TBD
brexpiprazole (Rexulti®)	Otsuka	Alzheimer's 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	Intraocular	Phase 3 - BLA	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, human (Cinryze®)	Shire	Hereditary angioedema	SC	Phase 3 - sBLA	TBD
calaspargase pegol	Shire	ALL	IV	Phase 3 - BLA	TBD
canakinumab (Ilaris®)	Novartis	Atherosclerosis (secondary prevention)	SC	Phase 3 - sBLA	TBD
cannabidiol (synthetic oral solution)	Insys	Dravet syndrome; Lennox-Gastaut syndrome	Oral	Phase 3 - NDA	TBD
caplacizumab	Ablynx	Thrombotic thrombocytopenic purpura	IV	Phase 3 - BLA; Fast track; Orphan drug	TBD
carotuximab	Tracon	Sarcoma	IV	Phase 3 - BLA; Orphan drug	TBD
cediranib	AstraZeneca	Ovarian 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	Cervical cancer; NSCLC	IV	Phase 3 - BLA	TBD
cetirizine	Pfizer	Urticaria	IV	Phase 3 - 505(b)(2) NDA	TBD
citrulline	Asklepion	Acute respiratory distress syndrome (ARDS)	IV	Phase 3 - NDA; Orphan drug	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
cortexolone 17a propionate	Cassiopea	Acne	Topical	Phase 3 - NDA	TBD
CTP-modified human growth hormone	Opko/ Pfizer	Growth hormone deficiency	SC	Phase 3 - BLA; Orphan drug	TBD
cyclobenzaprine	Tonix	Post-traumatic stress disorder	Oral, SL	Phase 3 - 505(b)(2) NDA; Breakthrough therapy	TBD
cytomegalovirus vaccine	Astellas	Cytomegalovirus infection prevention	IM	Phase 3 - BLA; Orphan drug	TBD
dapagliflozin (Farxiga®)	AstraZeneca	T1DM; Diabetic nephropathy; CKD (renal & CV outcomes); Chronic heart failure	Oral	Phase 3 - sNDA	TBD
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; Orphan drug	TBD
derazantinib	Arqule	Biliary tract cancer	Oral	Phase 3 - NDA; Orphan drug	TBD
dexamethasone, sustained-release	Otonomy	Meniere's disease	Intratympanic	Phase 3 - 505(b)(2) NDA; Fast track	TBD
dianhydrogalactitol	Delmar	Glioblastoma (recurrent)	IV	Phase 3 - NDA; Fast track; Orphan drug	TBD
dinutuximab beta	EUSA	Neuroblastoma	SC	Phase 3 - BLA; Breakthrough therapy; Fast track; 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	SCCHN; Small cell lung cancer	IV	Phase 3 - sBLA; Fast track	TBD
duvelisib	Verastem	CLL/ SLL; Follicular lymphoma	Oral	Phase 3 - NDA; Fast track; Orphan drug	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
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 Immunotherapeutics	NSCLC	SC	Phase 3 - NDA; Orphan drug	TBD
epacadostat	Incyte	Melanoma	Oral	Phase 3 - NDA; Fast track	TBD
epoetin alfa (biosimilar to Janssen's Procrit®)	Novartis	Anemia due to CKD (dialysis dependent)	IV, SC	Phase 3 - BLA	TBD
epratuzumab	Immunotherapeutics	ALL	IV	Phase 3 - BLA; Orphan drug	TBD
eptinezumab	Alder	Migraine prevention	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
fenfluramine	Zogenix	Dravet syndrome; Lennox-Gastaut syndrome	Oral	Phase 3 - NDA; Fast track; Orphan drug	TBD
ferric maltol	Shield	Anemia due to CKD (dialysis independent); IBS	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
fingolimod (Gilenya®)	Novartis	MS (relapsing; ≥ 10 years of age)	Oral	Phase 3 - sNDA; Breakthrough therapy; Fast track	TBD
fluticasone furoate/ umeclidinium bromide/ vilanterol (Trelegy® Ellipta®)	GlaxoSmithKline	Asthma	Inhaled	Phase 3 - sNDA	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

