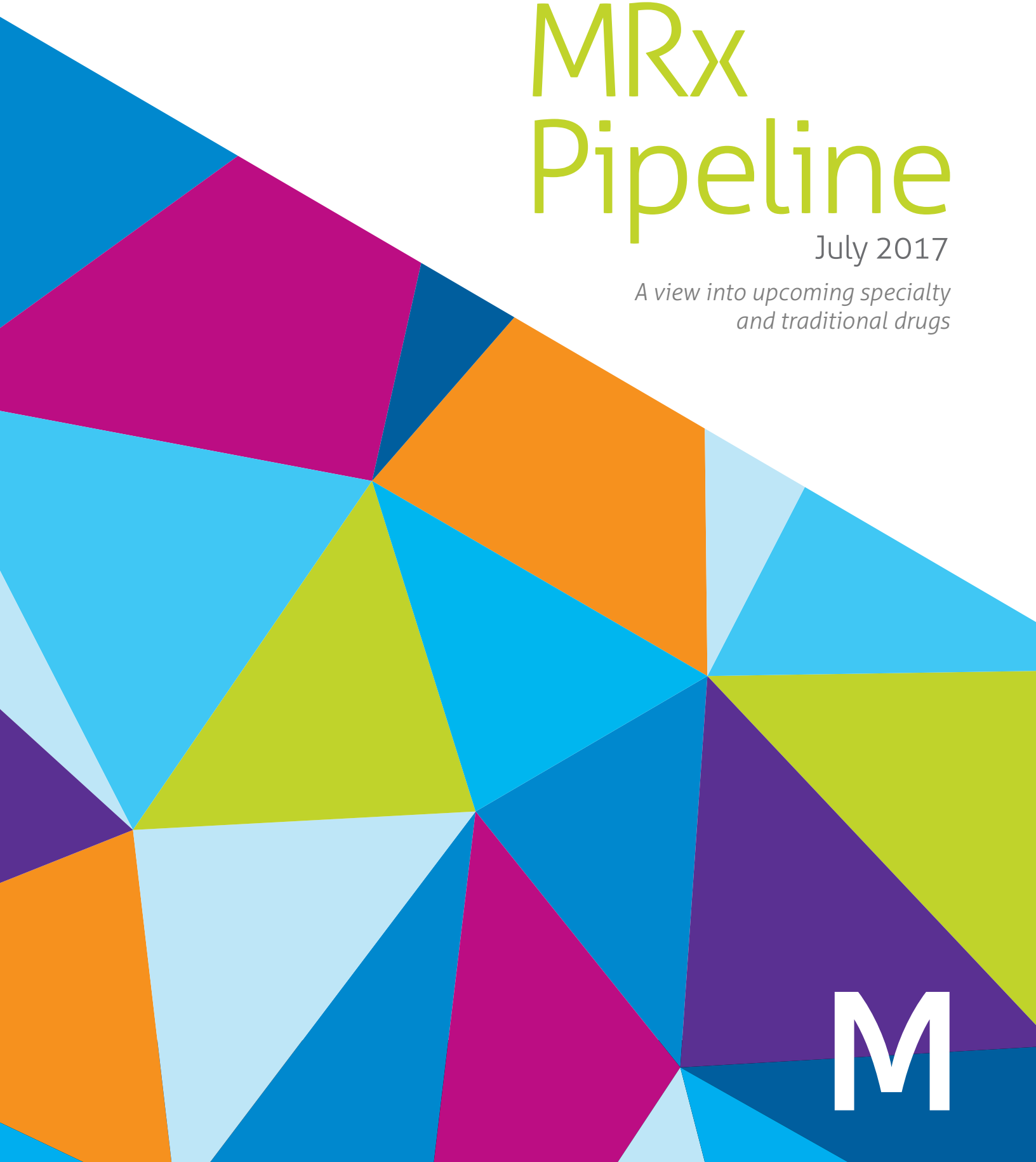
Magellan Rx MANAGEMENT℠

MRx Pipeline

July 2017

A view into upcoming specialty and traditional drugs



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INTRODUCTION

Welcome to the *MRx Pipeline*. 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.

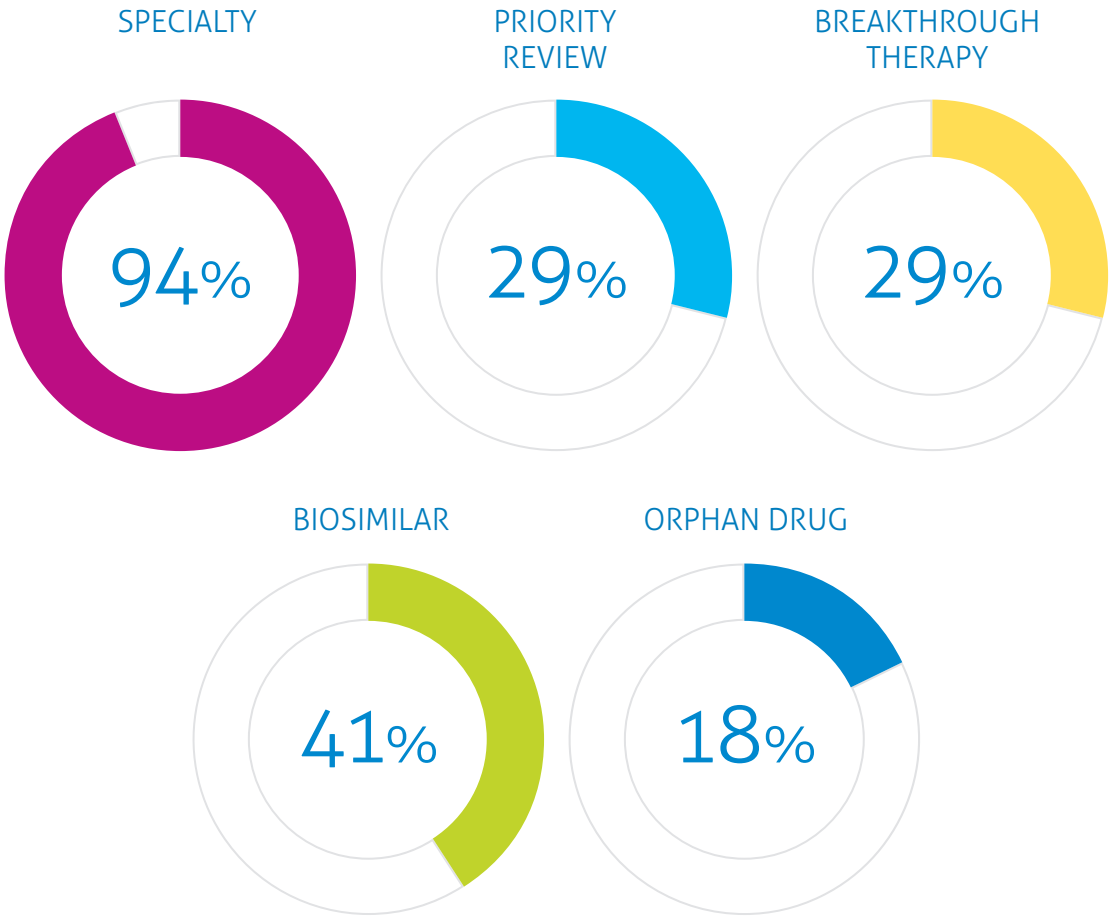
In order to assist payers to assess the potential impact of these pipeline drugs, where available, a financial forecast has been included for select products. Complemented by data from Evaluate™, this pipeline report looks ahead at the 5-year projected total annual US sales through the year 2021. These figures are not specific to a particular commercial or government line of business, rather look at forecasted sales in the US. 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 and immunotherapy fields have blazed the pipeline trail. 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, pangenotypic agents for hepatitis C, hemophilia, diabetes, 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.

Magellan Rx MANAGEMENT℠

Immunology

benralizumab *sc*

AstraZeneca/Kyowa Hakko Kirin

PROPOSED INDICATIONS

Severe, uncontrolled asthma

CLINICAL OVERVIEW

Benralizumab is a humanized monoclonal antibody that binds to interleukin-5 (IL-5) on eosinophils, thereby inhibiting their recruitment into the airway and decreasing airway inflammation.

Safety and efficacy of benralizumab were studied in 3 pivotal, phase 3, randomized, placebo-controlled trials in patients with severe, uncontrolled eosinophilic asthma. The 3 trials evaluated benralizumab at a dosage of 30 mg administered SC every 4 or 8 weeks (initial 3 doses were given every 4 weeks) as add-on to standard of care (high-dose inhaled corticosteroids [ICS] plus a long-acting beta2 agonist [LABA]).

The CALIMA (n=1,306) and SIROCCO (n=1,205) trials were similar in design and included patients as young as 12 years of age. The studies showed that, compared to placebo, benralizumab significantly decreased the annual rate of asthma exacerbations over 48 weeks by up to 45% and 51% when given every 4 and 8 weeks, respectively. Both studies demonstrated an improvement in forced expiratory volume at 1 second (FEV1) with both dosages (up to 159 mL); however, asthma symptoms were improved with only the every 8-week regimen.

The 28-week ZONDA trial (n=220) included patients who were also taking chronic oral corticosteroids (OCS). Benralizumab significantly reduced the median OCS dose by 75% versus 25% with placebo. The study also showed that 52% of patients on benralizumab every 8 weeks versus 19% on placebo were able to discontinue OCS therapy. Additionally, a 70% reduction in overall annual exacerbation rate was observed with benralizumab compared to placebo.

Benralizumab was well tolerated with similar adverse effects versus placebo in all 3 trials.

PLACE IN THERAPY

It is estimated that 24 million people in the US are affected by asthma. Up to 15% of cases are severe and difficult to control; of the severe cases, approximately 50% to 60% are eosinophilic phenotype.

If approved, benralizumab will be the third IL-5 inhibitor to treat severe eosinophilic phenotype asthma in the US. Like mepolizumab (Nucala®) and reslizumab (Cinqair®), benralizumab's use will likely be limited to those with severe asthma that is inadequately controlled with current standard of care. Reslizumab and mepolizumab are administered IV and SC, respectively, every 4 weeks by a healthcare professional. Benralizumab has been studied as a SC injection given every 8 weeks.

FDA APPROVAL TIMELINE

Q4, 2017

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 37	$ 100	$ 183	$ 291	$ 367

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

Oncology

Chimeric antigen receptor T cell (CAR-T) therapy

BACKGROUND

CAR-T therapy is a new approach to cancer therapy using adoptive cell transfer (ACT). It is a novel form of immunotherapy that helps the patient's own immune system fight cancer. With CAR-T, the patient's T cells are collected from their blood, then genetically altered to produce proteins on their cell surface called chimeric antigen receptors (CARs). After allowing to multiply in vitro, the re-engineered T cells are infused back into the patients' blood as a single dose. The CAR on the T cell surface enables it to recognize and attack cancerous B cells. In B cell lymphomas, the most common target for CAR modified T cells is CD19. Other targets under exploration include CD20 and CD22.

The most common serious side effects of CAR-T therapy include cytokine-release syndrome (CRS) and neurotoxicity. CRS typically occurs within the first weeks after the T cell infusion due to a rapid and massive release of cytokines. This can result in fever, hypotension, respiratory distress, coagulopathy, and end organ dysfunction. Patients with more extensive disease are at greater risk to experience severe CRS. CRS is manageable with standard supportive therapy (corticosteroids, which are not preferred because they may diminish CAR-T response) and/or an interleukin-6 inhibitor, such as tocilizumab. The exact cause of neurotoxicity (confusion, aphasia, seizure, hallucinations) is unknown, but may be due to increased cytokines. In addition, B cell aplasia and tumor lysis syndrome (TLS) can occur. B cell aplasia occurs as a result of the death of normal B cells, in addition to cancerous B cells. This decrease in B cells can lead to an increased risk of infection; IV immunoglobulin replacement therapy (short- or long-term) may be used to prevent infection. TLS can occur 1 month or more after the CAR modified T cell infusion due to the breakdown of tumor cells. TLS can also be life-threatening and is typically managed with standard supportive therapy.

axicabtagene ciloleucel *IV*

Kite

PROPOSED INDICATIONS

Refractory aggressive non-Hodgkin lymphoma (NHL) in patients who are ineligible for autologous stem cell transplant

CLINICAL OVERVIEW

In the pivotal, phase 1/2, open-label, ZUMA-1 trial, adult patients who did not respond to chemotherapy or had relapsed within 12 months of an autologous stem cell transplant received a single infusion of axicabtagene ciloleucel after fludarabine/cyclophosphamide lymphodepleting chemotherapy. At 12 months, the overall response rate (ORR) was 82%, with a complete response (CR) in 54% of patients. Response was consistent across disease subtype including diffuse large B cell lymphoma (DLBCL), primary mediastinal large B cell lymphoma (PMBCL), and transformed follicular lymphoma (TFL). The rate of grade 3 or higher CRS was 13% and neurologic events was 28%. Two deaths were reported that were deemed treatment-related and associated with CRS; 1 due to hemophagocytic lymphohistiocytosis and 1 due to cardiac arrest.

