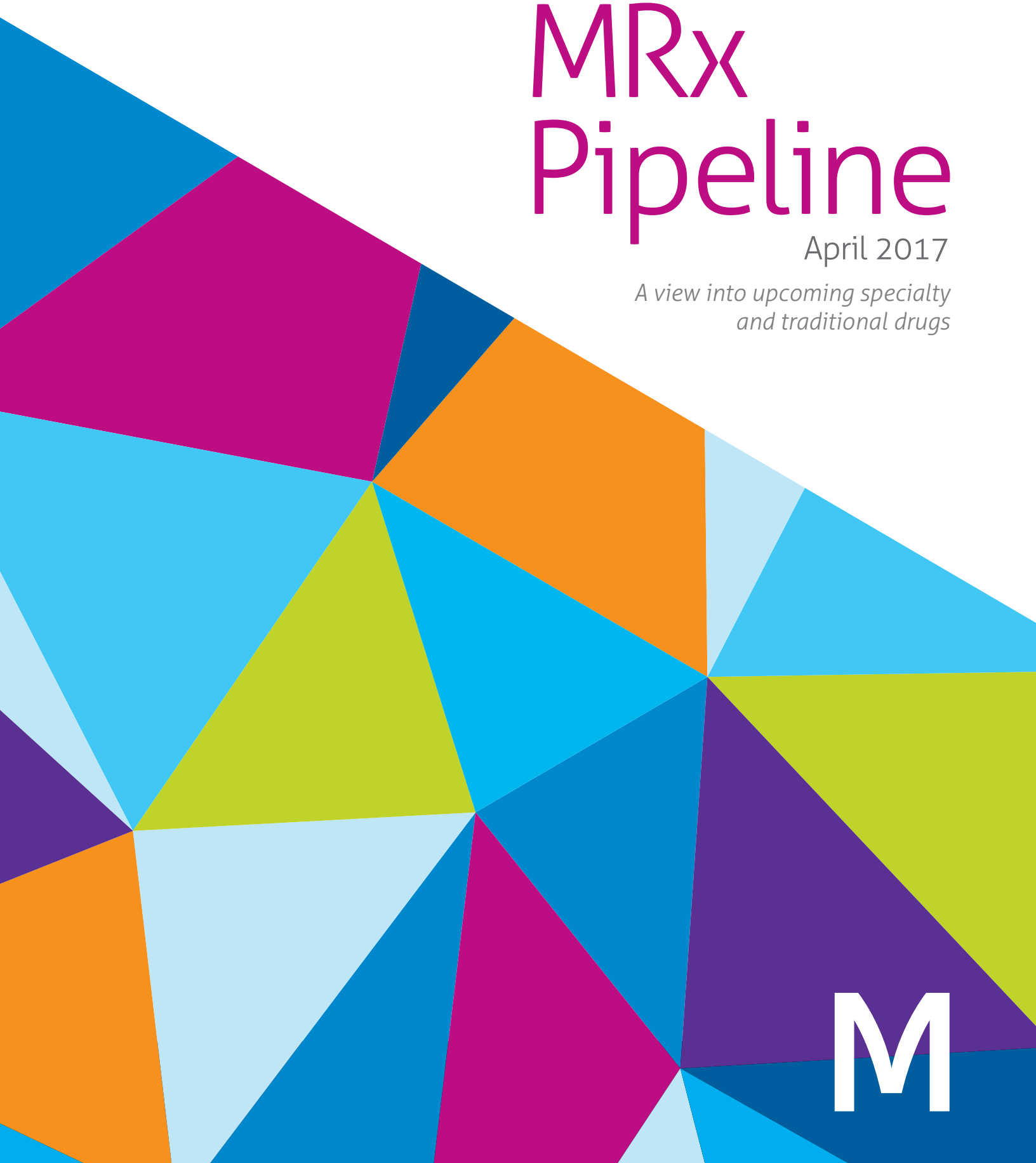
Magellan Rx MANAGEMENT℠

MRx Pipeline

April 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.

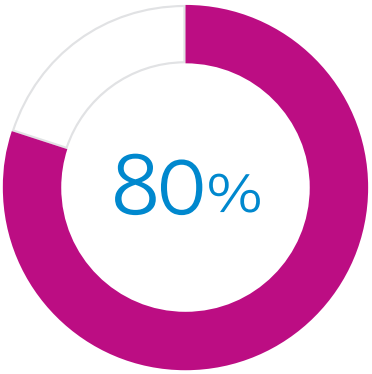
In the past few years, game changers such as products in the hepatitis C and immunotherapy fields have blazed the pipeline trail. A continued key trend toward the approval of specialty medications is expected. Noteworthy pipeline trends to watch in the upcoming quarters include the development of complex therapies, rare diseases, gene therapy, oncology, immunology, pangenotypic agents for hepatitis C, hemophilia, diabetes, and the 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.

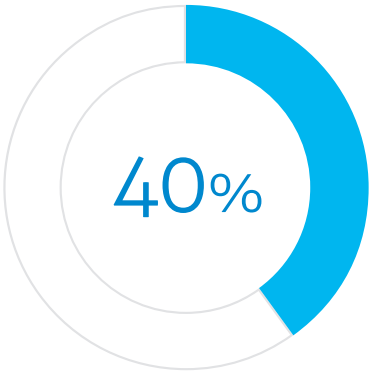
Pipeline Deep Dive

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.

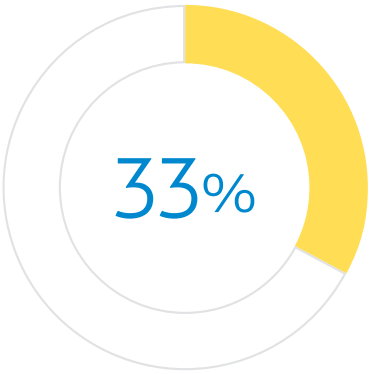
SPECIALTY



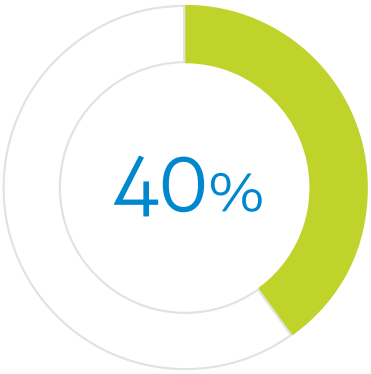
PRIORITY REVIEW



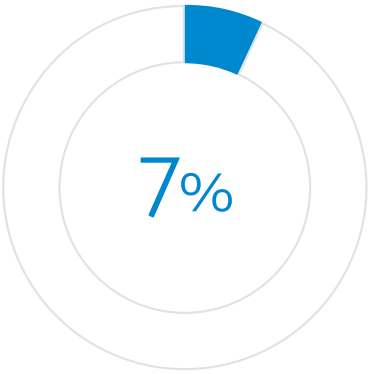
BREAKTHROUGH THERAPY



BIOSIMILAR



ORPHAN DRUG



Specialty drug names appear in magenta throughout the publication.

Magellan Rx MANAGEMENT℠

Oncology

atezolizumab (Tecentriq®) *IV*

Genentech/ Roche

PROPOSED INDICATIONS

Urothelial carcinoma that is locally advanced or metastatic in patients who are ineligible for cisplatin chemotherapy, and are either previously untreated (first-line) or have disease progression at least 12 months after receiving chemotherapy before surgery (neoadjuvant) or after surgery (adjuvant)

Atezolizumab is currently indicated for locally advanced or metastatic urothelial carcinoma that progressed either during or after platinum-based chemotherapy or within 12 months of neoadjuvant or adjuvant platinum-based therapy. It is also indicated to treat non-small cell lung cancer (NSCLC) that progressed during or after platinum-based chemotherapy.

CLINICAL OVERVIEW

Atezolizumab inhibits programmed death-ligand 1 (PD-L1), reducing the tumor's ability to escape the body's immune system.

The phase 2, open-label, single-arm Imvigor210 trial evaluated atezolizumab monotherapy (1,200 mg IV infusion once every 21 days for 16 cycles or 12 months) in patients who had progressed while on or after platinum-based chemotherapy (Cohort 1; n=310) and as first-line in cisplatin-ineligible patients (Cohort 2; n=119). In Cohort 1, at data cutoff, compared with a historical control response rate of 10%, atezolizumab monotherapy resulted in a significantly improved objective response rate (ORR) of 15% in all patients and ORR of 27% in those with PD-L1 expression ≥ 5%. Cohort 2 achieved an ORR of 24%. In both cohorts response was durable and atezolizumab was well tolerated. A phase 3 study of atezolizumab versus chemotherapy as second-line treatment is ongoing.

PLACE IN THERAPY

In 2016, an estimated 77,000 patients were diagnosed with bladder cancer in the US and over 16,000 related deaths were reported. Urothelial carcinoma accounts for 90% of all cases of bladder cancer and is common in elderly men. The standard of care for urothelial carcinoma is platinum-based chemotherapy. Despite initial high response rates, recurrence occurs in most patients leading to a 5-year survival rate of ≤ 10%. In patients that relapse, the median survival is about 6 months.

The PD-1 and PD-L1 inhibitors atezolizumab and nivolumab (Opdivo®) are currently indicated as second-line therapy for advanced/metastatic urothelial carcinoma. Approximately half of all patients with advanced urothelial carcinoma cannot receive platinum-based therapy, so a potential first-line expanded indication for atezolizumab in cisplatin-ineligible patients is a major step. AstraZeneca is also pursuing a second-line urothelial carcinoma indication for their PD-L1 inhibitor durvalumab.