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
fremanezumab	Teva	Cluster headache prevention	IV, SC	Phase 3 - BLA; Fast track	TBD
fusidic acid	Cempra	SSSI; Bone/joint infection	Oral	Phase 3 - NDA	TBD
galcanezumab	Eli Lilly	Cluster headache prevention	SC	Phase 3 - BLA; Fast track	TBD
givosiran	Alnylam	Porphyria	SC	Phase 3 - NDA; Breakthrough therapy; Orphan drug	TBD
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	Hepatitis C infection (with CKD)	Oral	Phase 3 - sNDA; Breakthrough therapy	TBD
GS010	Gensight	Leber's hereditary optic neuropathy	Intraocular	Phase 3 - BLA; Orphan drug	TBD
GSK-2696274	GlaxoSmithKline	Metachromatic leukodystrophy	IV	Phase 3 - BLA	TBD
ibritumomab tiuxetan (Zevalin®)	Spectrum	DLBCL	IV	Phase 3 - sBLA	TBD
iclaprim	Motif Bio	SSSI (bacterial)	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	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	IV	Phase 3 - BLA	TBD
infliximab (biosimilar to Janssen's Remicade)	Nichi-Iko	RA	IV	Phase 3 - BLA	TBD
insulin glargine (follow-on to Sanofi's Lantus)	Gan & Lee	T1DM; T2DM	SC	Phase 3 - NDA	TBD
isatuximab	Sanofi	Multiple myeloma	IV	Phase 3 - BLA; Orphan drug	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
ivosidenib	Agios	Biliary tract cancer	Oral	Phase 3 - NDA; Fast track; Orphan drug	TBD
lanadelumab	Shire	Hereditary angioedema	SC	Phase 3 - BLA; Breakthrough therapy; Fast track; Orphan drug	TBD
lasmiditan	Eli Lilly	Migraine treatment	Oral	Phase 3 - NDA	TBD
lefamulin	Nabriva	CAP (bacterial)	IV, Oral	Phase 3 - NDA; Fast track	TBD
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	N/A	Phase 3 - BLA; Orphan drug	TBD
leuprolide mesylate	Foresee	Prostate cancer	SC	Phase 3 - 505(b)(2) NDA	TBD
levodopa/ carbidopa (patch pump)	Mitsubishi Tanabe	Parkinson's disease	SC	Phase 3 - 505(b)(2) NDA	TBD
levoketoconazole	Strongbridge	Cushing's syndrome	Oral	Phase 3 - 505(b)(2) NDA; Orphan drug	TBD
liprotamase	Anthera	Exocrine pancreatic insufficiency	Oral	Phase 3 - NDA; Fast track	TBD
lorlatinib	Pfizer	NSCLC	Oral	Phase 3 - NDA; Breakthrough therapy	TBD
lubiprostone (Amitiza®)	Sucampo	Chronic constipation (pediatrics)	Oral	Phase 3 - sNDA	TBD
lumateperone	Intracellular Therapies	Schizophrenia	Oral	Phase 3 - NDA; Fast track	TBD
lurasidone (Latuda)	Sumitomo Dainippon	Autism spectrum disorders	Oral	Phase 3 - sNDA	TBD
luspatercept	Acceleron	Anemia; Myelodysplastic syndrome	SC	Phase 3 - BLA; Fast track; Orphan drug	TBD
lusutrombopag	Shionogi	Thrombocytopenia	Oral	Phase 3 - NDA; Fast track	TBD
margetuximab	Macrogenics	Breast cancer	IV	Phase 3 - BLA	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; Orphan drug	TBD
mepolizumab (Nucala®)	GlaxoSmithKline	Nasal polyposis	SC	Phase 3 - sBLA	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
meropenem/ vaborbactam (Vabomere®)	The Medicines Company	HAP; Bacteremia	IV	Phase 3 - sNDA	TBD
metoclopramide spray	Evoke	Diabetic gastroparesis	Intranasal	Phase 3 - 505(b)(2) 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 - 505(b)(2) NDA; Fast track; Orphan drug	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
monomethyl fumarate	Biogen	MS	Oral	Phase 3 - 505(b)(2) NDA	TBD