FDA APPROVAL TIMELINE

November 29, 2017

✓ Breakthrough therapy ✓ Orphan drug ✓ Priority review

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 2	$ 171	$ 428	$ 633	$ 866

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

tisagenlecleucel-T *IV*

Bluebird Bio/Celyad/Novartis/Oxford Biomedica

PROPOSED INDICATIONS

Relapsed and refractory B cell acute lymphoblastic leukemia (ALL) in pediatric patients and young adults

CLINICAL OVERVIEW

In the pivotal, phase 2, ELIANA study, patients (n=63) aged 3 to 27 years with relapsed or refractory CD19-positive B cell ALL received a single dose of weight-based tisagenlecleucel-T via IV infusion following fludarabine/cyclophosphamide lymphodepleting chemotherapy. Three months post infusion, CR was reported in 82.5% of patients. Six months after infusion, the estimated relapse-free rate among responders was 75.4% (95% CI: 57.2, 86.7). In the safety cohort, CRS was reported in 78% of patients; 47% of patients experienced grade 3 or 4 CRS; 38% of patients with CRS required anti-cytokine therapy and had complete resolution of CRS. No deaths were reported due to CRS. In addition, transient neurotoxicity, including encephalopathy and seizures, was reported in 44% of patients, 15% of which had ≥ grade 3 severity. Severe infectious complications occurred in 26% of patients who received tisagenlecleucel-T. The FDA is requiring follow-up for 15 years to monitor for malignant transformation in patients who received tisagenlecleucel-T.

FDA APPROVAL TIMELINE

October 3, 2017

✓ Breakthrough therapy ✓ Orphan drug ✓ Priority review

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 7	$ 74	$ 116	$ 193	$ 304

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

PLACE IN THERAPY

In 2017, it is estimated that over 72,000 people will be diagnosed with NHL, most occurring after the age of 45 years. Five-year survival rate for NHL is 71%. The estimate of new cases of ALL in the US in 2017 is nearly 6,000, with 56.1% of cases in patients less than 20 years of age. The overall 5-year survival for ALL is 68.2%.

For decades, the standard therapies for cancer treatment have been surgery, chemotherapy, and radiation therapy. More recently, therapies that target specific biomarkers on tumor cells and immunotherapies that stimulate the body's immune response against tumor cells have been FDA-approved.

Over 80% of children diagnosed with B cell ALL, which is the most common type, are cured with intensive chemotherapy. The majority of NHL cases (85%) are B cell type lymphomas; while some aggressive forms are often curable with intensive chemotherapy, others are less responsive. However, for patients who are refractory to or relapse after chemotherapy or stem cell transplant, there remain few options. CAR-T therapy has demonstrated high clinical response rates in short-term studies in treating ALL, with lower response rates reported for lymphomas. CAR-T also has the potential to clear malignancies in the central nervous system. If approved, CAR-T therapies, such as axicabtagene ciloleucel and tisagenlecleucel-T, may become valuable tools in the oncology arsenal for salvage therapy. Long-term studies are needed to confirm durability. In addition, challenges remain on how to best minimize the severity of CRS and neurotoxicity, while maximizing anti-tumor effect. Despite the acute toxicity associated with CAR-T, it may have less mid-to-long-term toxicity compared to stem cell transplant and may be appropriate for patients who are ineligible for transplant.

Use of CAR-T therapy will be limited to facilities that are able to handle cryopreserved cells and experienced in treating high-risk hematologic cancers.

Central Nervous System

deutetrabenazine (Austedo™) *oral*

Teva

PROPOSED INDICATIONS

Tardive dyskinesia (TD)

CLINICAL OVERVIEW

Deutetrabenazine is a vesicular monoamine 2 transporter (VMAT2) inhibitor that reduces dopamine levels in the brain.

Deutetrabenazine is currently approved to treat chorea associated with Huntington's disease.

Deutetrabenazine was evaluated in two 12-week, randomized, double-blind, placebo-controlled, phase 3 trials, ARM-TD (n=117) and AIM-TD (n=288), in adults with moderate to severe TD. In both trials, patients had a history of dopamine receptor antagonist treatment and a baseline Abnormal Involuntary Movement Scale (AIMS) score ≥ 6 (examination of items 1–7). Significant differences in mean change in AIMS score from baseline were reported for deutetrabenazine compared to placebo (AIM-TD: -1.8 for 24 mg/day and -1.9 for 36 mg/day; ARM-TD: -1.4 for mean dose of 38.8 mg/day). In AIM-TD, treatment success, as measured by Clinical Global Impression of Change (CGIC), was 49% (24 mg/day) and 44% (36 mg/day) versus 26% with placebo; in ARM-TD, there was no significant difference in CGIC compared to placebo. The incidence of adverse effects was similar among groups.

In ARM-TD, deutetrabenazine was started as 12 mg/day and titrated weekly, as needed; the mean daily dose was 38.8 mg. In AIM-TD, daily deutetrabenazine doses of 12 mg, 24 mg, and 36 mg were assessed.

PLACE IN THERAPY

An estimated 20% to 50% of patients on typical and atypical antipsychotics are affected by TD, which is characterized by repetitive and uncontrollable movements of the tongue, lips, face, trunk, and extremities. TD is often debilitating and is more prevalent in older patients. TD may be irreversible, even with discontinuation of the precipitating agent.

The first medication to treat TD, valbenazine (Ingrezza™), a VMAT2 inhibitor, was recently approved. Early TD symptoms have been treated by dose reduction or discontinuation of the offending agent. Moderate evidence supports off-label use of clonazepam. If approved, deutetrabenazine will provide another option for the management of patients with mood or psychotic disorders who experience TD by allowing continuation of the neuroleptic agent to control the underlying condition while treating TD symptoms.

FDA APPROVAL TIMELINE

August 30, 2017

✓ Breakthrough therapy ✓ Priority review

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 33	$ 141	$ 255	$ 395	$ 530

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

glecaprevir/pibrentasvir *oral*

Abbvie

PROPOSED INDICATIONS

Chronic hepatitis C virus (HCV) infection, genotypes (GT) 1-6

CLINICAL OVERVIEW

An estimated 2.7 to 3.9 million people in the US are chronically infected with HCV, up to 30% of whom will develop cirrhosis and 1% to 3% will develop liver cancer. In the US, GT1 accounts for over 75% of HCV cases, approximately 12% are GT2, and 10% are GT3. GT4-6 make up less than 2% combined.

Glecaprevir/pibrentasvir (G/P) is an oral, fixed-dose combination of an NS3/4A protease inhibitor and an NS5A inhibitor. The combination may have a high barrier to resistance and is potent against NS3 and NS5A polymorphism. Minimal metabolism and renal excretion occur. No dose adjustment is needed in patients with CKD, including those on dialysis.

Abbvie's suite of phase 3 clinical studies that included over 2,300 patients reported high (≥ 95%) sustained virologic response 12 weeks after treatment end (SVR12) across GT1-6, including in difficult-to-treat patients. High SVR12 rates were achieved in patients with GT 1, 2, 4, 5, or 6 who were treatment-naïve or treatment-experienced (pegylated interferon, ribavirin, sofosbuvir) after 8 weeks of G/P therapy in non-cirrhotic patients and after 12 weeks in cirrhotic patients. In patients with GT3, G/P achieved high SVR12 rates in those who were treatment-naïve and non-cirrhotic with 8 weeks of therapy, treatment-naïve and cirrhotic with 12 weeks, and treatment-experienced and cirrhotic with 16 weeks. This regimen has been evaluated in patients with HIV-1 co-infection, CKD, and liver or renal transplant with similar results. There are no ongoing studies of G/P use in patients with decompensated cirrhosis. Overall, G/P was well tolerated. Common adverse effects included headache and fatigue.

G/P was studied as 3 oral tablets (glecaprevir 300 mg/pibrentasvir 120 mg per tablet) taken once daily.

PLACE IN THERAPY

Currently, sofosbuvir/velpatasvir (Epclusa®; Gilead) is the only pangenotypic product approved to treat chronic HCV infection in the US. It achieves SVR12 ≥ 95%, regardless of genotype, in patients with or without compensated cirrhosis when dosed once daily for 12 weeks; the addition of ribavirin is recommended in patients with decompensated cirrhosis.

The need still remains for ribavirin-free regimens of shorter duration that will achieve high SVR12 rates, particularly in difficult-to-treat patient populations, such as renally-impaired, HIV-coinfected, post-liver transplant, and patients who have failed or relapsed on prior therapy (including DAAs failures). G/P is a once-daily ritonavir- and ribavirin-free pangenotypic product that meets many of these challenges.

Gilead has also requested approval for its investigational pangenotypic DAA, sofosbuvir/velpatasvir/voxilaprevir, in treatment-naïve and treatment-experienced patients.

FDA APPROVAL TIMELINE

August 18, 2017

✓ Breakthrough therapy *(GT1 with failure to prior DAA therapy)*

✓ Priority review

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 21	$ 536	$ 764	$ 824	$ 828

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

Immunology

guselkumab *sc*

Janssen/Morphsys

PROPOSED INDICATIONS

Moderate to severe plaque psoriasis (PSO) in adults

CLINICAL OVERVIEW

Guselkumab is a human monoclonal antibody that targets interleukin-23 (IL-23).

Safety and efficacy were demonstrated in three phase 3 trials in adults with moderate to severe PSO. The VOYAGE 1 (n=837) and VOYAGE 2 (n=992) trials demonstrated superiority of guselkumab over adalimumab (Humira®) at week 16 in the proportion of patients who achieved at least near complete clearance as reported by a 90% improvement in the Psoriasis Area Severity Index (PASI 90) and cleared (0) or minimal disease (1) on the Investigator's Global Assessment (IGA) scale. Guselkumab achieved a PASI 90 rate of 73.3% and 70% in VOYAGE 1 and VOYAGE 2, respectively, compared to 49.7% and 46.8% for adalimumab. The proportion of patients with IGA equal to 0 or 1 who were treated with guselkumab was 85.1% and 84.1%, respectively, compared to 65.9% and 67.7% with adalimumab.

The NAVIGATE trial (n=871) enrolled patients who had an inadequate response with ustekinumab (Stelara®) (IGA ≥ 2). Patients who switched to guselkumab experienced a significantly greater improvement in skin clearance compared to those who continued ustekinumab therapy, as recorded by the number of office visits with at least a 2-point improvement in IGA and an IGA of 0 or 1 (1.5 versus 0.7, respectively).

The guselkumab dosing regimen studied in all 3 trials was 100 mg administered SC, repeated in 4 weeks, then every 8 weeks thereafter.

PLACE IN THERAPY

An estimated 7.5 million Americans are living with psoriasis, with 80% to 90% having PSO. The condition is moderate to severe in approximately 20% of cases. The National Psoriasis Foundation considers the tumor necrosis factor alpha (TNFα) inhibitors, adalimumab (Humira) and etanercept (Enbrel®), and the IL-12/23 inhibitor, ustekinumab (Stelara), as acceptable first-line agents after failure of topical therapy alone when phototherapy is not available.

Guselkumab joins a list of several biologic agents to treat PSO. It will likely compete with ustekinumab, as well as other IL inhibitors, such as secukinumab (IL-17A; Cosentyx®) and ixekizumab (IL-17A; Taltz®), after failure of TNFα inhibitors. Other factors that may impact market uptake of guselkumab include emergence of TNFα inhibitor biosimilars (infliximab-dyyb [Inflectra™] is currently available in the US), approval of investigational IL-23 inhibitors in late phase development (risankizumab and tildrakizumab), and the oral route of administration of the phosphodiesterase 4 inhibitor apremilast (Otezla®).

FDA APPROVAL TIMELINE

November 17, 2017

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 56	$ 248	$ 381	$ 526	$ 676

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

herpes zoster vaccine (Shingrix) *IM*

GlaxoSmithKline

PROPOSED INDICATIONS

Herpes zoster (shingles) prevention in patients 50 years and older

CLINICAL OVERVIEW

Shingrix is a non-live, recombinant, varicella zoster virus (VZV), vaccine that combines a key surface VZV glycoprotein (E) with a T cell boosting adjuvant, AS01B.