FDA APPROVAL TIMELINE

April 30, 2017

✓ Priority review

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 375	$ 794	$ 1,298	$ 1,820	$ 2,163

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

Magellan Rx MANAGEMENT℠

Cardiovascular

betrixaban *oral*

Portola

PROPOSED INDICATIONS

Extended-duration prophylaxis of venous thromboembolism (VTE) in acute medically ill patients with risk factors for VTE

CLINICAL OVERVIEW

Betrixaban is an oral factor Xa inhibitor that blocks the conversion of prothrombin to thrombin, thereby preventing thrombosis.

The pivotal phase 3 APEX study failed to demonstrate a significant difference between oral betrixaban and a standard regimen of SC enoxaparin in risk reduction of VTE in hospitalized acute medically ill patients with an elevated D-dimer (an indicator of possible VTE). When patients who were age 75 years or older were included in the cohort, however, a significant difference was achieved. Risk of major bleeding did not differ significantly between betrixaban and enoxaparin.

Treatment arms included (1) oral betrixaban loading dose of 160 mg followed by 80 mg once daily for 35 to 42 days plus enoxaparin SC placebo, and (2) enoxaparin SC 40 mg once daily for 10 ± 4 days plus oral betrixaban placebo.

PLACE IN THERAPY

Due to immobility, approximately 7 million hospitalized acutely ill medical patients are at increased risk for VTE in the US each year. Standard prophylactic treatment for hospitalized patients is SC heparin or enoxaparin. Oral betrixaban is seeking approval for extended-duration prevention of VTE during hospitalization and post discharge.

There are several oral direct factor Xa inhibitors available: apixaban (Eliquis®), edoxaban (Savaysa®), and rivaroxaban (Xarelto®). Once-daily betrixaban may become the first novel oral anticoagulant (NOAC) to gain approval for prevention of VTE in acutely ill patients. It has low renal clearance and minimal hepatic metabolism.

Portola's antidote for the direct factor Xa inhibitors, andexanet alfa, is still in development; resubmission to the FDA for approval is planned for the first half of 2017.

FDA APPROVAL TIMELINE

June 24, 2017

✓ Fast track ✓ Priority review

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 17	$ 119	$ 223	$ 336	$ 428

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

Magellan Rx MANAGEMENT

Oncology

durvalumab *IV*

AstraZeneca/ Medimmune

PROPOSED INDICATIONS

Urothelial carcinoma in patients with locally advanced or metastatic disease that has progressed during or after platinum-based chemotherapy

CLINICAL OVERVIEW

Durvalumab is a programmed death-ligand 1 (PD-L1) inhibitor.

Efficacy and safety are supported by a phase 1/2 open-label trial in patients with urothelial carcinoma that progressed during or after 1 platinum-based chemotherapy regimen. Median follow-up period was 7.3 months. At data cut-off, the confirmed objective response rate (ORR) was 20.4% and the complete response rate was 5%. The median overall survival (OS) was 14.1 months. A higher confirmed ORR of 29.5% was reported in patients with high PD-L1 expression (defined as ≥ 25% PD-L1 staining in tumor cells or immune cells) compared to only 7.7% in those with a low or no PD-L1 expression. Adverse effects were manageable in all patients. Fatigue (19.4%) and decreased appetite (9.4%) were commonly reported.

Durvalumab was studied at a dose of 10 mg/kg IV every 2 weeks for up to 12 months or until disease progression.

PLACE IN THERAPY

The standard of care for urothelial carcinoma is platinum-based chemotherapy. Despite initial high response rates, recurrence of disease occurs in the majority of patients.

The PD-1 and PD-L1 inhibitors nivolumab (Opdivo) and atezolizumab (Tecentriq) are FDA-approved to treat locally advanced or metastatic urothelial carcinoma that has progressed during or after platinum-based chemotherapy, regardless of PD-L1 expression. Atezolizumab and pembrolizumab (Keytruda®) are also seeking approval as first-line in cisplatin-ineligible patients, which may include approximately half of all patients with the condition. If approved, durvalumab will be an additional second-line option for urothelial carcinoma. Durvalumab is also being studied as first-line therapy for metastatic urothelial carcinoma in phase 3 trials.

FDA APPROVAL TIMELINE

Q2, 2017

✓ Breakthrough therapy ✓ Priority review

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 15	$ 317	$ 538	$ 886	$ 1,190

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

Magellan Rx MANAGEMENT

Respiratory

fluticasone furoate/ umeclidinium bromide/ vilanterol trifenatate *inhalation*

GlaxoSmithKline/ Innoviva

PROPOSED INDICATIONS

Chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema

CLINICAL OVERVIEW

Fluticasone furoate/ umeclidinium bromide/ vilanterol trifenatate (FLU/UME/VIL) is a once-daily, fixed-dose triple combination therapy of an inhaled corticosteroid (ICS), long-acting muscarinic antagonist (LAMA), and a long-acting beta2-adrenergic agonist (LABA).

In the 24-week, phase 3, double-blind FULFIL trial, once-daily inhaled FLU/UME/VIL significantly improved lung function, as seen by a 171 mL increase in forced expiratory volume in 1 minute [FEV_1], and quality of life. It also reduced moderate to severe COPD exacerbations by 35%, compared to twice-daily budesonide/formoterol (Symbicort® Turbuhaler®) inhalation. Durable treatment benefits were reported with the triple regimen in a subset of patients who received 52 weeks of therapy. The most common adverse effects experienced were nasopharyngitis, headache, and worsening of COPD.

PLACE IN THERAPY

COPD is the third leading cause of death in the US. Approximately 120,000 adults in the US die from this chronic disease each year.

FLU/UME/VIL is aiming to be the first triple combination therapy containing an ICS, LAMA, and LABA. This inhaler may simplify treatment regimens of patients with very severe COPD (category D) who require multiple controller medications. Arrival of generic versions of Advair® (fluticasone propionate/ salmeterol) as well as other generic dual combination LAMA/LABA agents will have an impact on market uptake.

Other investigational triple combination inhalation therapies (ICS/LAMA/LABA) in phase 3 trials for COPD include AstraZeneca's budesonide/ glycopyrronium/ formoterol fumarate and Chiesi's beclomethasone dipropionate/ glycopyrronium / formoterol fumarate.

FDA APPROVAL TIMELINE

November 21, 2017

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 21	$ 72	$ 134	$ 235	$ 335

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

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Hepatitis C Agents

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. It is minimally excreted by the kidneys; therefore, no dose adjustment is needed in patients with CKD, including those on dialysis. G/P is eliminated primarily by biliary excretion. Minimal metabolism and renal excretion occur.

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. This regimen has been evaluated in treatment-naïve and treatment-experienced populations, in patients with or without compensated cirrhosis, and those with HIV-1 co-infection or CKD. It has also been studied for a 16-week duration in GT3 treatment-experienced patients regardless of cirrhosis status. Overall, G/P was well tolerated. Common adverse effects included headache and fatigue.

Doses studied were 3 oral tablets, each containing glecaprevir 300 mg and pibrentasvir 120 mg, administered 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 direct-acting antiviral [DAA] failures). G/P meets many of these challenges. It is a once-daily ritonavir- and ribavirin-free pangenotypic product that offers high SVR12 with a shorter 8-week duration in non-cirrhotic patients across all genotypes. It has also demonstrated high efficacy in difficult-to-treat populations.

Gilead has also requested approval for its investigational once-daily pangenotypic DAA, sofosbuvir/ velpatasvir/ voxilaprevir, in treatment-naïve and treatment-experienced patients. The currently available and investigational pangenotypic products are all dosed once-daily; Abbvie's product is dosed as 3 tablets per day, while both Gilead products require 1 tablet per day.

The role of genotype testing in practice remains to be determined with the increased availability of pangenotypic agents.

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
$ 23	$ 585	$ 777	$ 809	$ 781

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

Oncology

midostaurin *oral*

Novartis

PROPOSED INDICATIONS

Acute myeloid leukemia (AML) first-line induction, consolidation, and maintenance treatment in patients (< 60 years of age) with an FMS-like tyrosine kinase-3 (FLT3) mutation; and advanced systemic mastocytosis (SM)

CLINICAL OVERVIEW

Midostaurin is a multiple kinase inhibitor, particularly active against FMS-like tyrosine kinase 3 (FLT3), a cell-surface tyrosine kinase receptor that plays a role in the proliferation of certain blood cells. Midostaurin interferes with cellular signal transduction pathways. It has activity against both internal tandem duplication (ITD) and tyrosine kinase domain (TKD) mutant FLT3 AML.

In the phase 3 RATIFY trial, midostaurin, in combination with standard chemotherapy, led to significant improvements in overall survival (OS) by 23% and median event-free survival (EFS) from 3 to 8 months. Rates of serious adverse events and allogeneic stem cell transplant were not impacted by the addition of midostaurin. For FML3 AML, midostaurin was dosed as 50 mg orally twice daily on days 8 to 21 during both induction and consolidation phases and was continued as monotherapy at the same dose for up to 1 year in patients who continued in complete remission.

SM is characterized by an abnormal buildup of mast cells in the bone marrow, GI tract, liver, spleen, and skin. Approximately 90% of cases carry the KIT D816V mutation, which activates the KIT receptor tyrosine kinase resulting in increased cell proliferation.

A phase 2, single-arm study in patients with advanced SM demonstrated an overall response rate (ORR) of 60% with midostaurin monotherapy. The median OS was 28.7 months and median progression-free survival (PFS) was 14.1 months. New or worsening serious cytopenias occurred in up to 41% of patients and was pre-existing in most patients. For SM, patients received midostaurin 100 mg twice daily in 4-week continuous cycles until disease progression, death, unacceptable toxicity, or withdrawal of consent. Median duration of treatment was 11.4 months.