moxetumomab pasudotox	AstraZeneca	Hairy cell leukemia	IV	Phase 3 - BLA	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; Gastric cancer; Mesothelioma; Multiple myeloma; Small cell lung cancer	IV	Phase 3 - sBLA	TBD
NKTR-181	Nektar	Chronic pain	Oral	Phase 3 - NDA; Fast track	TBD
ofranergene obadenovec	VBL	Brain cancer; Ovarian cancer	IV	Phase 3 - BLA; Fast track; Orphan drug	TBD
olaparib (Lynparza®)	AstraZeneca	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
olumacostat glasaretil	Dermira	Acne	Topical	Phase 3 - NDA	TBD
omadacycline	Paratek	CAP (bacterial); SSSI (bacterial)	IV, Oral	Phase 3 - NDA; Fast track; Qualified infectious disease product	TBD
osilodrostat	Novartis	Cushing's syndrome	Oral	Phase 3 - NDA; Orphan drug	TBD
ozanimod	Celgene	MS (relapsing); UC	Oral	Phase 3 - NDA	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
peanut protein	Gan & Lee	Peanut allergy	Oral	Phase 3 - BLA; Breakthrough therapy; Fast track	TBD
pegilodecakin	ARMO	Pancreatic cancer	SC	Phase 3 - NDA; Fast track; Orphan drug	TBD
pegunigalsidase alfa	Protalix	Fabry's disease	IV	Phase 3 - BLA	TBD
pembrolizumab (Keytruda®)	Merck	Breast cancer; Esophageal cancer; RCC; Small cell lung cancer; HCC (including secondary metastesis)	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
plinabulin	Beyondspring	Neutropenia/ leukopenia; NSCLC	IV	Phase 3 - NDA	TBD
plitidepsin	Pharmamar	Multiple myeloma	IV	Phase 3 - NDA; Orphan drug	TBD
prucalopride	Shire	Chronic idiopathic constipation	Oral	Phase 3 - NDA	TBD
quizartinib	Daiichi Sankyo	AML	Oral	Phase 3 - NDA; Orphan drug	TBD
ramucirumab (Cyramza®)	Eli Lilly	Bladder cancer; HCC (including secondary metastesis)	IV	Phase 3 - sBLA; Orphan drug	TBD
ranibizumab (biosimilar to Genentech's Lucentis®)	Santo	Wet AMD	Intraocular	Phase 3 - BLA	TBD
ravulizumab	Alexion	Hemolytic uremic syndrome; Paroxysmal nocturnal hemoglobinuria	IV	Phase 3 - NDA; Orphan drug	TBD
recombinant factor VIII (Obizur®)	Shire	Hemophilia A (factor VIII inhibitors)	IV	Phase 3 - sBLA; Fast track; Orphan drug	TBD
relugolix	Myovant	Endometriosis; 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
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
risankizumab	Abbvie	PSO; CD	SC	Phase 3 - BLA; Orphan drug	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
risperidone	Apple Tree	Schizophrenia	SC implant	Phase 3 - 505(b)(2) NDA	TBD
rituximab (biosimilar to Genentech's Rituxan)	Amgen	RA; NHL	IV	Phase 3 - BLA	TBD
rituximab (biosimilar to Genentech's Rituxan)	Archigen	RA; NHL	IV	Phase 3 - BLA	TBD
rituximab (biosimilar to Genentech's Rituxan)	Pfizer	RA; NHL	IV	Phase 3 - BLA	TBD
rituximab (Rituxan)	Genentech	Pemphigus vulgaris	IV	Phase 3 - sBLA; Breakthrough therapy; Orphan drug	TBD
rivipansel	Pfizer	Sickle cell anemia	IV	Phase 3 - NDA; Fast track; Orphan drug	TBD
ropeginterferon alfa-2b	Pharmaessentia	Polycythemia vera	SC	Phase 3 - BLA; Orphan drug	TBD
rovalpituzumab tesirine	Abbvie	Small cell lung cancer	IV	Phase 3 - BLA; Orphan drug	TBD
roxadustat	AstraZeneca	Anemia due to CKD (dialysis dependent & independent); Anemia (chemotherapy induced)	Oral	Phase 3 - NDA	TBD
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; Fast track	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; Sarcoma	Oral	Phase 3 - NDA; 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