Over 90% of adults have been infected with VZV and, if reactivated, results in herpes zoster (HZ) infection (shingles), which is associated with a painful rash and can lead to postherpetic neuralgia (PHN). Risk of HZ increases with advanced age (≥ 50 years) or other causes of decreased T cell immunity.

Shingrix, given as 2 intramuscular doses administered 2 months apart, was studied in over 37,000 people in the phase 3, placebo-controlled trials, ZOE-50 (age ≥ 50 years) and ZOE-70 (age ≥ 70 years). Patients were excluded if they had a prior history of HZ infection or previous vaccination against VZV or HZ. During a median follow-up of over 3 years in each study, Shingrix demonstrated an overall efficacy of 97.2% in ZOE-50 (0.3 versus 9.1 per 1,000 person-years) and 89.8% in ZOE-70 (0.9 versus 9.2 per 1,000 person-years) in reducing the rate of HZ compared to placebo. Pooled data from both studies demonstrated vaccine efficacy against PHN of 88.8%. In both studies, efficacy was similar across all age groups. Injection sites reactions and myalgia were reported.

Moreover, the Zoster-048 study evaluated the use of Shingrix (2 doses) in patients (aged ≥ 65 years) who received the live attenuated zoster vaccine, Zostavax®, at least 5 years prior. A similar immune response as measured by antibody concentrations was produced in patients who received prior Zostavax vaccine compared to those without previous exposure to Zostavax. Shingrix was well tolerated in both groups.

PLACE IN THERAPY

About 1 in every 3 people in the US will develop HZ, leading to approximately 1 million cases each year. In addition, 1 in 5 people with HZ will develop PHN.

Zostavax, which is given as 1 single dose, is the only vaccine available against HZ in the US. However, immunity with Zostavax declines overtime and decreases with age; approximately 70% efficacy was reported in those 50 to 59 years of age and 37.6% in those 70 years and older. Although, Zostavax is FDA approved for use in adults as young as 50 years, based in part on the vaccine's duration of effectiveness, the CDC's Advisory Committee for Immunization Practices (ACIP) recommends it be used in adults at least 60 years of age.

The efficacy of Shingrix is consistent across all patients 50 years and older, including those at least 70 years of age. Shingrix is a recombinant sub-unit vaccine and, therefore, may play a role for use in immunocompromised patients; studies in these populations are ongoing. Comparison studies of Shingrix and Zostavax have not been performed.

FDA APPROVAL TIMELINE

October 24, 2017

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 35	$ 162	$ 261	$ 375	$ 471

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

Oncology

nivolumab (Opdivo®) *IV*

Bristol-Myers Squibb/Ono

PROPOSED INDICATIONS

- Mismatch repair deficient (dMMR) or microsatellite instability high (MSI-H) metastatic colorectal cancer (CRC) after prior fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
- Hepatocellular carcinoma (HCC) after prior sorafenib (Nexavar®) therapy

Current indications for nivolumab include specific patients with unresectable or metastatic melanoma, metastatic NSCLC, advanced renal cell carcinoma, classical Hodgkin lymphoma, recurrent or metastatic SCCHN, and locally advanced or metastatic urothelial carcinoma.

CLINICAL OVERVIEW

Nivolumab is a programmed death-1 (PD-1) blocker that inhibits the ability of the tumor to escape the body's immune system.

Metastatic colorectal cancer

Mismatch repair (MMR) is a process that corrects spontaneous errors that occur during DNA replication. When MMR is deficient (dMMR) in areas of repeated DNA sequences, known as microsatellites, the hypermutability that occurs is called microsatellite instability (MSI).

The phase 2, open-label, CheckMate-142 trial evaluated nivolumab monotherapy, as well as combination therapy with ipilimumab (Yervoy®), in patients with recurrent and metastatic MSI-H CRC. The investigator-assessed objective response rates (ORR) for mono- and combination therapy were 31.1% and 54.8%, respectively. In MMR-deficient patients, the median progression-free survival (PFS) was 5.3 months with monotherapy and was not reached with combination therapy; PFS was 1.4 months in the pooled MMR-proficient patients. The most common adverse reactions were diarrhea, nausea, fever, and fatigue. The rates of grade 3/4 adverse reactions were 14.3% for monotherapy and 26.7% for combination therapy.

Patients receiving combination therapy were treated with IV nivolumab 3 mg/kg and ipilimumab 1 mg/kg every 3 weeks for 4 doses, followed by nivolumab 3 mg/kg every 2 weeks; the monotherapy arm received nivolumab 3 mg/kg IV every 2 weeks. Both regimens were continued until disease progression or unacceptable toxicity.

Hepatocellular carcinoma

The open-label CheckMate-040, phase 1/2 study evaluated nivolumab in patients with advanced HCC who were either not eligible for or progressed after surgical and/or locoregional therapies. Eligible patients included those with hepatitis B or C virus infection (HBV, HCV); antiviral therapy was required in patients with HBV, but was not required in those with HCV. Nivolumab 3 mg/kg was associated with an ORR of 20% in the dose-expansion phase. In addition, top-line results of the phase 3, CheckMate-459 study comparing nivolumab to sorafenib (Nexavar) as first-line therapy are anticipated in the second half of 2017.

nivolumab (Opdivo®) *continued*

PLACE IN THERAPY

In 2017, nearly 135,000 new cases of CRC are estimated to be diagnosed in the US; approximately 12% to 15% of which will be characterized as dMMR/MSI-H. If approved for treatment of MSI-H metastatic CRC, nivolumab will be the second PD-1 inhibitor indicated in patients with dMMR/MSI-H metastatic CRC and will compete with the PD-1 inhibitor pembrolizumab (Keytruda®) in this setting. In 2017, the National Comprehensive Cancer Network (NCCN) added nivolumab and pembrolizumab as treatment options for patients with dMMR or MSI-H tumors in second- or third-line therapy.

In the US, HCC accounts for approximately 85% of all primary liver cancers. The majority of cases are due to chronic infection with HCV and, to a lesser extent, HBV and alcohol. While surgical resection and liver transplantation may be curative for early-stage disease, the majority of cases result in advanced disease with a low 5-year survival. If approved, nivolumab will be the first PD-1-directed therapy to treat HCC. The phase 1/2 trial of nivolumab showed preliminary efficacy against HCC and an acceptable safety profile; however, its place as first-line systemic therapy may depend on results of the phase 3 comparator trial against the standard of care, sorafenib (Nexavar). In addition, regorafenib (Stivarga®) was recently approved to treat HCC that progressed on or after treatment with sorafenib (Child-Pugh A only). Further, pembrolizumab (Keytruda) is currently being investigated for second-line treatment of HCC (Child-Pugh A only); its FDA approval is expected after nivolumab for HCC.

FDA APPROVAL TIMELINE

dMMR/MSI-H mCRC - August 2, 2017

✓ Priority review

HCC - September 24, 2017

✓ Orphan drug ✓ Priority review (Accelerated approval)

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 2,826	$ 2,831	$ 3,178	$ 3,687	$ 4,082

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

semaglutide *SC*

Novo Nordisk

PROPOSED INDICATIONS

Type 2 diabetes (T2DM) in adults

CLINICAL OVERVIEW

Semaglutide is a long-acting glucagon-like peptide-1 (GLP-1) analog.

The SUSTAIN clinical trials program includes 6 phase 3 trials with over 7,000 patients with T2DM. Over 30 weeks, semaglutide 0.5 mg and 1 mg SC once weekly reduced HbA1c by 2.75% and 3.56%, respectively, compared to placebo. Statistically significant reductions in HbA1c were also seen compared to sitagliptin (difference 0.8% and 1.1%, respectively), exenatide extended-release (Bydureon®; difference 0.6% with 1 mg semaglutide), and once-daily insulin glargine U-100 (Lantus®; difference 0.83% and 1.16%, respectively). In addition, semaglutide 0.5 mg and 1 mg resulted in an additional 1.3% and 1.7% reduction in HbA1c, respectively, when added to basal insulin. Semaglutide led to body weight loss of 2.75 kg with the 0.5 mg dose and 3.56 kg with 1 mg, as compared to placebo. Significant reductions in body weight compared to sitagliptin, exenatide ER, and insulin glargine were also reported. Furthermore, the incidence of severe or confirmed hypoglycemia occurred about half as often for semaglutide as compared to insulin glargine. The most common side effects reported were GI in nature; nausea was reported in 20% to 24% of patients treated with semaglutide.

In the SUSTAIN 6 CV outcomes trial (n=3,297), semaglutide demonstrated sustained glucose control for 104 weeks. When added to standard of care, semaglutide significantly reduced the risk of CV death, nonfatal MI, or nonfatal stroke by 26% compared to placebo (6.6% versus 8.9%). This composite reduction was primarily due to a significant 39% decrease in the rate of nonfatal stroke; reduction in nonfatal MI was not significant, and there was no difference in the occurrence of CV death. Semaglutide was also associated with less new or worsening nephropathy (3.8% versus 6.1%). Although, the incidence was low, patients treated with semaglutide had a higher risk of diabetic retinopathy complications (3% versus 1.8% for placebo).

PLACE IN THERAPY

T2DM makes up at least 90% of all cases of diabetes. If approved, semaglutide will be the fourth GLP-1 agonist with once-weekly administration available in US for the treatment of T2DM. Semaglutide will compete with the FDA-approved once-weekly GLP-1 agonists (albiglutide [Tanzeum®], dulaglutide [Trulicity®], exenatide ER [Bydureon®]), and the market leader once-daily liraglutide (Victoza®).

Compared to other GLP-1 agonists, semaglutide may be associated with a greater reduction in body weight (5.6 kg versus 1.9 kg for exenatide ER). However, a higher incidence of GI side effects has also been reported (22% versus 12% compared to exenatide ER). Moreover, semaglutide may lead to new or worsening diabetic retinopathy complications, an effect that has not been reported with other GLP-1 agonists. Semaglutide is the second GLP-1 agonist to demonstrate a reduced risk (26%) of CV events (CV death, MI, stroke); once-daily liraglutide (Victoza) is associated with a 13% reduction (n=9,340), while lixisenatide (Adlyxin®) was shown to have a neutral effect on CV events (n=6,068).

FDA APPROVAL TIMELINE

December 5, 2017

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 0	$ 157	$ 399	$ 616	$ 801

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

Hepatitis C Agents

sofosbuvir/velpatasvir/voxilaprevir *oral*

Gilead

PROPOSED INDICATIONS

Chronic hepatitis C virus (HCV) infection, genotypes (GT) 1-6

CLINICAL OVERVIEW

Sofosbuvir/velpatasvir/voxilaprevir (SOF/VEL/VOX) is an oral fixed-dose, single-tablet combination of an NS5B nucleotide polymerase inhibitor, an NS5A inhibitor, and an NS3/4A protease inhibitor.

Two phase 3 clinical trials, POLARIS-1 and POLARIS-4, evaluated SOF/VEL/VOX in patients with HCV genotypes 1-6 who have failed prior treatment with a direct-acting antiviral (DAA), including NS5A-containing regimens (ledipasvir or daclatasvir). The studies reported an SVR12 ≥ 96% in patients treated with 12 weeks of SOF/VEL/VOX compared to 90% in those treated with SOF/VEL (Epclusa) and 0% in patients treated with placebo for the same duration. In 2 additional phase 3 studies, POLARIS-2 and POLARIS-3, DAA-naïve patients with genotypes 1-6, including patients with cirrhosis, achieved SVR12 ≥ 95% after 8 weeks of SOF/VEL/VOX treatment. SOF/VEL/VOX was well tolerated. The most common adverse events were headache, fatigue, diarrhea, and nausea.

The studied dose was 1 tablet containing sofosbuvir 400 mg, velpatasvir 100 mg, and voxilaprevir 100 mg, taken orally once daily.

PLACE IN THERAPY

Sofosbuvir/velpatasvir (Epclusa; Gilead) is the only approved pangenotypic product on the US market for the treatment of chronic HCV. Products to treat patients who have failed previous therapy with DAAs continue to be an unmet medical need. SOF/VEL/VOX aims to become the first approved salvage therapy. It has been studied as a 12-week duration in this population. Moreover, SOF/VEL/VOX is seeking a shorter 8-week regimen in patients who are treatment-naïve. As a pangenotypic agent, SOF/VEL/VOX will provide another single-tablet, once-daily option in the HCV armamentarium.