PLACE IN THERAPY

AML is the most common acute leukemia in adults with an estimated 62,000 new cases and 10,500 deaths expected in the US in 2017. It is associated with low survival rates and about a third of cases have FLT3 mutations, which carries an even poorer prognosis.

Advanced SM is a rare condition without a cure. Treatment for advanced SM include cladribine, interferon, and hydroxyurea. Use of tyrosine kinase inhibitors is limited with low response. Allogeneic hematopoietic stem cell transplantation offers a potential for cure, but carries substantial mortality risk. Median OS for aggressive SM is 3.5 years, 2 years for SM with hematologic neoplasm, and < 6 months for mast-cell leukemia. Indolent forms carry normal life expectancy.

Midostaurin could become the first targeted therapy for AML, a disease without new options in a quarter of a century. It is paving the way for FLT3 targeted mutations. The next generation FLT3-directed therapies would ideally negate the need for an allogenic transplant. An FLT3 companion diagnostic test has also been submitted for approval.

FDA APPROVAL TIMELINE

May, 2017

✓ Breakthrough therapy *(AML FLT-3 only)* ✓ Orphan drug ✓ Priority review

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 43	$ 108	$ 166	$ 221	$ 265

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

Magellan Rx MANAGEMENT

neratinib *oral*

Puma Biotechnology

PROPOSED INDICATIONS

Extended adjuvant treatment of patients with early stage human epidermal growth factor receptor (HER2) positive breast cancer who have received prior adjuvant trastuzumab-based therapy

CLINICAL OVERVIEW

Neratinib is a tyrosine kinase inhibitor that specifically binds to epidermal growth factor receptor (EGFR) kinase and HER2.

The double-blind, placebo-controlled, phase 3 ExteNET clinical trial enrolled 2,840 women with early-stage HER2-positive breast cancer, who had undergone surgery and adjuvant treatment with trastuzumab followed by 1 year of extended adjuvant treatment with neratinib or placebo. Two years after randomization, there was a significant 33% risk reduction of invasive disease recurrence or death with neratinib, but improvement in disease-free survival (DFS), the primary endpoint, was only by 2.3% for neratinib over placebo (93.9% versus 91.6%). An updated 5-year analysis reported a difference in DFS for neratinib compared to placebo of 2.5% and a 26% reduction of invasive disease recurrence or death. Almost 40% of patients experienced grade 3 or higher diarrhea; however, not all patients received prophylactic treatment with loperamide. When loperamide was given in a phase 2 trial, the incidence was 13-18.5% and was limited to the first 3 weeks of therapy.

In the open-label, phase 2 NEfERT-T trial, 479 women with previously untreated recurrent and/or metastatic ErbB2-positive (also known as HER2-positive) breast cancer were randomly assigned to paclitaxel plus either neratinib or trastuzumab. The median progression-free survival (PFS), the primary efficacy endpoint, was 12.9 months in both groups; however, the neratinib/paclitaxel arm appeared to delay the onset (by 52%) and reduce the frequency (by 55%) of central nervous system (CNS) progression, compared to trastuzumab/paclitaxel. Grade 3 diarrhea occurred more often with neratinib (30.4% versus 3.8%); no grade 4 diarrhea was experienced.

Neratinib was given orally as 240 mg daily for 1 year in the ExteNET trial, and at the same dose until disease progression, symptomatic deterioration, unacceptable toxicity, death, or withdrawal of consent in the NEfERT-T trial.

PLACE IN THERAPY

Breast cancer is the leading cause of cancer-related death in women. An estimated 250,000 people were diagnosed with invasive breast cancer and over 40,000 related deaths occurred in the US in 2016. Although the use of the standard of care, trastuzumab (Herceptin®), in the adjuvant setting reduces disease recurrence in patients with early stage HER2-positive breast cancer, there remains an unmet clinical need to further reduce the risk of recurrence. Neratinib is the first targeted therapy to show a statistically significant clinical benefit in this setting. Although, first-line therapy with neratinib did not improve PFS compared to trastuzumab, when either drug was added to paclitaxel, neratinib did appear to significantly reduce CNS metastases; however, larger trials are needed to confirm this potential benefit.

FDA APPROVAL TIMELINE

July 21, 2017

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 67	$ 165	$ 323	$ 421	$ 486

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

Oncology

pembrolizumab (Keytruda) *IV*

Merck

PROPOSED INDICATIONS

Non-small cell lung cancer (NSCLC) (advanced or metastatic) as first-line therapy in combination with chemotherapy regardless of PD-L1 expression and with no EGFR or ALK genomic tumor mutations

Urothelial carcinoma (locally advanced or metastatic) as first-line therapy in patients who are ineligible for cisplatin-containing therapy and as second-line therapy for disease progression during or after platinum-containing therapy

Previously-treated patients with advanced microsatellite instability-high (MSI-H) cancer

Pembrolizumab is currently approved as first-line therapy for patients with metastatic NSCLC and high PD-L1 expression (tumor proportion score [TPS] ≥ 50%), as determined by an FDA-approved test, with no EGFR or ALK mutations; as second-line in patients with PD-L1 expression (TPS ≥ 1%); as second-line for unresectable or malignant melanoma; recurrent or metastatic SCCHN; and for refractory classical Hodgkin's lymphoma that relapsed after 3 or more lines of therapy.

CLINICAL OVERVIEW

Pembrolizumab is a programmed death-ligand 1 (PD-L1) inhibitor.

NSCLC

In the pivotal open-label, phase 1/2 KEYNOTE-021 study (Part 2, Cohort G), the addition of pembrolizumab to the standard treatment of carboplatin plus pemetrexed was evaluated in therapy-naïve EGFR- and ALK-negative patients with metastatic non-squamous NSCLC. Pembrolizumab resulted in a statistically significantly higher objective response rate (ORR) and progression-free survival (PFS) compared to carboplatin/ pemetrexed doublet therapy alone (ORR 55% versus 29%; PFS 13 versus 8.9 months). Median follow-up was 10.6 months. PD-L1 expression did not impact response rate. Overall survival (OS) was similar between the 2 groups (72% and 75% at 12 months). A double-blind, phase 3 trial of pembrolizumab as first-line therapy in combination with chemotherapy is ongoing; results are expected by the end of 2017.

Urothelial Carcinoma

The open-label, phase 3, KEYNOTE-045 trial evaluated pembrolizumab or investigators choice of paclitaxel, docetaxel, or vinflunine (not available in the US) in patients with advanced urothelial carcinoma that recurred or progressed after platinum-based therapy. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or completion of 2 years of pembrolizumab therapy. Pembrolizumab was associated with a significantly greater OS and longer PFS than chemotherapy (median OS 10.3 versus 7.4 months; median PFS 8 versus 5.2 months). The degree of tumor PD-L1 expression did not impact PFS.

In the single-arm, phase 2, Keynote-052 trial pembrolizumab monotherapy, as first-line treatment in patients with inoperable or metastatic urothelial cancer who were ineligible for cisplatin-based therapy, resulted in an overall ORR of 24% and a complete response (CR) rate of 6%. A higher ORR of 37% and CR rate of 13.3% were seen in patients with PD-L1 expression ≥ 10%. Adverse effects with pembrolizumab monotherapy included fatigue (14%) and pruritus (12%).

Microsatellite Instability
Mismatch repair (MMR) is a process that corrects spontaneous errors that occur during DNA replication. When MMR is deficient in areas of repeated DNA sequences, known as microsatellites, the hypermutability that occurs is called microsatellite instability (MSI). MSI may occur in various cancers and it is often linked to colon cancers. In the phase 2 KEYNOTE-016 study, pembrolizumab provided an ORR of 62% in patients with MMR-deficient metastatic colorectal cancer (mCRC) compared to 0% in patients with MMR-proficient mCRC. The ongoing phase 3 KEYNOTE-177 trial is evaluating pembrolizumab as first-line versus investigators choice of standard of care chemotherapy. The phase 2 KEYNOTE-164 trial is also ongoing and studying pembrolizumab in previously-treated patients. Both trials include patients with MMR-deficient or MSI-H mCRC.

Pembrolizumab was administered as 200 mg IV every 3 weeks in the trials discussed above.

PLACE IN THERAPY

It is estimated that in 2017 there will be 222,500 new cases of lung/bronchus cancer and over 150,000 related deaths in the US; approximately 85% of these cases will be NSCLC. Chemotherapy provides modest benefit in previously-treated patients with advanced or metastatic NSCLC. The PD-1 or PD-L1 inhibitors, atezolizumab (Tecentriq), nivolumab (Opdivo), and pembrolizumab, are preferred over cytotoxic chemotherapy in patients who have progressed on prior chemotherapy. Pembrolizumab is also currently approved as first-line treatment in select patients. AstraZeneca's PD-L1 inhibitor, durvalumab, is in phase 3 clinical trials for NSCLC; results are expected in 2017.

There are an estimated 77,000 new cases of bladder cancer and 16,000 related deaths in the US each year. Despite initial high response rates with platinum-based chemotherapy for urothelial carcinoma, recurrence and death occur in the majority of patients resulting in an OS of 9 to 15 months. Atezolizumab and nivolumab are among therapies for second-line treatment of advanced or metastatic urothelial carcinoma, regardless of PD-L1 expression. Atezolizumab may gain approval for first-line therapy in cisplatin-ineligible patients in April 2017. Other PD-L1 inhibitors seeking indications for urothelial carcinoma include durvalumab (AstraZeneca/ Medimmune) and avelumab (Bavencio®; EMD Serono/ Pfizer); FDA decisions are expected in 2017 for both products.