siponimod	Novartis	MS (secondary progressive)	Oral	Phase 3 - NDA	TBD
sodium oxybate (once nightly dosing)	Avadel	Narcolepsy	Oral	Phase 3 - 505(b)(2) NDA; Orphan drug	TBD
sodium oxybate (low sodium)	Jazz	Narcolepsy	Oral	Phase 3 - NDA	TBD
sodium oxybate (Xyrem®)	Jazz	Cataplexy (pediatrics)	Oral	Phase 3 - sNDA	TBD
sodium thiosulfate	Fennec	Hearing loss (chemotherapy-Induced)	IV	Phase 3 - NDA; Orphan drug	TBD
somavaratan	Versartis	Growth hormone deficiency	SC	Phase 3 - BLA; Orphan drug	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
sotagliflozin	Sanofi	T1DM; T2DM	Oral	Phase 3 - NDA	TBD
tadalafil (versafilm)	Intelgenx	Erectile dysfunction	Oral	Phase 3 - 505(b)(2) NDA	TBD
taselisib	Roche	Breast cancer	Oral	Phase 3 - NDA	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
tocilizumab (Actemra®)	Roche	Scleroderma	SC	Phase 3 - sBLA; Breakthrough therapy	TBD
tralokinumab	AstraZeneca	Asthma (severe, uncontrolled); Atopic dermatitis	SC	Phase 3 - BLA	TBD
treprostinil (patch pump)	Steadymed	Pulmonary arterial hypertension	SC	Phase 3 - 505(b)(2) NDA; Orphan drug	TBD
triamcinolone acetonide	Clearside	Uveitis	Intraocular	Phase 3 - 505(b)(2) NDA	TBD
trigriluzole	Portage	Obsessive compulsive disorder; Spinocerebellar ataxia	Oral	Phase 3 - NDA; Fast track; Orphan drug	TBD
turoctocog alfa pegol	Novo Nordisk	Hemophilia A	IV	Phase 3 - BLA	TBD
ublituximab	TG Therapeutics	CLL/ SLL	IV	Phase 3 - BLA; Orphan drug	TBD
ublituximab + umbralisib	TG Therapeutics	CLL/ SLL	IV + Oral	Phase 3 - BLA; Orphan drug	TBD
udenafil	Allergan	Erectile dysfunction; CVD	Oral	Phase 3 - NDA; Orphan drug	TBD
upadacitinib	Abbvie	RA; CD; PsA	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
viaskin peanut	DBV Technologies	Peanut allergy	Transdermal	Phase 3 - BLA; Breakthrough therapy; Fast track	TBD
vilanterol trifenatate	GlaxoSmithKline	Asthma; COPD	Inhaled	Phase 3 - NDA	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
vocimagene amiretrorepvec	Tocagen	Brain cancer	Intratumoral	Phase 3 - BLA; Breakthrough therapy; Fast track	TBD
voclosporin	Aurinia	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
voxelotor	Global Blood Therapeutics	Sickle cell anemia	Oral	Phase 3 - NDA; Breakthrough therapy; Fast track; Orphan drug	TBD
zolmitriptan (microneedle patch)	Zosano	Migraine treatment	Transdermal	Phase 3 - 505(b)(2) NDA	TBD
abixaban (Eliquis®)	Bristol-Myers Squibb	Stroke prevention in atrial fibrillation	Oral	Phase 4 - sNDA	TBD

Complete Response Letter (CRL) / Withdrawn Drugs

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
anacetrapib	Merck	Dyslipidemia	Oral	Withdrawn	N/A
ataluren	PTC	Duchenne muscular dystrophy	Oral	CRL	TBD
levonorgestrel/ ethinyl estradiol (low dose)	Agile	Contraception	Transdermal	CRL	TBD
pregabalin CR	Pfizer	Fibromyalgia	Oral	CRL	TBD
sirolimus	Santen	Uveitis	Intraocular	CRL	TBD
sufentanil	AcelRx	Pain (moderate to severe)	SL	CRL	TBD
testosterone auto-injector	Antares	Hypogonadism	SC	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

CKD Chronic Kidney Disease

CHF Congestive Heart Failure

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

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

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

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