Abbvie is also pursuing approval for its investigational fixed-dose combination pangenotypic DAA, glecaprevir/pibrentavir, in treatment-naïve and treatment-experienced patients (including patients who have previously failed a DAA). It is dosed as 3 tablets once daily.

FDA APPROVAL TIMELINE

August 8, 2017

✓ Breakthrough therapy *(GT1 with failure of prior NS5A inhibitor therapy)*

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 74	$ 291	$ 412	$ 413	$ 387

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 guidance, 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 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. But, 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 and a 180-day clock after FDA approval can result in significant delays before an FDA-approved biosimilar can launch. Sandoz' Zarxio® filgrastim-sndz and Pfizer's Inflectra™ infliximab-dyyb are currently the only FDA-approved biosimilars that have entered the market. Eli Lilly's Basaglar® insulin glargine, a follow-on biologic to Sanofi's Lantus®, is also available. Amgen's Amjevita™ adalimumab-atto, Sandoz' Erelzi™ etanercept-szzs, and Samsung Bioepsis' Renflexis™ infliximab-abda are approved but not commercially available yet.

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.

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. 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 know 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.

Immunology

adalimumab (BI 695501) *injectable*

Boehringer Ingelheim

BI 695501 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 (UV).

FDA APPROVAL TIMELINE

September, 2017

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 12,360	$13,686	$ 14,424	$ 14,723	$ 14,548

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

Oncology

bevacizumab (ABP215) *injectable*

Allergan/Amgen

ABP215 is a biosimilar to Genentech's Avastin®, a vascular endothelial growth (VEGF)-specific angiogenesis inhibitor indicated for the treatment of metastatic colorectal cancer, non-squamous non-small cell lung cancer (NSCLC), glioblastoma, metastatic renal cell carcinoma (RCC), and recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

FDA APPROVAL TIMELINE

September 14, 2017

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 2,846	$ 2,720	$ 2,567	$ 2,207	$ 1,878

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

Blood modifier

filgrastim (Grastofil) *injectable*

Apotex/Intas

Grastofil is a biosimilar 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; acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS]).

FDA APPROVAL TIMELINE

Pending

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 370	$ 314	$ 274	$ 248	$ 229

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

Immunology

infliximab (PF-06438179) *injectable*

Pfizer

PF-06438179 is a tumor necrosis factor alpha (TNFα) inhibitor biosimilar to Janssen's Remicade®, indicated to treat rheumatoid arthritis (RA), ankylosing spondylitis (AS), Crohn's disease (CD), plaque psoriasis (PSO), psoriatic arthritis (PsA), and ulcerative colitis (UC).

FDA APPROVAL TIMELINE

December, 2017 to January, 2018

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 4,427	$ 3,721	$ 2,921	$ 2,292	$ 1,795

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

Blood modifier

pegfilgrastim *injectable*

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

Apotex/Intas (Lapelga)
Pending

Biocon/Mylan (MYL-1401H)
October 9, 2017

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 3,824	$ 3,720	$ 3,387	$ 3,165	$ 3,004

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

Oncology

trastuzumab (HERMyl 1401O) *injectable*

Biocon/Mylan

HERMyl 1401O is a biosimilar to Genentech's Herceptin®, a HER2/neu receptor antagonist indicated for the treatment of HER2-positive breast cancer and HER2-positive gastric or gastroesophageal junction adenocarcinoma.

FDA APPROVAL TIMELINE

September 3, 2017

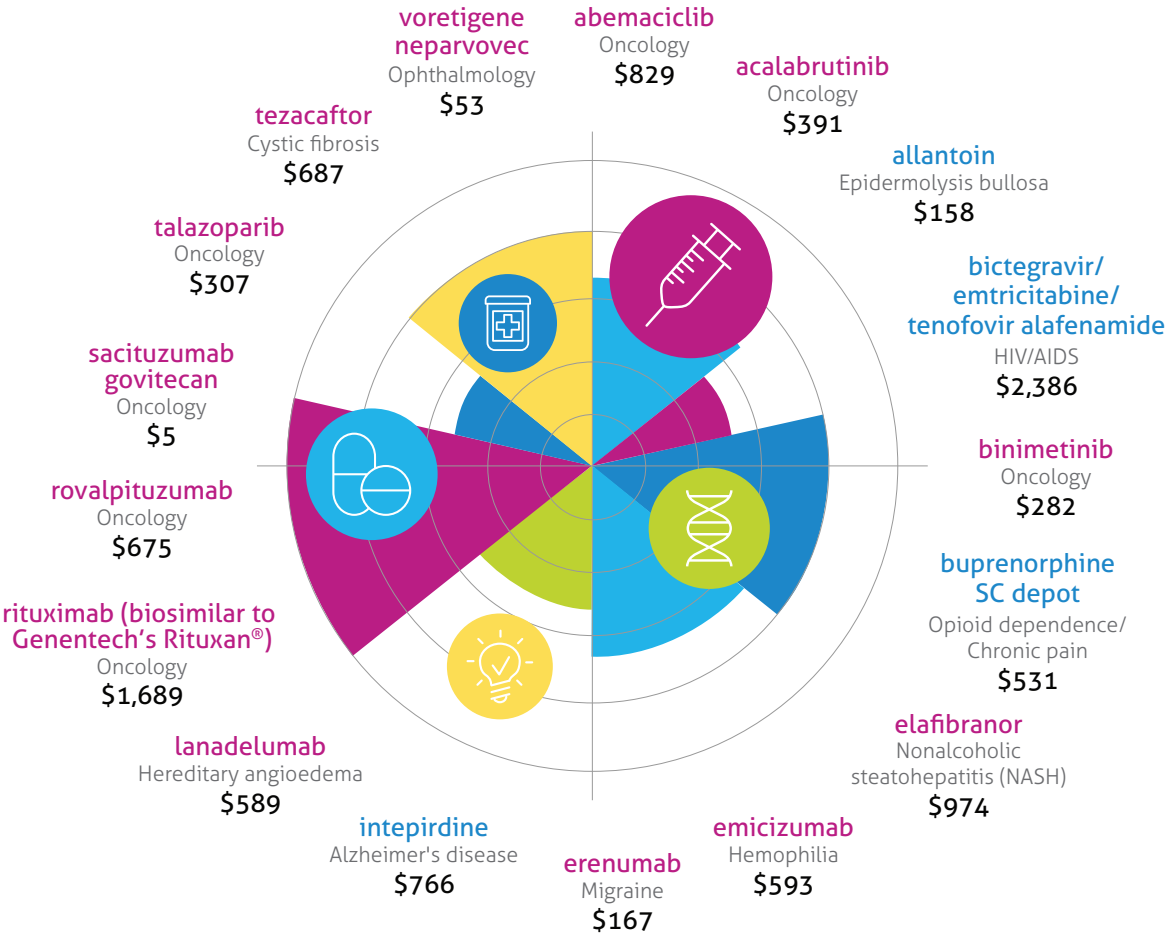
FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 2,591	$ 2,505	$ 2,306	$ 1,832	$ 1,484

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 2021 are displayed. The financials are projected total annual US sales, reported in millions.



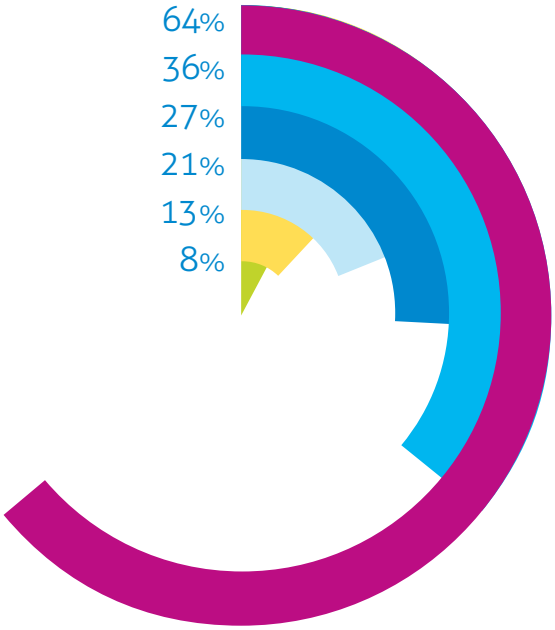
★ Specialty drug names appear in magenta throughout the publication.

Magellan Rx MANAGEMENT℠

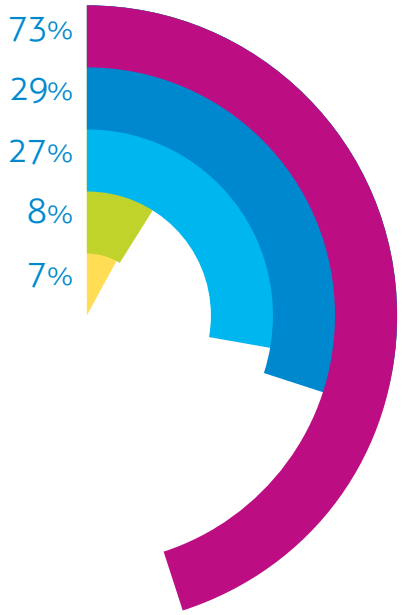
Pipeline Drug List

An aerial outline of drugs with anticipated FDA approval through 2018. 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
osimertinib (Tagrisso®)	AstraZeneca	NSCLC (EGFRm T790M, ≥ 2nd-line)	Oral	Submitted; Breakthrough therapy; Orphan drug; Priority review	July, 2017
olaparib (Lynparza®)	AstraZeneca	Ovarian cancer (germline mutated)	Oral	Submitted; Orphan drug; Priority review	Q3, 2017
allopurinol/ lesinurad	AstraZeneca/ Ironwood	Hyperuricemia	Oral	Submitted	H2, 2017
neratinib	Puma Biotechnology	Breast cancer (early stage, HER2+)	Oral	Submitted	07/21/2017
dantrolene (Ryanodex®)	Eagle	Exertional heat stroke (EHS)	IV	Submitted; Fast track; Orphan drug; Priority review	07/23/2017
perampanel (Fycompa®)	Eisai	Partial onset seizure (monotherapy, ≥ 12 years of age)	Oral	Submitted	07/26/2017
aripiprazole (Abilify Maintena®)	Bristol-Myers Squibb/ Otsuka	Bipolar I disorder (maintenance)	IM	Submitted	07/28/2017
methylphenidate HCl (night-time dosing)	Highland/ Ironshore	ADHD	Oral	Submitted	07/30/2017
inotuzumab ozogamicin	Pfizer	ALL (adults, B cell precursor)	IV	Submitted; Breakthrough therapy; Orphan drug; Priority review	August, 2017
meropenem/ vaborbactam	The Medicines Company	Complicated UTI	IV	Submitted; Fast track; Priority review	Aug-Sep, 2017
beclomethasone dipropionate (QVAR® BAI)	Teva	Asthma	Inhalation	Submitted	Aug-Nov 2017
nivolumab (Opdivo)	Bristol-Myers Squibb/ Ono	Colorectal cancer (dMMR or MSI-H)	IV	Submitted; Priority review	08/02/2017
sofosbuvir/ velpatasvir/ voxilaprevir	Gilead	Chronic HCV (pangenotypic)	Oral	Submitted; Breakthrough therapy	08/08/2017
hepatitis B vaccine	Dynavax	Hepatitis B immunization	IM	Submitted	08/10/2017
glecaprevir/ pibrentasvir	Abbvie	Chronic HCV (pangenotypic)	Oral	Submitted; Breakthrough therapy; Priority review	08/18/2017
amantadine ER	Adamas	Dyskinesia (drug-induced)	Oral	Submitted; Orphan drug	08/24/2017
latanoprostene bunod 0.024%	Bausch & Lomb/ Nicox	Glaucoma; Ocular hypertension	Ophthalmic	Submitted	08/24/2017