MSI is detected in various cancers and may confer a better prognosis and similar clinical characteristics that allow for stratification of treatment. MSI-H CRCs are appropriate for targeted immunotherapy with immune checkpoint inhibitors. Nivolumab is also seeking an indication for MSI-H CRC.

FDA approval of these new indications, will (1) expand pembrolizumab's use as first-line therapy for all patients with advanced non-squamous NSCLC regardless of PD-L1 expression, (2) add pembrolizumab as an option for treating metastatic urothelial carcinoma, including first-line for patients who cannot receive cisplatin, and (3) make it the first agent indicated for to treat MSI-H cancers.

pembrolizumab (Keytruda) *continued*

FDA APPROVAL TIMELINE

NSCLC - May 10, 2017
✓ Breakthrough therapy *(EGFR/ALK negative)* ✓ Priority review

MSI-H cancer - June 8, 2017
✓ Breakthrough therapy ✓ Priority review

Urothelial carcinoma - June 14, 2017
✓ Breakthrough therapy ✓ Priority review *(first-line use)*

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 2,520	$ 3,021	$ 3,288	$ 3,495	$ 3,481

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 GT1-6 who have failed prior treatment with a direct-acting antiviral (DAA), including NS5A-containing regimens (ledipasvir or daclatasvir). The studies reported an SVR12 rate ≥ 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 GT1-6, including patients with cirrhosis, achieved SVR12 rate ≥ 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.

The role of genotype testing in practice remains to be elucidated with the increased availability of pangenotypic agents.

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
$ 29	$ 196	$ 321	$ 393	$ 400

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

Biosimilar Overview

CLINICAL OVERVIEW

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

Many controversies surround biosimilars. The FDA has issued final and draft guidances, but regulatory hurdles remain. In February 2017, the agency issued final guidance on the nonproprietary naming of biologic products, which also applies to biosimilars. The biological products must bear a core name, followed by a distinguishing 4-letter, lowercase hyphenated suffix that is devoid of meaning. The FDA is still considering how to implement the nomenclature for previously approved 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 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. Sandoz' Erelzi™ etanercept-szzs and Amgen's Amjevita™ adalimumab-atto, 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.

Blood modifier

epoetin zeta (Retacrit) *injectable*

Hospira/ Pfizer

Retacrit is a biosimilar to Amgen's Epogen® and Janssen's Procrit®, erythropoiesis-stimulating agents (ESA) indicated for the treatment of anemia due to CKD, zidovudine therapy, or effects of myelosuppressive chemotherapy, and also for the reduction of allogeneic red blood cell transfusions in select patients undergoing surgery.

FDA APPROVAL TIMELINE

June, 2017

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 1,839	$1,683	$ 1,495	$ 1,312	$ 1,172

The forecast is a projection of total US sales per year for *all branded products*.

Blood modifier

filgrastim (Grastofil) *injectable*

Accord/ 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; and acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS]).

FDA APPROVAL TIMELINE

June, 2017

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 458	$ 411	$ 377	$ 349	$ 322

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

Immunology
infliximab (SB2) *injectable*

Merck/ Samsung Bioepis

SB2 is a tumor necrosis factor-alpha (TNF-α) inhibitor biosimilar to Janssen's Remicade®, indicated to treat RA, ankylosing spondylitis, Crohn's disease, plaque psoriasis, psoriatic arthritis, and ulcerative colitis. Clinical trials reported equivalent efficacy and similar safety of SB2 to Remicade in patients with moderate to severe RA.

FDA APPROVAL TIMELINE
June, 2017

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 4,541	$ 4,192	$ 3,633	$ 3,176	$ 2,795

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

Endocrine
insulin glargine (MK-1293) *injectable*

Merck/ Samsung Bioepis

MK-1293 is a follow-on biologic to Sanofi's Lantus, a long-acting insulin indicated for the treatment of T1DM and T2DM. MK-1293 has the same amino acid sequence as the originator product.

FDA APPROVAL TIMELINE
April, 2017

FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 2,585	$ 1,846	$ 1,558	$ 1,340	$ 1,191

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

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Blood modifier

pegfilgrastim *injectable*

CHS-1701 and Lapelga 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
Coherus (CHS-1701)
June 9, 2017

FDA APPROVAL TIMELINE
Accord/ Apotex/ Intas (Lapelga)
June, 2017

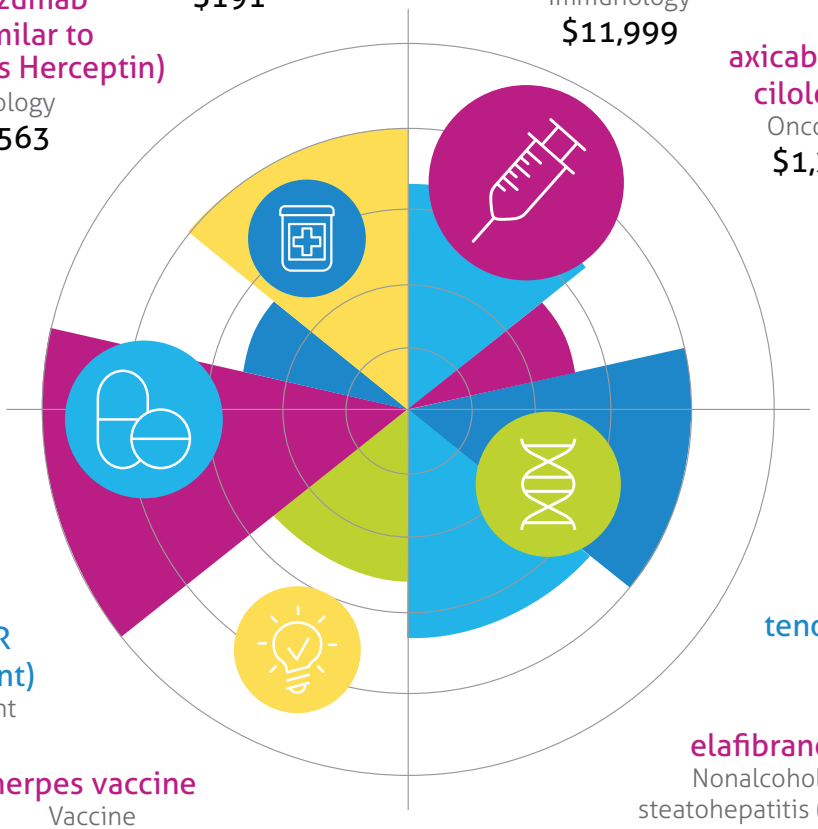
FINANCIAL FORECAST (reported in millions)

2017	2018	2019	2020	2021
$ 3,716	$ 3,530	$ 3,230	$ 2,922	$ 2,625

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.



abemaciclib
Oncology
$805

voretigene neparvovec
Ophthalmology
$191

adalimumab (biosimilar to Abbvie's Humira®)
Immunology
$11,999

trastuzumab (biosimilar to Genentech's Herceptin)
Oncology
$1,563

axicabtagene ciloleucel
Oncology
$1,248

sirukumab
Immunology
$511

benralizumab
Asthma
$364

semaglutide
Diabetes
$1,179

bevacizumab (biosimilar to Genentech's Avastin®)
Oncology
$2,123

sacituzumab govitecan
Oncology
$5

bictegravir/ emtricitabine/ tenofovir alafenamide
HIV/AIDS
$2,151

oxycodone ER (abuse deterrent)
Pain management
$10

elafibranor
Nonalcoholic steatohepatitis (NASH)
$974

herpes vaccine
Vaccine
$534

exenatide minipump
Diabetes
$433

emicizumab
Hemophilia
$702

Specialty drug names appear in magenta throughout the publication.

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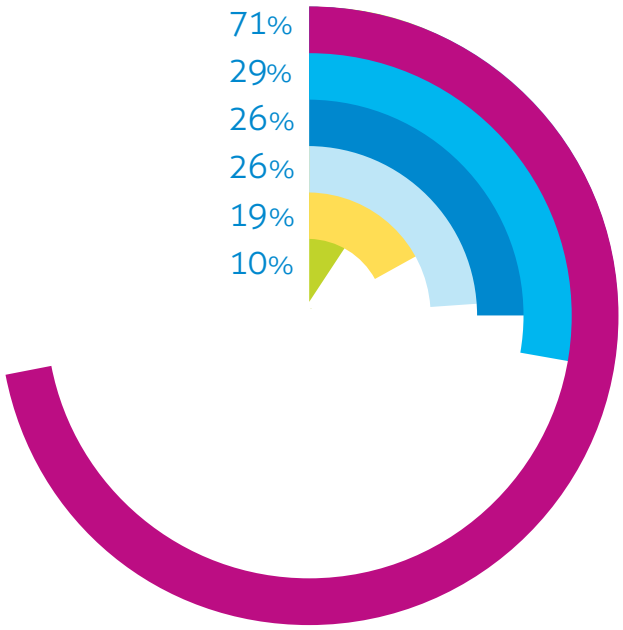
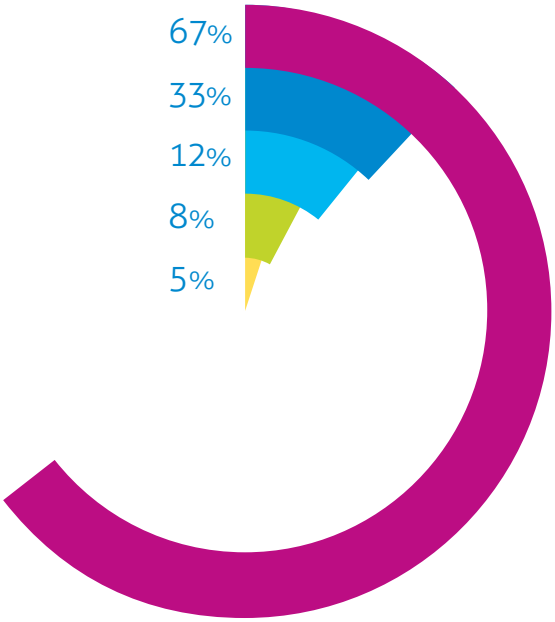
Pipeline Drug List

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

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PIPELINE DRUG LIST

Specialty drug names appear in magenta throughout the publication.