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
liraglutide (Victoza)	Novo Nordisk	CV risk reduction with T2DM	SC	Submitted	08/25/2017
rabies immune globulin (human)	Kamada	Post-exposure rabies treatment	IM	Submitted	08/29/2017
deutetrabenazine (Austedo)	Teva	Tardive dyskinesia	Oral	Submitted; Breakthrough therapy; Priority review	08/30/2017
enasidenib	Agios/ Celgene	AML	Oral	Submitted; Fast track; Orphan drug; Priority review	08/30/2017
adalimumab (biosimilar to Abbvie's Humira)	Boehringer Ingelheim	RA; AS; PSO; PsA: JIA; CD; UC	SC	Submitted	September, 2017
fluticasone proprionate	Optinose	Nasal polyps	Intranasal	Submitted	September, 2017
gemtuzumab ozogamicin	PDL/ Pfizer/ UCB	AML	IV	Submitted; Orphan drug	September, 2017
immune globulin (human) 10% (Privigen®)	CSL Behring	Chronic inflammatory demyelinating polyneuritis (CIDP)	IV	Submitted	September, 2017
peramivir (Rapivab®)	Biocryst/ CSL	Influenza vaccine (pediatrics)	IV	Submitted; Priority review	September, 2017
fulvestrant (Faslodex®)	AstraZeneca	Breast cancer (1st-line)	IM	Submitted	Sep-Oct, 2017
trastuzumab (biosimilar to Genentech's Herceptin)	Biocon/ Mylan	Breast cancer (HER2+)	IV	Submitted	09/03/2017
eslicarbazepine acetate (Aptiom®)	Sunovion	Partial-onset seizures (4-17 years of age)	Oral	Submitted	09/13/2017
bevacizumab (biosimilar to Genentech's Avastin)	Allergan/ Amgen	Colorectal cancer; NSCLC; Ovarian/fallopian tube/ peritoneal cancer; Glioblastoma; RCC	IV	Submitted	09/14/2017
amphetamine XR oral suspension	Neos	ADHD	Oral	Submitted	09/15/2017
secnidazole	Symbiomix	Bacterial vaginosis	Oral	Submitted; Fast track; Priority review; Qualified infectious disease product	09/17/2017
exenatide, minipump	AstraZeneca/ Intarcia	T2DM	SC	Submitted	09/21/2017
belimumab (Benlysta® SC)	GlaxoSmithKline	SLE	SC	Submitted	09/23/2017
sirukumab	GlaxoSmithKline/ Janssen	RA	SC	Submitted	09/23/2017
nivolumab (Opdivo)	Bristol-Myers Squibb/ Ono	HCC	IV	Submitted; Orphan drug; Priority review	09/24/2017

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
pregabalin controlled-release (Lyrica® CR)	Pfizer	Fibromyalgia; Postherpetic neuralgia pain	Oral	Submitted	October, 2017
cariprazine HCl (Vraylar®)	Allergan/ Gedeon Richter	Schizophrenia (maintenance, adults)	Oral	Submitted	Oct-Nov, 2017
aripiprazole (Abilify® sensor tablet)	Otsuka/ Proteus	Bipolar 1 disorder (acute); Schizophrenia; Major depressive disorder	Oral	Submitted	Q4, 2017
benralizumab	AstraZeneca/ Kyowa Hakko Kirin	Asthma (severe, uncontrolled)	SC	Submitted	Q4, 2017
cinacalcet (Sensipar®)	Amgen/ Shire	Hyperparathyroidism (pediatrics)	Oral	Submitted; Orphan drug	Q4, 2017
ivabradine (Corlanor®)	Amgen	CVD (pediatrics)	Oral	Submitted; Orphan drug (pediatrics)	Q4, 2017
plasminogen	Prometic	Hypoplasminogenemia	IV	Submitted; Fast track; Orphan drug	Q4, 2017
tisagenlecleucel-T	Bluebird Bio/ Celyad/ Novartis/ Oxford Biomedica	ALL	IV	Submitted; Breakthrough therapy; Orphan drug; Priority review	10/03/2017
pegfilgrastim (biosimilar to Amgen's Neulasta)	Biocon/ Mylan	Chemotherapy-related neutropenia	SC	Submitted	10/09/2017
ustekinumab (Stelara)	Janssen	PSO (ages 12-17 years)	IV, SC	Submitted	10/13/2017
golimumab (Simponi Aria®)	Janssen	PsA; AS	SC	Submitted	10/20/2017
testosterone enanthate (auto-injector)	Antares	Testosterone deficiency	SC	Submitted	10/20/2017
eculizumab (Soliris®)	Alexion	Myasthenia gravis	IV	Submitted; Orphan drug	10/23/2017
ataluren	PTC	Duchenne muscular dystrophy	Oral	Submitted; Fast track; Orphan drug	10/24/2017
herpes zoster vaccine (Shingrix)	GlaxoSmithKline	Herpes zoster (shingles) immunization	IM	Submitted	10/24/2017
rolapitant (Varubi® IV)	OPKO Health/ Tesaro	Chemotherapy-induced nausea and vomiting (CINV)	IV	Submitted	10/25/2017
rivaroxaban 10 mg (Xarelto®)	Janssen	Recurrent venous thromboembolism risk reduction	Oral	Submitted; Priority review	10/28/2017
eptacog beta	LFB	Hemophilia A or B	IV	Submitted	November, 2017
dasatinib (Sprycel®)	Bristol-Myers Squibb	CML (Ph+, pediatrics)	Oral	Submitted; Orphan drug; Priority review	11/09/2017

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
beta-glucuronidase (recombinant human)	Ultragenyx	Mycopolysaccarideosis VII (Sly syndrome)	IV	Submitted; Fast track; Orphan drug; Priority review	11/16/2017
brivaracetam (Briviact®)	Dermira/ Royalty/ UCB	Partial onset seizures (monotherapy, ≥ 16 years of age)	Oral	Submitted	11/17/2017
guselkumab	Janssen/ Morphsys	PSO	SC	Submitted	11/17/2017
fluticasone furoate/ umeclidinium bromide/ vilanterol trifenatate	GlaxoSmithKline/ Innoviva	COPD	Inhalation	Submitted	11/21/2017
axicabtagene ciloleucel	Kite	NHL (aggressive)	IV	Submitted; Breakthrough therapy; Orphan drug; Priority review	11/29/2017
cytarabine/ daunorubicin (liposomal)	Jazz	AML	IV	Submitted; Breakthrough therapy; Fast track (older adults, secondary AML); Orphan drug; Priority review	11/30/2017
dengue tetravalent vaccine	Sanofi	Dengue immunization	SC	Submitted; Fast track	December, 2017
ertugliflozin	Merck/ Pfizer	T2DM	Oral	Submitted	December, 2017
ertugliflozin/ metformin	Merck/ Pfizer	T2DM	Oral	Submitted	December, 2017
ertugliflozin/ sitagliptin	Merck/ Pfizer	T2DM	Oral	Submitted	December, 2017
hydrogen peroxide	Aclaris	Seborrheic keratosis	Topical	Submitted	December, 2017
solifenacin (Vesicare®)	Astellas	Neuorgenic detrusor overactivity (pediatrics)	Oral	Submitted	December, 2017
tofacitinib citrate (Xeljanz®, Xeljanz® XR)	Pfizer/ Takeda	PsA	Oral	Submitted	December, 2017
infliximab (biosimilar to Janssen's Remicade)	Pfizer	AS; CD; PSO; PsA; RA; UC	SC	Submitted	Dec, 2017 - Jan, 2018
semaglutide	Novo Nordisk	T2DM	SC	Submitted	12/05/2017
glycopyrrolate	Sunovion	COPD	Inhalation	Submitted	12/15/2017
sirolimus (intravitreal)	Santen	Uveitis (non-infectious)	Intravitreal	Submitted; Orphan drug	12/22/2017
romosozumab	Amgen/ UCB	Postmenopausal osteoporosis	SC	Submitted	2018
alectinib (Alecensa®)	Roche	NSCLC (ALK+, 1st-line)	Oral	Submitted; Breakthrough therapy; Orphan drug	January, 2018

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
sunitinib (Sutent®)	Pfizer	Renal cell carcinoma (adjuvant)	Oral	Submitted; Fast track	January, 2018
abemaciclib	Eli Lilly	Breast cancer (HR+, HER2-)	Oral	Submitted; Breakthrough therapy; Priority review	Q1, 2018
rituximab (biosimilar to Genentech's Rituxan)	Celltrion/ Teva	NHL; RA; CLL; Polyangiitis	IV	Submitted	Q1, 2018
ibalizumab	Genentech/ Taimed / Theratechnologies	HIV-1 infection (multi-drug resistant)	IV	Submitted; Breakthrough therapy; Fast track; Orphan drug; Priority review	01/03/2018
mometasone furoate sinus implant	Intersect ENT	Recurrent ethmoid sinus obstruction	Intranasal	Submitted	01/07/2018
influenza vaccine (Fluarix® Quadrivalent)	GlaxoSmithKline	Influenza prevention (6-35 months of age)	IM	Submitted	01/15/2018
plecanatide (Trulance™)	Synergy	Irritable bowel syndrome with constipation (IBS-C)	Oral	Submitted	01/24/2018
lurasidone (Latuda®)	Sunovion	Biopolar 1 depression (10-17 years of age); Major depressive disorder; Autism spectrum disorder	Oral	Submitted	Feb-Mar, 2018
dolutegravir/ rilpivirine	Janssen/ Viiv	HIV-1 infection	Oral	Submitted; Priority review	02/01/2018
denosumab (Xgeva®)	Amgen	Prevention of skeletal-related events associated with Multiple myeloma	SC	Submitted; Orphan drug	02/03/2018
hydroxyprogesterone (Makena® auto-injector)	AMAG	Preterm labor	SC	Submitted; Orphan drug	02/14/2018
netarsudil	Aerie	Glaucoma; Ocular hypertension	Ophthalmic	Submitted	02/28/2018
tildrakizumab	Merck/ Sun	PSO	SC	Submitted	Mar-Apr, 2018
abiraterone acetate (ultramicrosize)	Churchill/ Iceutica	Prostate cancer	Oral	Submitted	03/23/2018
insulin degludec (Tresiba®)	Novo Nordisk	CV risk reduction with T2DM	SC	Submitted	03/27/2018
buprenorphine depot	Indivior	Opioid dependence	SC	Submitted; Fast track	03/30/2018
HIV vaccine	Immune Response Biopharma	HIV-1 infection treatment	IM	Submitted; Breakthrough therapy; Orphan drug; Priority review	03/31/2018

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
voretigene neparvovec	Spark	Biallelic *RPE65* mutation-associated retinal disease	Ophthalmic	Submitted; Breakthrough therapy; Orphan drug	Q2, 2018
ixekizumab (Taltz)	Eli Lilly	PsA	SC	Submitted	04/13/2018
fostamatinib disodium	AstraZeneca/ Rigel	Immune thrombocytopenic purpura	Oral	Submitted; Orphan drug	04/17/2018
mepolizumab (Nucala®)	Bristol-Myers Squibb/ GlaxoSmithKline	Eosinophilic granulomatosis with polyangiitis (EGPA)	SC	Submitted	4/28/2018
levodopa inhalation powder	Acorda	Parkinson's disease	Inhalation	Submitted	04/29/2018
mirabegron/ solifenacin	Astellas	Overactive bladder	Oral	Submitted	04/30/2018
erenumab	Amgen/ Novartis	Migraine	SC	Submitted	05/18/2018
bictegravir/ emtricitabine/ tenofovir alafenamide	Gilead	HIV-1 infection	Oral	Submitted; Orphan drug (pediatrics)	06/12/2018
binimetinib	Array Biopharma/ Ono	Colorectal cancer (BRAF-mutant)	Oral	Submitted	07/05/2018
encorafenib	Array Biopharma	Colorectal cancer (BRAF-mutant); Melanoma	Oral	Submitted	07/05/2018
emicizumab	Chugai/ Genentech/ Roche	Hemophilia A	SC	Submitted; Breakthrough therapy; Orphan drug	Pending
filgrastim (biosimilar to Amgen's Neupogen)	Apotex/ Intas	Cancer patients receiving bone marrow transplant or myelosuppressive chemotherapy; Severe chronic neutropenia	IV, SC	Submitted	Pending
pegfilgrastim (biosimilar to Amgen's Neulasta)	Apotex/ Intas	Chemotherapy-related neutropenia	SC	Submitted	Pending
treprostinil (patchpump)	Cardiome/ Steadymed	Pulmonary arterial hypertension	Injection	Submitted	Pending
abatacept (Orencia®)	Bristol-Myers Squibb	Sjogren's syndrome; Lupus nephritis; Dermatomyositis	IV, SC	Phase 3; Orphan drug (Dermatomyositis)	TBD
abemaciclib	Eli Lilly	NSCLC	Oral	Phase 3	TBD
abicipar pegol	Actavis/ Allergan/ Molecular Partners	AMD (Wet)	Intravitreal	Phase 3	TBD
abobotulinum toxin A (Dysort®)	Ipsen	Overactive bladder	IM	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
acalabrutinib	Acerta/ AstraZeneca/ Merck	CLL; Mantle cell lymphoma	Oral	Phase 3; Orphan drug	TBD
adalimumab (biosimilar to Abbvie's Humira)	Biocon/ Mylan	RA; AS; PSO; PsA; JIA; CD; UC	SC	Phase 3	TBD
adalimumab (biosimilar to Abbvie's Humira)	Coherus	RA; AS; PSO; PsA; JIA; CD; UC	SC	Phase 3	TBD
adalimumab (biosimilar to Abbvie's Humira)	EMD Serono	RA; AS; PSO; PsA; JIA; CD; UC	SC	Phase 3	TBD
adalimumab (biosimilar to Abbvie's Humira)	Fujifilm Kyowa Kirin	RA; AS; PSO; PsA; JIA; CD; UC	SC	Phase 3	TBD
adalimumab (biosimilar to Abbvie's Humira)	Inventiv/ Ligand/ Oncobiologics/ Viropro/ Zhejiang Huahai	RA; AS; PSO; PsA; JIA; CD; UC	SC	Phase 3	TBD
adalimumab (biosimilar to Abbvie's Humira)	Momenta	RA; AS; PSO; PsA; JIA; CD; UC	SC	Phase 3	TBD
adalimumab (biosimilar to Abbvie's Humira)	Pfizer	RA; AS; PSO; PsA; JIA; CD; UC	SC	Phase 3	TBD
adalimumab (biosimilar to Abbvie's Humira)	Sandoz	RA; AS; PSO; PsA; JIA; CD; UC	SC	Phase 3	TBD
aducanumab	Biogen/ Neurimmune	Alzheimer's disease	IV	Phase 3; Fast track	TBD
afatinib (Gilotrif®)	Boehringer Ingelheim	SCCHN	Oral	Phase 3	TBD
aglatimagene besadenovec	Advantagene	Prostate cancer; Glioma	Injectable (trans-rectal ultrasound guided)	Phase 3; Orphan drug (Glioma)	TBD
albuvirtide	Frontier	HIV-1 infection	IV	Phase 3	TBD
allantoin	Scioderm (Amicus)	Epidermolysis bullosa	Topical	Phase 3; Breakthrough therapy; Orphan drug	TBD
allopregnanolone	Ligand/ SAGE	Super-refractory status epilepticus (SRSE); Major depressive disorder	IV	Phase 3; Breakthrough therapy (MDD); Fast track; Orphan drug (seizure)	TBD
ALXN1210	Alexion	Hemolytic uremic syndrome; Paroxysmal nocurnal hemoglobinuria	IV	Phase 3; Orphan drug (PNH)	TBD
anacetrapib	Merck	Dyslipidemia	Oral	Phase 3	TBD
anamorelin	Helsinn	Cachexia/anorexia (cancer-related)	Oral	Phase 3; Fast track	TBD
andolast	Mylan	Asthma (atopic)	Inhalation	Phase 3	TBD
anifrolumab	AstraZeneca/ Medimmune	SLE	IV	Phase 3; Fast track	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
apalutamide	Janssen	Prostate cancer	Oral	Phase 3	TBD
apatinib	LSK Biopartners/ Bukwang	Gastric cancer	Oral	Phase 3; Orphan drug	TBD
apremilast (Otezla®)	Celgene	Axial spondyloarthritis; Behcet's syndrome	Oral	Phase 3; Orphan drug (Behcet syndrome)	TBD
asialic acid	Ultragenyx	Hereditary inclusion body myopathy	Oral	Phase 3; Orphan drug	TBD
atacicept	EMD Serono	SLE	SC	Phase 3	TBD
atezolizumab (Tecentriq®)	Genentech/ Roche	Breast cancer; Ovarian cancer; Colorectal cancer; Small cell lung cancer; RCC; Melanoma; Prostate cancer	IV	Phase 3; Orphan drug (SCLC, Melanoma)	TBD
avatrombopag	Akarx/ Eisai/ PBM Capital/ dova	Thrombocytopenia	Oral	Phase 3	TBD
avelumab (Bavencio®)	EMD Serono/ Pfizer	RCC; NSCLC; Gastric cancer; Ovarian cancer; DLBCL; SCCHN	IV	Phase 3; Orphan drug (Gastric cancer)	TBD
axalimogene filolisbac	Advaxis	Cervical cancer	IV	Phase 3; Fast track; Orphan drug	TBD
azeliragon	VTV	Alzheimer's disease	Oral	Phase 3; Fast track	TBD
bardoxolone methyl	Abbvie/ Reata	Pulmonary arterial hypertension; Alport syndrome	Oral	Phase 3	TBD
begelomab	Adienne	Graft versus host disease	IV	Phase 3; Orphan drug	TBD
belimumab (Benlysta IV)	GlaxoSmithKline/ Human Genome Sciences	Antineutrophil cytoplasmic antibodies associated vasculitis; Lupus nephritis	IV	Phase 3	TBD
bempedoic acid	Esperion	Hypercholesterolemia (in patients at high CVD risk with atherosclerotic CVD and/ or heterozygous familial hypercholesterolemia)	Oral	Phase 3	TBD
bevacizumab (Avastin)	Genentech/ Roche	Glioblastoma multiforme	IV	Phase 3	TBD
bevacizumab (biosimilar to Genentech's Avastin)	AstraZeneca/ Centus/ Fujifilm Kyowa Kirin	Colorectal cancer; NSCLC; Ovarian cancer; Cervical cancer; Glioblastoma; RCC	IV	Phase 3	TBD
bevacizumab (biosimilar to Genentech's Avastin)	Boehringer Ingelheim	Colorectal cancer; NSCLC; Ovarian cancer; Cervical cancer; Glioblastoma; RCC	IV	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
bevacizumab (biosimilar to Genentech's Avastin)	Pfizer	Colorectal cancer; NSCLC; Ovarian cancer; Cervical cancer; Glioblastoma; RCC	IV	Phase 3	TBD
bexagliflozin	Theracos	T2DM	Oral	Phase 3	TBD
bortezomib (Velcade®)	Janssen/ Takeda	DLBCL	IV, SC	Phase 3	TBD
bremelanotide	SMSG/ Palatin	Female sexual dysfunction	SC	Phase 3	TBD
brexpiprazole (Rexulti®)	H. Lundbeck/ Otsuka	Alzheimer's disease-related agitation	Oral	Phase 3; Fast track	TBD
brincidofovir	Chimerix	Adenovirus infection; Cytomegalovirus prevention	Oral	Phase 3; Fast track	TBD
brolucizumab	Delenex/ Novartis	AMD (Wet)	Intravitreal	Phase 3	TBD
buprenorphine depot	Braeburn/ Camurus	Opioid dependence; Chronic pain	SC	Phase 3; Fast track	TBD
buprenorphine spray	Insys	Acute pain	Oral	Phase 3	TBD
buprenorphine/ samidorphan	Alkermes	Major depressive disorder	Oral	Phase 3; Fast track	TBD
cabozantinib (Cabometyx®/ Cometriq®)	Exelixis	HCC	Oral	Phase 3; Orphan drug	TBD
cadazolid	Actelion/ Janssen	*Clostridium difficile* associated diarrhea	Oral	Phase 3; Fast track	TBD
canakinumab (Ilaris®)	Bristol-Myers Squibb/ Novartis/ Regeneron	Secondary prevention of CV events	IV, SC	Phase 3	TBD
carotuximab	Tracon	Angiosarcoma	IV	Phase 3; Orphan drug	TBD
C-Cure	Celyad	Chronic heart failure; Cardiomyopathy	Injectable (percutaneous catheter)	Phase 3; Fast track	TBD
cebranopadol	Depomed/ Grunenthal	Cancer pain	Oral	Phase 3	TBD
ceftolozane/ tazobactam	Cubist	Nosocomial pneumonia	IV	Phase 3; Fast track	TBD
celiprolol	Acer	Ehlers-Danlos syndrome	Oral	Phase 3; Orphan drug	TBD
cenicriviroc	Allergan/ Takeda	Nonalcoholic steatohepatitis (NASH)	Oral	Phase 3; Fast track	TBD
certolizumab pegol (Cimzia®)	Dermira/ Royalty/ UCB	JIA; PSO	SC	Phase 3	TBD
clarithromycin/ clofazimine/ rifabutin	Giaconda/ RedHill	CD	Oral	Phase 3; Orphan drug	TBD
crenezumab	AC Immune/ Genentech/ Roche	Alzheimer's disease	IV	Phase 3	TBD
crenolanib	Arog	Gastrointestinal stromal tumor (GIST)	Oral	Phase 3; Fast track	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
cytomegalovirus vaccine	Astellas/ Vical	Prevention of cytomegalovirus in transplant patients	IM	Phase 3; Orphan drug	TBD
daprodustat	GlaxoSmithKline	CKD-related anemia	Oral	Phase 3	TBD
darolutamide	Bayer/ Endo/ Orion	Prostate cancer	Oral	Phase 3	TBD
denosumab (Prolia®)	Amgen	RA; Osteogenesis imperfecta (pediatrics)	SC	Phase 3	TBD
deuterated dextromethorphan HBr/ quinidine sulfate	Concert/ Otsuka	Alzheimer's disease	Oral	Phase 3; Fast track	TBD
dexamethasone phosphate (iontophoresis)	Eyegate/ Valeant	Anterior uveitis	Ophthalmic	Phase 3	TBD
dexamethasone SR 0.4% ocular insert	Ocular Therapeutix/ Ora	Allergic conjunctivitis	Ophthalmic	Phase 3	TBD
dimesna disulfide	Bionumerik/ Lantern	NSCLC	IV	Phase 3	TBD
dinutuximab beta	Apeiron/ Endo/ EUSA	Neuroendocrine tumors	SC	Phase 3; Orphan drug	TBD
diroximel fumarate	Alkermes	MS	Oral	Phase 3	TBD
doravirine	Merck	HIV-1 infection	Oral	Phase 3	TBD
doxorubicin	Bioalliance/ Onxeo	HCC	IV	Phase 3; Fast track; Orphan drug	TBD
doxorubicin (liposomal)	Celsion/ Hisun	HCC	IV	Phase 3; Fast track; Orphan drug	TBD
dupilumab (Dupixent®)	Regeneron/ Sanofi	Nasal polyps; Asthma	SC	Phase 3	TBD
durvalumab (Imfinzi™)	AstraZeneca/ Medimmune	NSCLC; Small cell lung cancer; SCCHN; Urothelial carcinoma (1st-line)	IV	Phase 3; Fast track (SCCHN)	TBD
duvelisib	Infinity	NHL (Indolent); CLL/SLL	Oral	Phase 3; Fast track; Orphan drug (CLL/ SLL)	TBD
eculizumab (Soliris®)	Alexion	Neuromyelitis optica (Devic's syndrome); Delayed graft function	IV	Phase 3; Orphan drug	TBD
eflapegrastim	Hanmi/ Spectrum	Chemotherapy-induced neutropenia	SC	Phase 3	TBD
elafibranor	Genfit	Nonalcoholic steatohepatitis (NASH)	Oral	Phase 3; Fast track	TBD
elagolix	Abbvie/ Neurocrine	Endometriosis; Uterine fibroids	Oral	Phase 3	TBD
elenbecestat	Biogen/ Eisai	Alzheimer's disease	Oral	Phase 3; Fast track	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
entinostat	Syndax	Breast cancer	Oral	Phase 3; Breakthrough therapy	TBD
epacadostat	Incyte	Melanoma	Oral	Phase 3; Orphan drug	TBD
epidiolex	GW	Dravet syndrome; Infantile spasm; Lennox-Gastaut syndrome	Oral	Phase 3; Fast track; Orphan drug	TBD
epoetin alfa (biosimilar to Janssen's Procrit®)	Sandoz	CKD-related anemia	IV, SC	Phase 3	TBD
epratuzumab	Immunomedics	ALL	IV	Phase 3; Orphan drug	TBD
eptinezumab	Alder Bio	Migraine	IM, IV, SC	Phase 3	TBD
eravacycline	Tetraphase	Complicated intra-abdominal infections; Urinary tract/reproductive tract infections	IV, Oral	Phase 3; Fast track	TBD
esketamine	Janssen	Major depressive disorder (treatment resistent)	Intranasal	Phase 3; Breakthrough therapy; Fast track	TBD
etanercept (biosimilar to Amgen's Enbrel)	Coherus/ Daiichi Sankyo	PsA; RA; JIA; AS; PSO	SC	Phase 3	TBD
etanercept (biosimilar to Amgen's Enbrel®)	Lupin	PsA; RA; JIA; AS; PSO	SC	Phase 3	TBD
etirinotecan pegol	Daiichi-Sankyo/ Nektar	Breast cancer	IV	Phase 3; Fast track	TBD
fasinumab	Regeneron/ Sanofi	Chronic pain	IV, SC	Phase 3	TBD
fenfluramine (low-dose)	Zogenix	Dravet syndrome	Oral	Phase 3; Fast track; Orphan drug	TBD
fevipiprant	Novartis	Asthma (severe, uncontrolled)	Oral	Phase 3	TBD
filgotinib	Galapagos/ Gilead	RA; CD; UC	Oral	Phase 3	TBD
fingolimod (Gilenya®)	Mitsubishi Tanabe/ Novartis	MS (pediatric)	Oral	Phase 3	TBD
fluocinolone acetonide	Alimera/ pSivida	Non-infectious uveitis	Intravitreal	Phase 3; Orphan drug	TBD
fosbretabulin tromethamine	Azanta/ Mateon	Ovarian cancer	IV	Phase 3; Fast track	TBD
fostemsavir	Bristol-Myers Squibb/ GlaxoSmithKline/ Viiv	HIV-1 infection	Oral	Phase 3; Breakthrough therapy; Fast track	TBD
fremanezumab	Teva	Migraine	SC	Phase 3	TBD
furosemide (wearable pump)	scPharmaceuticals	Congestive heart failure	SC	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
galcanezumab	Eli Lilly	Migraine; Cluster headache	SC	Phase 3; Fast track	TBD
galeterone	Tokai	Prostate cancer	Oral	Phase 3; Fast track	TBD
gantenerumab	Morphosys/ Roche	Alzheimer's disease	IV, SC	Phase 3	TBD
gilteritinib	Astellas/ Kotobuki	AML	Oral	Phase 3	TBD
glufosfamide	Eleison	Pancreatic cancer	IV	Phase 3; Fast track; Orphan drug	TBD
glycopyrronium/ formoterol fumarate/ budesonide	AstraZeneca/ Pearl	COPD	Inhalation	Phase 3	TBD
grazoprevir/ elbasvir (Zepatier®)	Merck	Chronic HCV gentoype 6	Oral	Phase 3	TBD
guadecitabine	Astex/ Otsuka	Myelodysplastic syndrome; AML	SC	Phase 3; Orphan drug (AML)	TBD
hypericin	Soligenix	Cutaneous T-cell lymphoma	Topical	Phase 3; Fast track; Orphan drug	TBD
ibrutinib (Imbruvica®)	Janssen/ Pharmacyclics	DLBCL; Follicular lymphoma; Pancreatic cancer	Oral	Phase 3; Orphan drug	TBD
ibuprofen/ acetaminophen	AFT	Post-operative pain	IV	Phase 3	TBD
icosapent ethyl (Vascepa®)	Amarin	Hypertriglyceridemia (≥ 200 mg/dL to < 500 mg/dL) with mixed dyslipidemia; Reduction of CV risk	Oral	Phase 3	TBD
imetelstat	Geron/ Janssen	Myelodysplastic syndromes	IV	Phase 3; Orphan drug	TBD
immune globulin (IVIG)	Biotest	Primary immunodeficiency; Immune thrombocytopenic purpura	IV	Phase 3	TBD
indacaterol maleate/ mometasone furoate/ glycopyrronium bromide	Novartis	Asthma	Inhalation	Phase 3	TBD
infliximab (biosimilar to Janssen's Remicade)	Amgen	RA; AS; PSO; PsA; CD; UC	IV	Phase 3	TBD