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
durvalumab	AstraZeneca/ Medimmune	Urothelial carcinoma	IV	Submitted; Breakthrough therapy; Priority review	Q2, 2017
infliximab (biosimilar to Centocor's Remicade)	Merck/ Samsung Bioepis	RA; AS; PSO; PSA; CD; UC	SC	Submitted	Q2, 2017
nonacog beta pegol	Novo Nordisk	Hemophilia B	IV	Submitted; Orphan drug	Q2, 2017
baricitinib	Eli Lilly/ Incyte	RA	Oral	Submitted	H1, 2017
insulin glargine (MK-1293; follow-on to Sanofi's Lantus)	Merck/ Samsung Bioepis	T1DM; T2DM	SC	Submitted	April, 2017
valbenazine	Neurocrine	Tardive dyskinesia	Oral	Submitted; Breakthrough therapy; Priority review	4/11/2017
cerliponase alfa	Biomarin	Classic late infantile neuronal ceroid lipofuscinosis (CLN2) disease	IV	Submitted; Breakthrough therapy; Orphan drug; Priority review	4/27/2017
brigatinib	Ariad/ Takeda	NSCLC	Oral	Submitted; Breakthrough therapy; Orphan drug; Priority review	4/29/2017
glycerol phenylbutyrate (Ravicti®)	Horizon	Urea cycle disorders (ages 2 months to 2 years)	Oral	Submitted; Orphan drug	4/29/2017
atezolizumab (Tecentriq)	Genentech/ Roche	Urothelial carcinoma	IV	Submitted; Priority review	4/30/2017
midostaurin	Novartis	AML (newly diagnosed adults with FLT3 mutation); Advanced mastocytosis	Oral	Submitted; Breakthrough therapy; Orphan drug; Priority review	May, 2017
bio-identical 17beta-estradiol	Therapeutics MD	Dyspareunia	Vaginal	Submitted	5/07/2017
pembrolizumab (Keytruda)	Merck	NSCLC (first-line, regardless of PD-L1 expression & with no EGFR or ALK tumor aberrations)	IV	Submitted; Breakthrough therapy; Priority review	5/10/2017
epoetin zeta (biosimilar to Amgen's Epogen and Janssen's Procrit)	Hospira/ Pfizer	Anemia due to CKD	IV, SC	Submitted	June, 2017

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
filgrastim (biosimilar to Amgen's Neupogen)	Accord/ Apotex/ Intas	Cancer patients receiving bone marrow transplant or myelosuppressive chemotherapy; Severe chronic neutropenia	IV, SC	Submitted	June, 2017
pegfilgrastim (biosimilar for Neulasta)	Accord/ Apotex/ Intas	Cancer patients receiving myelosuppressive chemotherapy	SC	Submitted	June, 2017
C1-esterase inhibitor (C1-INH)	CSL Behring	Hereditary angioedema	SC	Submitted	Jun-Jul, 2017
aripiprazole lauroxil (Aristada®)	Alkermes	Schizophrenia	IM	Submitted	6/05/2017
pembrolizumab (Keytruda)	Merck	Microsatellite instability-high (MSI-H) cancer (previously treated)	IV	Submitted; Breakthrough therapy; Priority review	6/08/2017
pegfilgrastim (biosimilar to Amgen's Neulasta)	Coherus	Cancer patients receiving myelosuppressive chemotherapy	SC	Submitted	6/09/2017
pembrolizumab (Keytruda)	Merck	Urothelial carcinoma	IV	Submitted; Breakthrough therapy; Priority review	6/14/2017
epinephrine pre-filled syringe (505b2 NDA)	Adamis	Anaphylactic reaction	Injectable	Submitted	6/15/2017
edaravone	Jiangsu Simcere/ Mitsubishi Tanabe	Amyotrophic lateral sclerosis	IV	Submitted; Orphan drug	6/16/2017
daratumumab (Darzalex®)	Genmab/ Janssen	Multiple myeloma	IV	Submitted; Breakthrough therapy; Orphan drug; Priority review	6/17/2017
delafloxacin meglumine	Abbvie/ Ligand/ Melinta Therapeutics	Hospital-treated acute bacterial skin and skin structure infections (ABSSSI)	Oral, IV	Submitted; Priority review; Qualified infectious disease product	6/19/2017
dextroamphetamine/ amphetamine	Shire	ADHD	Oral	Submitted	6/20/2017
betrixaban	Portola	Venous thromboembolism prevention in acute medically ill patients	Oral	Submitted; Fast track; Priority review	6/24/2017
rituximab SC	Genentech/ Roche	Diffuse large B cell lymphoma; Follicular lymphoma	SC	Submitted; Orphan drug	6/26/2017
ozenoxacin	Ferrer/ Medimetriks	Impetigo	Topical	Submitted	6/27/2017
abaloparatide	Radius Health	Postmenopausal osteoporosis	SC	Submitted	6/30/2017

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
binimetinib	Array Biopharma	Malignant melanoma (BRAF-mutant)	Oral	Submitted	6/30/2017
methylphenidate XR orally disintegrating tablet	Neos Therapeutics	ADHD	Oral	Submitted	6/30/2017
regorafenib (Stivarga®)	Bayer	Hepatocellular carcinoma (unresectable, second-line)	Oral	Submitted; Fast track; Priority review	July, 2017
tocilizumab (Actemra®)	Genentech/ Roche	Giant cell arteritis	SC	Submitted; Breakthrough therapy; Priority review	July, 2017
pharmaceutical grade L-glutamine (PGLG)	Emmaus	Sickle cell disease	Oral	Submitted; Fast track; Orphan drug; Priority review	7/07/2017
dexamethasone SR 0.4% ocular insert	Ocular Therapeutix/ Ora	Post-operative ocular pain	Ophthalmic	Submitted	7/19/2017
romosozumab	Amgen/ UCB	Postmenopausal osteoporosis	SC	Submitted	7/19/2017
neratinib	Puma Biotechnology	Breast cancer (HER2+)	Oral	Submitted	7/21/2017
dantrolene (Ryanodex®)	Eagle	Exertional heat stroke (EHS)	IV	Submitted; Fast track; Orphan drug; Priority review	7/23/2017
aripiprazole (Abilify Maintena®)	Bristol-Myers Squibb/ Otsuka	Bipolar I disorder (maintenance)	IM	Submitted	7/28/2017
methylphenidate HCl	Ironshore/ Highland Therapeutics	ADHD (night-time dosing)	Oral	Submitted	7/30/2017
ceritinib (Zykadia®)	Novartis	NSCLC (first-line; ALK+)	Oral	Submitted; Breakthrough therapy; Orphan drug; Priority review	August, 2017
inotuzumab ozogamicin	Pfizer	ALL (adults with relapsed or refractory B cell precursor ALL)	IV	Submitted; Breakthrough therapy; Orphan drug; Priority review	August, 2017
meropenem/ vaborbactam	The Medicines Company/ Rempex	Complicated UTI	IV	Submitted; Priority review	Aug-Sep, 2017
nivolumab (Opdivo®)	Bristol-Myers Squibb/ Ono	Previously treated dMMR or MSI-H metastatic colon cancer	IV	Submitted; Priority review	8/02/2017
sofosbuvir/ velpatasvir/ voxilaprevir	Gilead	HCV (pangenotypic)	Oral	Submitted; Breakthrough therapy	8/08/2017
hepatitis B vaccine	Dynavax	Hepatitis B	IM	Submitted	8/10/2017

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
glecaprevir/ pibrentasvir	Abbvie	HCV (pangenotypic)	Oral	Submitted; Breakthrough therapy; Priority review	8/18/2017
amantadine ER	Adamas	Dyskinesia (levodopa-induced)	Oral	Submitted; Orphan drug	8/24/2017
liraglutide (Victoza®)	Novo Nordisk	CV risk reduction with T2DM	SC	Submitted	8/25/2017
avelumab	EMD Serono/ Pfizer	Urothelial carcinoma	IV	Submitted; Orphan drug; Priority review	8/27/2017
rabies immune globulin (human)	Kamada	Post-exposure treatment of rabies	IM	Submitted	8/29/2017
deutetrabenazine (Austedo™)	Auspex/ Teva	Tardive dyskinesia	Oral	Submitted; Breakthrough therapy; Priority review	8/30/2017
enasidenib	Agios/ Celgene	AML	Oral	Submitted; Fast track; Orphan drug; Priority review	8/30/2017
adalimumab (biosimilar to Abbvie's Humira)	Boehringer Ingelheim	RA; AS; JIA; UC; CD; PSO; PSA	SC	Submitted	September, 2017
immune globulin (human) 10% (Privigen™)	CSL Behring	Chronic inflammatory demyelinating polyneuritis (CIDP)	IV	Submitted	September, 2017
fulvestrant (Faslodex®)	AstraZeneca	Breast cancer (first-line)	IM	Submitted	Sep-Oct, 2017
pasireotide diaspartate (Signifor® LAR)	Novartis	Cushing's disease (adults)	IM, SC	Submitted	Sep-Oct, 2017
gemtuzumab ozogamicin	Pfizer/ PDL/ UCB	AML	IV	Submitted; Orphan drug	9/01/2017
trastuzumab (biosimilar to Genentech's Herceptin)	Biocon/ Mylan	Breast cancer (HER2+)	IV	Submitted	9/03/2017
cetirizine	Nicox	Allergic conjunctivitis	Ophthalmic	Submitted	9/09/2017
abatacept (Orencia®)	Bristol-Myers Squibb	PSA	SC	Submitted	9/14/2017
bevacizumab (biosimilar to Genentech's Avastin)	Allergan/ Amgen	NSCLC; Cervical cancer; Ovarian cancer; Glioblastoma multiforme; Colorectal cancer; Kidney cancer	IV	Submitted	9/14/2017
secnidazole	Symbiomix Therapeutics	Bacterial vaginosis	Oral	Submitted; Fast track; Qualified infectious disease product; Priority review	9/17/2017
exenatide, minipump	Intarcia Therapeutics	T1DM; T2DM	SC	Submitted	9/21/2017