infliximab (biosimilar to Janssen's Remicade)	Aprogen/ Nichi-Iko	RA; AS; PSO; PsA; CD; UC	SC	Phase 3	TBD
influenza virus vaccine	bioCSL	Influenza prevention (≥ 5 years of age)	IM	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
inotersen	GlaxoSmithKline/ Ionis	Familial amyloidotic polyneuropathy (herediatry transthyretin amyloidosis with polyneuropathy)	SC	Phase 3; Fast track; Orphan drug	TBD
intepirdine	Axovant/ Roivant	Alzheimer's disease	Oral	Phase 3	TBD
isatuximab	Immunogen/ Sanofi	Multiple myeloma	IV	Phase 3; Orphan drug	TBD
istradefylline	Kyowa Hakko Kirin	Parkinson's disease	Oral	Phase 3	TBD
ivosidenib	Agios	AML; Biliary tract cancer	Oral	Phase 3; Fast track; Orphan drug	TBD
ixazomib citrate (Ninlaro®)	Millennium/ Takeda	Amyloidosis	Oral	Phase 3; Breakthrough therapy; Orphan drug	TBD
ixekizumab (Taltz)	Eli Lilly	Axial spondyloarthritis	SC	Phase 3	TBD
lampalizumab	Genentech/ Roche	AMD (Dry)	Intravitreal	Phase 3; Fast track	TBD
lanadelumab	Dyax/ Shire	Hereditary angioedema	SC	Phase 3; Breakthrough therapy; Fast track; Orphan drug	TBD
lasmiditan	Colucid	Migraine	Oral	Phase 3	TBD
lefamulin	Nabriva	Community-acquired pneumonia	IV	Phase 3; Fast track	TBD
lemborexant	Eisai/ Purdue	Insomnia	Oral	Phase 3	TBD
lenalidomide (Revlimid®)	Celgene	NHL (Indolent); Marginal zone lymphoma (MZL); DLBCL; CLL/SLL	Oral	Phase 3; Orphan drug (MZL, Indolent NHL)	TBD
lenvatinib mesylate (Lenvima®)	Eisai	HCC	Oral	Phase 3; Orphan drug	TBD
leuprolide mesylate depot	Foresee	Prostate cancer	SC	Phase 3	TBD
lumateperone	Bristol-Myers Squibb/ Intra-cellular Therapies	Schizophrenia; Biopolar disorder; Alzheimer's disease	IV, Oral	Phase 3	TBD
lurbinectedin	Pharmamar	Ovarian cancer; Small cell lung cancer	IV	Phase 3; Orphan drug (Ovarian cancer)	TBD
luspatercept	Acceleron/ Celgene	Myelodysplastic syndromes; Beta thalassemia	SC	Phase 3; Fast track; Orphan drug	TBD
lusutrombopag	Shionogi	Thrombocytopenia	Oral	Phase 3; Fast track	TBD
margetuximab	Macrogenics/ Green Cross	Breast cancer (HER2+)	IV	Phase 3	TBD
meloxicam (nanocrystal)	Alkermes/ Recro	Post-operative pain	IV	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
melphalan (percutaneous hepatic perfusion)	Delcath	HCC; Biliary tract cancer; Uveal melanoma	Injectable	Phase 3; Fast track; Orphan drug	TBD
methylthioninium	Taurx	Alzheimer's disease; Dementia	Oral	Phase 3	TBD
metoclopramide nasal spray	Evoke/ Mallincrodt	Diabetic gastroparesis (women)	Intranasal	Phase 3	TBD
midazolam	Upsher-Smith	Seizure clusters (rescue)	Intranasal	Phase 3; Fast track; Orphan drug	TBD
mirogabalin	Daiichi Sankyo	Fibromyalgia	Oral	Phase 3	TBD
mirvetuximab soravtansine	Immunogen	Ovarian cancer	IV	Phase 3; Orphan drug	TBD
mongersen	Celgene/ Nogra	CD	Oral	Phase 3; Orphan drug	TBD
nalbuphine ER	Trevi	Uremic pruritus	Oral	Phase 3	TBD
nalmefene	Acorda/ H. Lundbeck A-S/ Otsuka	Alcohol use disorder	Oral	Phase 3	TBD
napabucasin	Boston Biomedical/ Sumitomo Dainippon	Colorectal cancer; Pancreatic cancer; NSCLC	Oral	Phase 3; Orphan drug (Pancreatic cancer)	TBD
natalizumab (Tysabri®)	Biogen/ Elan	Secondary progressive MS	IV	Phase 3	TBD
neridronic acid	Grunenthal	Complex reginal pain syndrome	IM, IV	Phase 3; Breakthrough therapy; Fast track; Orphan drug	TBD
nintedanib (Ofev®)	Boehringer Ingelheim	NSCLC; Colorectal cancer; Scleroderma	Oral	Phase 3; Orphan drug (Scleroderma)	TBD
niraparib (Zejula™)	Janssen/ Tesaro	Breast cancer	Oral	Phase 3	TBD
nivolumab (Opdivo)	Bristol-Myers Squibb/ Ono	Small cell lung cancer; NSCLC; Glioblastoma multiforme; Gastric cancer; Esophageal cancer; Mesothelioma; Multiple myeloma	IV	Phase 3; Orphan drug (Esophageal cancer)	TBD
NKTR-181 (polymer-conjugated opioid)	Nektar	Chronic pain	Oral	Phase 3; Fast track	TBD
ofatumumab (Arzerra SC)	Stiefel Labs/ Novartis	MS	IV, SC	Phase 3	TBD
ofranergene obadenovec	VBL	Glioblastoma multiforme	IV	Phase 3; Fast track; Orphan drug	TBD
olanzapine/ samidorphan	Alkermes	Schizophrenia	Oral	Phase 3	TBD
olaparib (Lynparza®)	AstraZeneca	Breast cancer (1st-line; neoadjuvant); Pancreatic cancer	Oral	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
oliceridine	Trevena	Acute pain	IV	Phase 3; Breakthrough therapy; Fast track	TBD
olokizumab	R-Pharm/ UCB	RA	SC	Phase 3	TBD
omadacycline	Paratek	Acute Bacterial Skin and Skin Structure Infections (ABSSSI); Community-acquired bacterial pneumonia	IV, Oral	Phase 3; Fast track; Qualified infectious disease product	TBD
omecamtiv mecarbil	Amgen/ Cytokinetics/ Servier	Congestive heart failure	Oral	Phase 3	TBD
opicapone	Bial/ Neurocrine Biosciences	Parkinson's disease	Oral	Phase 3	TBD
oxycodone delayed-release	Egalet	Pain (moderate to severe)	Oral	Phase 3; Fast track	TBD
ozanimod	Celgene/ Receptos	Relapsing MS; UC	Oral	Phase 3	TBD
pacritinib	Baxalta/ CTI Biopharma/ Shire	Myelofibrosis	Oral	Phase 3; Fast track; Orphan drug	TBD
patisiran	Alnylam / Arbutus/ Sanofi	Familial amyloidotic polyneuropathy	IV	Phase 3; Fast track; Orphan drug	TBD
peficitinib	Astellas/ Janssen	RA	Oral	Phase 3	TBD
PEGPH20	Halozyme/ Nektar	Pancreatic cancer	IV	Phase 3; Fast track; Orphan drug	TBD
pegunigalsidase alfa	Protalix	Fabry disease	IV	Phase 3	TBD
pelareorep	Oncolytics	SCCHN	IV	Phase 3	TBD
pembrolizumab (Keytruda®)	Merck	Breast cancer; Esophageal cancer; HCC; RCC	IV	Phase 3; Orphan drug (Esophageal cancer; HCC; Phase 3; Orphan drug (Esophageal cancer; HCC)	TBD
pertuzumab	Genentech/ Roche	Breast cancer (HER2+); Gastric cancer	IV	Phase 3	TBD
piclidenoson	Can-Fite	PSO; RA	Oral	Phase 3	TBD
pitolisant	Bioprojet/ Grupo Ferrer	Narcolepsy; Excessive daytime sleepiness related to obstructive sleep apnea	Oral	Phase 3	TBD
pixantrone dimaleate	CTI Biopharma	DLBCL	IV	Phase 3; Fast track; Orphan drug	TBD
plazomicin	Achaogen/ Ionis	Complicated UTI; Septicemia/Bacteremia; Hospital-acquired pneumonia	IV	Phase 3; Breakthrough therapy; Fast track	TBD
plinabulin	Beyondspring	NSCLC	IV	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
plitidepsin	Pharmamar	Multiple myeloma	IV	Phase 3; Orphan drug	TBD
ponesimod	Actelion/ Janssen	Relapsing MS	Oral	Phase 3	TBD
pregabalin controlled-release (Lyrica CR)	Pfizer	Partial onset seizures (4-16 years of age)	Oral	Phase 3	TBD
prucalopride	Janssen/ Shire	Chronic idiopathic constipation	Oral	Phase 3	TBD
quizartinib	Daiichi Sankyo	AML	Oral	Phase 3; Orphan drug	TBD
ramucirumab (Cyramza)	AstraZeneca/ Eli Lilly/ Shire	HCC; Bladder cancer	IV	Phase 3; Orphan drug (HCC)	TBD
ranibizumab	Formycon/ Santo	AMD (Wet)	Intravitreal	Phase 3	TBD
rapastinel	Allergan	Major depressive disorder	IV	Phase 3; Breakthrough therapy; Fast track	TBD
recombinant factor VIIa fusion protein	CSL Behring	Hemophilia A or B	IV	Phase 3	TBD
relebactam/ imipenem cilastatin	Merck	Nosocomial pneumonia; Complicated intra-abdominal infections	IV	Phase 3; Fast track	TBD
remestemcel-L	Mesoblast	CD; Graft versus host disease	IV	Phase 3; Fast track; Orphan drug (GVHD)	TBD
retosiban	GlaxoSmithKline	Preterm labor	IV, Oral	Phase 3	TBD
revefenacin	Mylan/ Theravance	COPD	Inhalation	Phase 3	TBD
rigerimod	Immupharma/ Teva	SLE	SC	Phase 3; Fast track	TBD
rigosertib	Onconova	Myelodysplastic syndrome; Pancreatic cancer	IV	Phase 3; Orphan drug	TBD
rilimogene galvacirepvec/ rilimogene glafolivec	Bavarian Nordic/ Bristol-Myers Squibb	Prostate cancer	SC	Phase 3; Fast track	TBD
riluzole	Portage Biotech/ Biohaven	Social anxiety disorder	Oral	Phase 3	TBD
risankizumab	Abbvie/ Boehringer Ingelheim	PSO	SC	Phase 3	TBD
ritonavir/ elvitegravir	Gilead	HIV-1 infection	Oral	Phase 3	TBD
rituximab (biosimilar to Genentech's Rituxan)	Allergan/ Amgen	NHL; RA; CLL; Polyangiitis	IV	Phase 3	TBD
rituximab (biosimilar to Genentech's Rituxan)	Archigen/ AstraZeneca/ Samsung	NHL; RA; CLL; Polyangiitis	IV	Phase 3	TBD
rituximab (biosimilar to Genentech's Rituxan)	Pfizer	NHL; RA; CLL; Polyangiitis	IV	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
rituximab (biosimilar to Genentech's Rituxan)	Sandoz	NHL; RA; CLL; Polyangiitis	IV	Phase 3	TBD
rituximab (Rituxan)	Biogen/ Genentech/ Roche	Pemphigus vulgaris	IV	Phase 3; Breakthrough therapy; Orphan drug	TBD
rivaroxaban (Xarelto®)	Janssen	Congestive heart failure; Coronary artery disease; Ischemic stroke; Peripheral artery disease	Oral	Phase 3; Fast track (CHF, CAD)	TBD
rivipansel	Glycomimetics/ Pfizer	Sickle cell disease vaso-occlusive crisis	IV	Phase 3; Fast track; Orphan drug	TBD
romosozumab	Amgen/ UCB	Osteoporosis in men	SC	Phase 3	TBD
ropeginterferon alfa-2b	Pharmaessentia	Polycythemia vera	SC	Phase 3; Orphan drug	TBD
rose bengal disodium	Provectus	Melanoma	Intralesional	Phase 3	TBD
rovalpituzumab	Abbvie	Small cell lung cancer	IV	Phase 3; Orphan drug	TBD
roxadustat	Astellas/ Fibrogen	CKD-related anemia	Oral	Phase 3	TBD
RS-baclofen/ naltrexone/ d-sorbitol	Pharnext/ Tasly	Charcot–Marie–Tooth neuropathy X type 1	Oral	Phase 3	TBD
rucaparib (Rubraca®)	Clovis Oncology	Prostate cancer	Oral	Phase 3	TBD
ruxolitinib phosphate (Jakafi®)	Incyte	Graft versus host disease	Oral	Phase 3; Breakthrough therapy; Orphan drug	TBD
sacituzumab govitecan	Immunomedics/ Seattle Genetics	Breast cancer (triple negative)	IV	Phase 3; Breakthrough therapy; Fast track	TBD
selumetinib	Array Biopharma/ AstraZeneca	Thyroid cancer	Oral	Phase 3; Orphan drug	TBD
semaglutide	Emisphere/ Novo Nordisk	T2DM	Oral	Phase 3	TBD
seviprotimut	CK Life Sciences	Melanoma	Intradermal	Phase 3	TBD
siponimod	Novartis	Secondary progressive MS; Relapsing MS	Oral	Phase 3	TBD
sirukumab	Eli Lilly/ GlaxoSmithKline/ Janssen	Giant cell arteritis	SC	Phase 3	TBD
sodium oxybate (Xyrem®)	Jazz	Narcolepsy with cataplexy (pediatrics)	Oral	Phase 3	TBD
somavaratan (long-acting formulation)	Versartis	Growth hormone deficiency (pediatrics)	SC	Phase 3	TBD
sorafenib tosylate (Nexavar)	Bayer	Breast cancer	Oral	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
sotagliflozin	Lexicon/ Sanofi	T1DM; T2DM	Oral	Phase 3	TBD
talazoparib	Biomarin/ Pfizer	Breast cancer (triple negative)	Oral	Phase 3	TBD
tanezumab	Eli Lilly/ Pfizer	Chronic back pain; Cancer pain; Osteoarthritis pain	SC	Phase 3; Fast track	TBD
taselisib	Chugai/ Roche	Breast cancer	Oral	Phase 3	TBD
tecarfarin	Armetheon	Stroke risk reduction	Oral	Phase 3	TBD
tenapanor	Ardelyx	Irritable bowel syndrome; Hyperphosphatemia	Oral	Phase 3	TBD
terlipressin	Ikaria/ Mallinckrodt	Hepatorenal syndrome	IV	Phase 3; Fast track; Orphan drug	TBD
tezacaftor	Vertex	CF patients with CFTR gene mutations (≥ 12 years of age with 2 copies of the F508del mutation)	Oral	Phase 3; Breakthrough therapy; Orphan drug	TBD
TG4010	Transgene/ Virax	NSCLC	SC	Phase 3; Fast track	TBD
tirasemtiv	Cytokinetics	ALS	Oral	Phase 3; Fast track; Orphan drug	TBD
tivozanib	Aveo/ EUSA/ Kyowa Hakko Kirin	RCC	Oral	Phase 3	TBD
tocilizumab (Actemra®)	Genentech/ Roche	Scleroderma	SC	Phase 3	TBD
tofacitinib citrate (Xeljanz, Xeljanz XR)	Pfizer/ Takeda	UC; JIA; PSO	Oral	Phase 3	TBD
tozadenant	Acorda	Parkinson's disease	Oral	Phase 3	TBD
trabectedin (Yondelis®)	Janssen/ Pharmamar	Ovarian Cancer	IV	Phase 3; Orphan drug	TBD
tralokinumab	AstraZeneca/ LEO	Asthma; Atopic dermatitis	SC	Phase 3	TBD
trastuzumab (biosimilar to Genentech's Herceptin)	Pfizer	Gastroesophageal cancer; Gastric cancer; Breast cancer (HER2+)	IV	Phase 3	TBD
trastuzumab (biosimilar to Genentech's Herceptin)	Celltrion/ Teva	Gastroesophageal cancer; Gastric cancer; Breast cancer (HER2+)	IV	Phase 3	TBD
trastuzumab (Herceptin)	Genentech/ Roche	Breast cancer (HER2+)	SC	Phase 3	TBD
trigriluzole	Portage	Spinocerebellar ataxia	Oral	Phase 3; Fast track	TBD
turgenpumatucel-L	Newlink Genetics	NSCLC	Intradermal	Phase 3	TBD
ublituximab	TG	CLL/SLL	IV	Phase 3; Orphan drug	TBD
ubrogepant	Allergan	Migraine	Oral	Phase 3	TBD
upadacitinib	Abbvie	RA; PsA	Oral	Phase 3	TBD
ustekinumab (Stelara)	Janssen	UC; Axial spondyloarthritis	IV, SC	Phase 3; Orphan drug (UC)	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
vadadustat	Akebia	CKD-related anemia	Oral	Phase 3	TBD
valnivudine	Contravir	Herpes zoster (shingles) treatment	Oral	Phase 3	TBD
varicella zoster virus vaccine	Merck	Herpes zoster (shingles) vaccine	SC	Phase 3	TBD
veliparib	Abbvie	Ovarian cancer	Oral	Phase 3; Orphan drug	TBD
venetoclax (Venclexta®)	Abbvie/ Genentech/ Roche	Multiple myeloma; AML	Oral	Phase 3; Breakthrough therapy; Orphan drug (AML)	TBD
Vigil EATC	Gradalis	Ovarian cancer; Breast cancer	Intradermal	Phase 3	TBD
vocimagene amiretrorepvec/ flucytosine	Tocagen	Glioblastoma multiforme; Anaplastic astrocytoma	Oral	Phase 3; Breakthrough therapy	TBD
voclosporin	Aurinia	Lupus nephritis	Oral	Phase 3; Fast track	TBD
volanesorsen	Akcea/ Ionis	Familial chylomicronemia syndrome; Hypertriglyceridemia; Partial lipodystrophy	SC	Phase 3; Orphan drug	TBD
volasertib	Boehringer Ingelheim	AML	IV	Phase 3; Breakthrough therapy; Orphan drug	TBD
vonapanitase	Proteon	Prevention of arteriovenous fistula and arteriovenous graft failure in CKD	IV	Phase 3; Breakthrough therapy; Fast track; Orphan drug	TBD
vosaroxin	Sunesis	AML	IV	Phase 3; Fast track; Orphan drug	TBD
zanamivir	GlaxoSmithKline	Influenza treatment (≥ 7 years of age)	IV	Phase 3	TBD