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
belimumab	GlaxoSmithKline	SLE (active autoantibody-positive)	SC	Submitted	9/23/2017
sirukumab	GlaxoSmithKline/ Janssen	RA	SC	Submitted	9/23/2017
oxycodone ER (abuse deterrent)	Intellipharmaceutics	Pain (moderate to severe)	Oral	Submitted	9/25/2017
amphetamine XR oral solution	Neos Therapeutics	ADHD	Oral	Submitted	Q4, 2017
axicabtagene ciloleucel	Kite	Diffuse large B cell lymphoma; Primary mediastinal B cell lymphoma; Follicular lymphoma	IV	Submitted; Breakthrough therapy; Orphan drug	Q4, 2017
benralizumab	AstraZeneca/ Kyowa Hakko Kirin/ Medimmune	Asthma (severe, eosinophilic phenotype)	SC	Submitted	Q4, 2017
cytarabine/ daunorubicin	Celator	AML	IV	Submitted; Breakthrough therapy; Fast track; Orphan drug	Q4, 2017
plasminogen	Prometic	Hypoplasminogenemia	IV	Submitted	Q4, 2017
voretigene neparvovec	Spark Therapeutics	Inherited retinal disease (IRD)	Ophthalmic	Submitted; Breakthrough therapy; Orphan drug	Q4, 2017
triamcinolone	Flexion Therapeutics	Osteoarthritis pain	Intra-articular	Submitted	10/06/2017
pegfilgrastim (biosimilar to Amgen's Neulasta)	Biocon/ Mylan	Cancer patients receiving myelosuppressive chemotherapy	SC	Submitted	10/09/2017
ustekinumab (Stelara®)	Janssen	PSO (adolescent)	IV	Submitted	10/15/2017
golimumab (Simponi Aria®)	Janssen	PSA; AS	SC	Submitted; Orphan drug	10/21/2017
eculizumab (Soliris®)	Alexion	Myasthenia gravis (refractory anti-AChR antibody positive)	IV	Submitted; Orphan drug	10/23/2017
ataluren	PTC Therapeutics	Duchenne muscular dystrophy (nonsense mutation)	Oral	Submitted	10/24/2017
herpes vaccine	GlaxoSmithKline	Herpes zoster (shingles) vaccine	Injectable	Submitted	10/24/2017
pemetrexed, ready to dilute (RTD)	Eagle	Mesothelioma; NSCLC	IV	Submitted; Orphan drug (mesothelioma)	10/30/2017
eptacog beta	Revo Biologics	Hemophilia A or B	IV	Submitted	November, 2017
guselkumab	Janssen	PSO	SC	Submitted	11/17/2017

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
fluticasone furoate/ umeclidinium bromide/ vilanterol trifenatate	GlaxoSmithKline/ Innoviva	COPD	Inhalation	Submitted	11/21/2017
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
dengue tetravalent vaccine	Sanofi	Dengue vaccine	SC	Submitted; Fast track	12/01/2017
semaglutide	Novo Nordisk	T1DM; T2DM	SC	Submitted	12/05/2017
blinatumomab (Blincyto®)	Amgen/ Onyx Micromet	ALL	IM, IV	Submitted; Orphan drug; Priority review	12/14/2017
plecanatide	Synergy	IBS with constipation	Oral	Submitted	Q1, 2018
netarsudil	Aerie	Glaucoma; Ocular hypertension	Ophthalmic	Submitted	2/28/2018
abametapir	Hatchtech/ Dr. Reddy's	Head lice	Topical	Submitted	Pending
cabazitaxel	Fresenius	Prostate cancer	IV	Submitted	Pending
HIV vaccine	Immune Response BioPharma	HIV	IM	Submitted; Fast track; Orphan drug (pediatrics)	Pending
romidepsin	Teva	Cutaneous T cell lymphoma	IV	Submitted; Orphan drug	Pending
abatacept (Orencia®)	Bristol-Myers Squibb	Lupus nephritis; Sjogren's syndrome; Dermatomyositis	SC	Phase 3	TBD
abemaciclib	Eli Lilly	Breast cancer (HR+/HER2-); NSCLC	Oral	Phase 3; Breakthrough therapy	TBD
abicipar pegol	Actavis/ Allergan/ Molecular Partners	Wet AMD	Intravitreal	Phase 3	TBD
abiraterone acetate	Churchill/ Iceutica	Prostate cancer	Oral	Phase 3	TBD
abobotulinum toxin A (Dysport®)	Ipsen	Overactive bladder	IM	Phase 3	TBD
adalimumab (Humira)	Abbvie	Pustular psoriasis	SC	Phase 3	TBD
adalimumab (biosimilar of Abbvie's Humira)	Biocon/ Mylan	RA; AS; JIA; PSO; PSA; UC; CD; Pediatric CD; Hidradenitis suppurativa	SC	Phase 3	TBD
adalimumab (biosimilar of Abbvie's Humira)	Coherus	RA; JIA; UC; AS; PSO; PSA; Pediatric CD; Hidradenitis suppurativa	SC	Phase 3	TBD
adalimumab (biosimilar of Abbvie's Humira)	EMD Serono	RA; PSO	SC	Phase 3	TBD
adalimumab (biosimilar of Abbvie's Humira)	Fujifilm Kyowa Kirin	RA; AS; JIA; PSO; PSA; UC; CD; Pediatric CD; Hidradenitis suppurativa	SC	Phase 3	TBD

Magellan Rx MANAGEMENT℠

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
adalimumab (biosimilar of Abbvie's Humira)	Inventiv/ Ligand/ Oncobiologics/ Viropro/ Zhejiang Huahai	RA; AS; JIA; PSO; PSA; UC; CD; Pediatric CD; Hidradenitis suppurativa	SC	Phase 3	TBD
adalimumab (biosimilar of Abbvie's Humira)	Momenta	RA; PSO	SC	Phase 3	TBD
adalimumab (biosimilar of Abbvie's Humira)	Pfizer	RA; AS; JIA; PSO; PSA; UC; CD; Pediatric CD; Hidradenitis suppurativa	SC	Phase 3	TBD
adalimumab (biosimilar of Abbvie's Humira)	Sandoz	RA; JIA; UC; AS; PSO; PSA; Pediatric CD; Hidradenitis suppurativa	SC	Phase 3	TBD
aducanumab	Biogen/ Neurimmune	Alzheimer's disease	IV	Phase 3; Fast track	TBD
afatinib (Gilotif®)	Boehringer Ingelheim	SCCHN	Oral	Phase 3	TBD
afibercept (Eylea®)	Bayer/ Regeneron	Diabetic retinopathy; Neovascular glaucoma	Intravitreal	Phase 3	TBD
aglatimagene besadenovec	Advantagene	Prostate cancer	Injectable	Phase 3	TBD
albuvirtide	Frontier	HIV	IV	Phase 3	TBD
allopregnanolone	Sage Therapeutics	Super-refractory status epilepticus (SRSE)	IV	Phase 3; Fast track; Orphan drug	TBD
amisulpride	Acacia	Postoperative nausea and vomiting (PONV)	IV	Phase 3	TBD
anacetrapib	Merck	Dyslipidemia; Artherosclerosis	Oral	Phase 3	TBD
anamorelin HCl	Helsinn Healthcare	Cancer cachexia and anorexia	Oral	Phase 3	TBD
andolast	Rittapharn Madaus	Asthma	Inhalation	Phase 3	TBD
anifrolumab	AstraZeneca/ Medimmune	SLE	IV, SC	Phase 3; Fast track	TBD
apabetalone	Resverlogix	Myocardial infarction and stroke risk reduction in diabetic patients	Oral	Phase 3	TBD
apalutamide	Janssen	Prostate cancer	Oral	Phase 3	TBD
apatinib	Jiangsu Chiatai Qingjang	Gasatric cancer (third-line)	Oral	Phase 3	TBD
asenapine maleate	Noven	Schizophrenia	Transdermal	Phase 3	TBD
asimadoline	Tioga	IBS	Oral	Phase 3; Fast track	TBD
ASP8273	Astellas	NSCLC	Oral	Phase 3	TBD
atacicept	EMD Serono	SLE	SC	Phase 3	TBD
atogepant	Allergan	Migraine	Oral	Phase 3	TBD
avacopan	Chemocentryx	Vasculitis	Oral	Phase 3; Orphan drug	TBD
avatrombopag	Akarx/ Eisai/ PBM Capital	Thrombocytopenia	Oral	Phase 3	TBD