Complete Response Letter (CRL) / Withdrawn Drugs

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
baricitinib	Eli Lilly/ Incyte	RA	Oral	CRL	TBD
bio-identical 17beta-estradiol	Therapeutics MD	Dyspareunia	Vaginal	CRL	TBD
CCP-07	Tris/ Vernalis	Common cold	Oral	CRL	TBD
dexamethasone SR 0.4% ocular insert	Ocular Therapeutix/ Ora	Post-operative occular pain	Ophthalmic	CRL	TBD

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
epoetin zeta (Biosimilar to Amgen's Epogen® & Janssen's Procrit)	Hospira/ Pfizer	CKD-related anemia	IV, SC	CRL	TBD
glycopyrronium bromide	Sumitomo Dainippon/ Sunovion	COPD	Inhalation	CRL	TBD
insulin glargine (MK-1293; follow-on to Sanofi's Lantus)	Merck/ Samsung Bioepis	T1DM; T2DM	SC	CRL	TBD
naquotinib	Astellas	NSCLC	Oral	Withdrawn	N/A
pegfilgrastim (biosimilar to Amgen's Neulasta)	Coherus	Chemotherapy-related neutropenia	SC	CRL	TBD
sitagliptin (Januvia®)	Merck	CV risk reduction with T2DM	Oral	CRL	TBD
sitabliptin/metformin-XR (Janumet®)	Merck	CV risk reduction with T2DM	Oral	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
CD Crohn's Disease
CDC Centers for Disease Control and Prevention
CF Cystic Fibrosis
CKD Chronic Kidney Disease
CLL Chronic Lymphocytic Leukemia
COPD Chronic Obstructive Pulmonary Disease
CRL Complete Response Letter
CV Cardiovascular
CVD Cardiovascular Disease
DLBCL Diffuse Large B Cell Lymphoma
FDA Food and Drug Administration
ER Extended-release
GI Gastrointestinal
GLP-1 Glucagon-like peptide-1
H Half
HCC Hepatocellular Carcinoma
HCP Healthcare Professional
HCV Hepatitis C Virus
HIT Heparin Induced Thrombocytopenia
HTN Hypertension
IBS Irritable Bowel Syndrome
IM Intramuscular
IV Intravenous
JIA Juvenile Idiopathic Arthritis
LDL-C Low-density Lipoprotein Cholesterol
MS Multiple Sclerosis
N/A Not Applicable
NDA New Drug Application
NHL Non-Hodgkin Lymphoma
NSCLC Non-Small Cell Lung Cancer
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
sBLA supplemental Biologics License Application
SC Subcutaneous
SCCHN Squamous Cell Cancer of the Head and Neck
SLE Systemic Lupus Erythematosus
SLL Small Lymphocytic Lymphoma
sNDA supplemental New Drug Application
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
XR Extended-release