Magellan Rx MANAGEMENT℠

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
avelumab	EMD Serono/ Pfizer	Renal cell carcinoma; NSCLC; Gastric cancer; Ovarian cancer; Diffuse large B cell lymphoma	IV	Phase 3	TBD
avoralstat	Biocryst	Hereditary angioedema	Oral	Phase 3; Fast track; Orphan drug	TBD
axalimogene filolisbac	Advaxis	Cervical cancer	IV	Phase 3; Fast track; Orphan drug	TBD
azeliragon	VTV Therapeutics	Alzheimer's disease (mild-moderate)	Oral	Phase 3; Fast track	TBD
azeliragonum	Transtech	Alzheimer's disease (mild-moderate)	Oral	Phase 3; Fast track	TBD
bardoxolone methyl	Reata	Pulmonary arterial hypertension; Alport syndrome	Oral	Phase 3	TBD
beclomethasone dipropionate/ glycopyrronium/ formoterol fumarate	Chiesi	COPD	Inhalation	Phase 3	TBD
begelomab	Adienne	Graft versus host disease	IV	Phase 3; Orphan drug	TBD
belimumab (Benlysta®)	GlaxoSmithKline/ Human Genome Sciences	Vasculitis; Refractory idiopathic inflammatory myositis; Lupus nephritis	IV	Phase 3	TBD
bempedoic acid	Esperion Therapeutics	Hypercholesterolemia	Oral	Phase 3	TBD
bevacizumab (Avastin)	Genentech/ Roche	Glioblastoma multiforme	IV	Phase 3	TBD
bevacizumab (biosimilar to Genentech's Avastin)	AstraZeneca/ Centus Biotherapeutics/ Fujifilm Kyowa Kirin	NSCLC	IV	Phase 3	TBD
bevacizumab (biosimilar to Genentech's Avastin)	Boehringer Ingelheim	Colorectal cancer; NSCLC; Ovarian cancer; Cervical cancer; Glioblastoma; Kidney cancer	IV	Phase 3	TBD
bevacizumab (biosimilar to Genentech's Avastin)	Pfizer	Colorectal cancer; NSCLC; Ovarian cancer; Cervical cancer; Glioblastoma; Kidney cancer	IV	Phase 3	TBD
bexagliflozin	Theracos	T1DM; T2DM	Oral	Phase 3	TBD
bictegravir/ emtricitabine/ tenofovir alafenamide	Gilead	HIV	Oral	Phase 3	TBD
binimetinib	Array Biopharma	Colorectal cancer	Oral	Phase 3	TBD
blonanserin	Sumitomo Dainiippon Pharma	Schizophrenia	Oral	Phase 3	TBD
bremelanotide	Palatin	Female sexual dysfunction	SC	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
brexpiprazole (Rexulti®)	Otsuka	Alzheimer's disease; Post traumatic stress disorder	Oral	Phase 3; Fast track (Alzheimer's)	TBD
brincidofovir	Chimerix	Adenovirus infection; Cytomegalovirus prevention	Oral	Phase 3; Fast track	TBD
brodalumab (Siliq™)	AstraZeneca/ Valeant	PSA	SC	Phase 3	TBD
brolucizumab	Alcon	Wet AMD	Intravitreal	Phase 3	TBD
busulfan	Otsuka	Multiple myeloma	Oral	Phase 3	TBD
C1-esterase inhibitor (human) (Cinryze®)	Shire	Transplant rejection	IV	Phase 3	TBD
cadazolid	Actelion	*Clostridium difficile* associated diarrhea	Oral	Phase 3; Fast track	TBD
carotuximab	Tracon	Angiosarcoma	IV	Phase 3; Orphan drug	TBD
cebranopadol	Grunenthal/ Depomed	Pain (chronic)	Oral	Phase 3	TBD
cefiderocol	Shionogi	Bacterial sepsis; Catheter related bloodstream infections (CRBI); Hospital-acquired Gram-negative pneumonia; Ventilator-associated pneumonia (VAP); Complicated UTI	IV	Phase 3	TBD
ceftolozane/ tazobactam	Cubist	Nosocomial pneumonia	IV	Phase 3; Fast track	TBD
cenicriviroc	Takeda/ Tobira	Nonalcoholic steatohepatitis (NASH)	Oral	Phase 3; Fast track	TBD
certolizumab pegol (Cimzia®)	Dermira/ Royalty/ UCB	RA; JIA; PSO	SC	Phase 3	TBD
clarithromycin/ clofazimine/ rifabutin	Giaconda/ RedHill Biopharma	CD	Oral	Phase 3; Orphan drug	TBD
copanlisib	Bayer	Non-Hodgkin's lymphoma	Oral	Phase 3; Orphan drug	TBD
crenezumab	AC Immune/ Genentech/ Roche	Alzheimer's disease (mild)	IV	Phase 3	TBD
crenolanib	Arog	Gastrointestinal cancer; AML	Oral	Phase 3	TBD
cytomegalovirus vaccine	Astellas/ Vical	Cytomegalovirus disease prevention in transplant patients	IM	Phase 3; Orphan drug	TBD
daclatasvir/ asunaprevir	Bristol-Myers Squibb	HCV genotype 1	Oral	Phase 3	TBD
daclatasvir/ asunaprevir/ beclabuvir	Bristol-Myers Squibb	HCV genotype 1	Oral	Phase 3	TBD
dalcetrapib	Dalcor	Acute coronary syndrome	Oral	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
daprodustat	GlaxoSmithKline	Anemia due to CKD	Oral	Phase 3	TBD
dasiprotimut-T	Biovest International	Follicular lymphoma; Mantel cell lymphoma	SC	Phase 3; Orphan drug	TBD
denosumab (Prolia®)	Amgen	Multiple myeloma; RA; Pediatric osteogenesis imperfecta (ages 2-17 years)	SC	Phase 3	TBD
deuterated dextromethorphan/ quinidine sulfate	Avanir/ Concert/ Otsuka	Alzheimer's disease	Oral	Phase 3; Fast track	TBD
dexamethasone phosphate (iontophoresis)	Eyegate	Anterior uveitis	Ophthalmic	Phase 3	TBD
diepalrestat choline	Bionevia/ Neuromax	Diabetic peripheral neuropathy pain	Oral	Phase 3	TBD
dimesna disulfide	Baxter/ Bionumerik	NSCLC	IV	Phase 3	TBD
diroximel fumarate	Alkermes	MS	Oral	Phase 3	TBD
doravirine	Merck	HIV	Oral	Phase 3	TBD
doxorubicin	Bioalliance/ Onxeo	Liver cancer (second-line)	IV	Phase 3; Fast track; Orphan drug	TBD
doxorubicin	Celsion/ Hisun	Liver cancer	IV	Phase 3; Fast track; Orphan drug	TBD
dupilumab	Regeneron/ Sanofi	Nasal polyps; Asthma	SC	Phase 3	TBD
durvalumab (Dupixent®)	AstraZeneca/ Medimmune	NSCLC; SCCHN; Solid tumors	IV	Phase 3; Fast track	TBD
eflapegrastim	Hanmi/ Spectrum	Neutropenia due to myelosuppressive chemotherapy	SC	Phase 3	TBD
elafibranor	Genfit	Nonalcoholic steatohepatitis (NASH)	Oral	Phase 3; Fast track	TBD
elagolix	Abbvie/ Neurocrine	Uterine fibroids; Endometriosis	Oral	Phase 3	TBD
elenbecestat	Biogen/ Eisai	Alzheimer's disease (early)	Oral	Phase 3; Fast track	TBD
emicizumab	Chugai/ Genentech/ Roche	Hemophilia A	Oral	Phase 3; Breakthrough therapy; Orphan drug	TBD
entinostat	Bayer/ Kyowa Hakko Kirin/ Syndax	Breast cancer	Oral	Phase 3; Breakthrough therapy	TBD
enzalutamide (Xtandi®)	Astellas	Breast cancer	Oral	Phase 3	TBD
epidiolex	GW	Dravet syndrome; Infantile spasm; Lennox-Gastaut syndrome	Oral	Phase 3; Fast track; Orphan drug	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
epoetin alfa (biosimilar of Janssen's Procrit)	Sandoz	Anemia due to CKD	IV, SC	Phase 3	TBD
eptinezumab	Alder Biopharmaceutics	Migraine	IM, IV, SC	Phase 3	TBD
eravacycline	Tetraphase	Complicated intra-abdominal infections; Complicated UTI	Oral, IV	Phase 3; Fast track	TBD
erenumab	Amgen/ Novartis	Migraine	SC	Phase 3	TBD
erlotinib	Genentech/ Roche	NSCLC (first-line, EGFR+)	Oral	Phase 3	TBD
esketamine	Janssen	Major depressive disorder (treatment resistant)	Intranasal	Phase 3; Breakthrough therapy; Fast track	TBD
etanercept (biosimilar to Amgen's Enbrel®)	Coherus/ Daiichi Sankyo	RA; JIA; AS; PSA; PSO	SC	Phase 3	TBD
etanercept (biosimilar to Amgen's Enbrel)	Lupin	RA; JIA; AS; PSA; PSO	SC	Phase 3	TBD
etirinotecan pegol	Daiichi-Sankyo/ Nektar	Breast cancer (advanced)	IV	Phase 3; Fast track	TBD
fasinumab	Regeneron/ Sanofi	Osteoarthritis; pain; Chronic low back pain	IV, SC	Phase 3	TBD
ferric carboxymaltose (Injectafer®)	Vifor	Restless leg syndrome; Anemia due to chemotherapy	IV	Phase 3	TBD
ferumoxytol (Feraheme™)	AMAG	Iron deficiency	IV	Phase 3	TBD
fevipiprant	Novartis	Eosinophilic asthma	Oral	Phase 3	TBD
filgotinib	Galapagos/ Gilead	CD; UC; RA	Oral	Phase 3	TBD
fimasartan	Boryung/ Stendhal	Hypertension	Oral	Phase 3	TBD
finerenone	Bayer	T1DM; T2DM; Diabetic nephropathy	Oral	Phase 3	TBD
fingolimod (Gilenya®)	Mitsubishi Tanabe/ Novartis	Primary progressive MS	Oral	Phase 3	TBD
flomoxef	Takeda	Complicated UTI	IV	Phase 3	TBD
fluocinolone acetonide	pSivida	Non-infectious uveitis	Intravitreal	Phase 3	TBD
fostemsavir	Bristol-Myers Squibb/ GlaxoSmithKline/ Viiv Healthcare	HIV	Oral	Phase 3; Breakthrough therapy; Fast track	TBD
fremanezumab	Teva	Migraine	SC	Phase 3	TBD
fruquintinib	Eli Lilly/ Hutchison Medipharma	Colorectal cancer	Oral	Phase 3	TBD
furosemide (wearable pump)	scPharmaceuticals	Heart failure	SC	Phase 3	TBD
galcanezumab	Eli Lilly	Migraine; Cluster headache	SC	Phase 3; Fast track	TBD
galeterone	Tokai	Prostate cancer	Oral	Phase 3; Fast track	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
gantenerumab	Genentech/ Morphosys/ Roche	Alzheimer's disease (prodromal-mild)	IV, SC	Phase 3	TBD
gemigliptin	LG Life Sciences/ Sanofi	T1DM; T2DM	Oral	Phase 3	TBD
gilteritinib	Astellas/ Kotobuki	AML	Oral	Phase 3	TBD
glycopyrronium/ formoterol fumarate/ budesonide	AstraZeneca/ Pearl Therapeutics	COPD	Inhalation	Phase 3	TBD
grazoprevir/ elbasvir (Zepatier™)	Merck	HCV genotype 6	Oral	Phase 3	TBD
ibodutant	Menarini	IBS	Oral	Phase 3	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
icotinib HCl	Beta Pharma	NSCLC	Oral	Phase 3	TBD
immune globulin (IVIG)	Biotest	Primary immunodeficiency	IV	Phase 3	TBD
inebilizumab	AstraZeneca	Neuromyelitis optica	IV	Phase 3; Orphan drug	TBD
infliximab (biosimilar to Centocor's Remicade)	Amgen	RA	IV	Phase 3	TBD
infliximab (biosimilar to Centocor's Remicade)	Aprogen/ Nichi-Iko	RA	SC	Phase 3	TBD
influenza virus vaccine	bioCSL	Prophylaxis of influenza in ages ≥ 5 years	IM	Phase 3	TBD
intepirdine	Axovant/ Roivant	Alzheimer's disease (mild to moderate)	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
ITI-007	Intra-Cellular Therapies	Alzheimer's disease; Bipolar disorder I or II; Schizophrenia	Oral	Phase 3	TBD
ixekizumab (Taltz®)	Eli Lilly	Axial spondyloarthritis; Genital psoriasis; PSA	SC	Phase 3	TBD
lampalizumab	Genentech/ Roche	Dry AMD	Intravitreal	Phase 3; Fast track	TBD
lanadelumab	Dyax/ Shire	Hereditary angioedema	SC	Phase 3; Breakthrough therapy; Fast track; Orphan drug	TBD
laquinimod	Active Biotech/ Teva	Relapsing-remitting MS	Oral	Phase 3; Fast track	TBD
lasmiditan	Colucid	Migraine	Oral	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
lebrikizumab	Genentech/ Roche	Asthma	SC	Phase 3	TBD
lefamulin	Nabriva	Community-acquired pneumonia	IV	Phase 3; Fast track	TBD
lemborexant	Eisai/ Purdue	Insomnia	Oral	Phase 3	TBD
lercanidipine/ valsartan	LG Life Sciences	Hypertension	Oral	Phase 3	TBD
leuprolide mesylate	Foresee	Prostate cancer	SC	Phase 3	TBD
lofexidine	Britannia/ US Worldmeds	Acute opioid withdrawal	Oral	Phase 3	TBD
lumacaftor	Vertex	CF (homozygous F508del mutation in ages 2-5 years)	Oral	Phase 3; Breakthrough therapy; Orphan drug	TBD
lurasidone (Latuda®)	Sunovion	Biopolar 1 depression (10-17 years of age)	Oral	Phase 3	TBD
luseogliflozin hydrate	Novartis/ Taisho	T1DM; T2DM	Oral	Phase 3	TBD
luspatercept	Acceleron/ Celgene	Myelodysplastic syndromes; Beta thalassemia	SC	Phase 3; Fast track; Orphan drug	TBD
lusutrombopag	Shionogi	Thrombocytopenia	Oral	Phase 3	TBD
margetuximab	Macrogenics	Breast cancer (HER2+)	IV	Phase 3	TBD
meloxicam	Recro	Post-operative pain	IV	Phase 3	TBD
methylthioninium	Taurx	Alzheimer's disease; Dementia	Oral	Phase 3	TBD
midazolam	Upsher-Smith	Seizure clusters	Intranasal	Phase 3; Fast track; Orphan drug	TBD
mirogabalin	Daiichi Sankyo	Postherpetic neuralgia pain; Fibromyalgia	Oral	Phase 3	TBD
mirvetuximab soravtansine	Immunogen	Ovarian cancer	IV	Phase 3; Orphan drug	TBD
momelotinib	Gilead	Myelofibrosis; Pancreatic cancer	Oral	Phase 3; Orphan drug	TBD
mongersen	Celgene/ Nogra	CD	Oral	Phase 3; Orphan drug	TBD
nalmefene	Biotie Therapies/ H. Lundbeck A-S	Alcohol dependence	Oral	Phase 3	TBD
natalizumab (Tysabri®)	Biogen/ Elan	Secondary progressive MS	IV	Phase 3	TBD
neratinib	Puma Biotechnology	NSCLC	Oral	Phase 3	TBD
neridronic acid	Grunenthal	Complex reginal pain syndrome	IV	Phase 3	TBD
nilvadipine	Archer	Alzheimer's disease	Oral	Phase 3	TBD
niraparib (Zejula™)	Janssen/ Tesaro	Breast cancer	Oral	Phase 3	TBD
NKTR-181	Nektar	Low back pain (moderate-severe)	Oral	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
ODM-201	Bayer/ Orion	Prostate cancer	Oral	Phase 3	TBD
ofatumumab (Arzerra® SC)	Stiefel Labs/ Novartis	MS	SC	Phase 3	TBD
olanzapine/ samidorphen	Alkermes	Schizophrenia	Oral	Phase 3	TBD
olaparib	AstraZeneca	Breast cancer; Pancreatic cancer; Ovarian cancer (germline mutated)	Oral	Phase 3	TBD
oliceridine	Trevena	Pain (acute)	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	Oral, IV	Phase 3; Fast track	TBD
omecamtiv mecarbil	Amgen/ Cytokinetics/ Servier	Heart failure	Oral	Phase 3	TBD
opicapone	Bial	Parkinson's disease	Oral	Phase 3	TBD
ozanimod	Celgene/ Receptos	Relapsing MS	Oral	Phase 3	TBD
patisiran	Alnylam / Arbutus/ Sanofi	Familial amyloidotic polyneuropathy	IV	Phase 3; Fast track; Orphan drug	TBD
pefcalcitol	Maruho	PSO	Topical	Phase 3	TBD
peficitinib HBr	Astellas/ Janssen	RA	Oral	Phase 3	TBD
peginterferon alfa-2b (biosimilar to Merck's Peg-Intron®)	Biocad	HCV	SC	Phase 3	TBD
peginterferon lambda-1a	Bristol-Myers Squibb	HCV	SC	Phase 3	TBD
pembrolizumab (Keytruda)	Merck	Gastric cancer; Breast cancer; Colorectal cancer; Gastroesophageal cancer; Multiple myeloma; Liver cancer; Kidney cancer	IV	Phase 3	TBD
pegunigalsidase alfa	Protalix	Fabry disease	IV	Phase 3	TBD
pertuzumab	Genentech/ Roche	Breast cancer (HER2+)	IV	Phase 3	TBD
piclidenoson	Can-Fite Biopharma	PSO; RA	Oral	Phase 3	TBD
pitolisant	Bioprojet	Excessive daytime sleepiness in obstructive sleep apnea; Narcolepsy	Oral	Phase 3	TBD
pixantrone dimaleate	CTI Biopharma	Diffuse large B cell lymphoma	IV	Phase 3	TBD
plazomicin	Achaogen	Complicated UTI; Septicemia/Bacteremia; Hospital aquired pneumonia	IV	Phase 3; Fast track	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
plinabulin	Beyondspring	NSCLC	IV	Phase 3	TBD
pneumococcal conjugate vaccine	Sinovac Biotech	Pneumonia prevention	IM	Phase 3	TBD
ponesimod	Actelion	Relapsing MS	Oral	Phase 3	TBD
pregabalin (Lyrica®)	Pfizer	Partial onset seizures (4-16 years of age)	Oral	Phase 3	TBD
prucalopride	Janssen/ Shire	Chronic idiopathic constipation	Oral	Phase 3	TBD
quizartinib	Ambit Biosciences/ Daiichi Sankyo	AML	Oral	Phase 3; Orphan drug	TBD
ranibizumab (biosimilar to Genentech's Lucentis®)	Bioeq/ Formycon/ Polpharma/ Santo Holding/ Swiss Pharma International AG	Wet AMD; Macular edema; Diabetic macular edema; Diabetic retinopathy	Intravitreal	Phase 3	TBD
rapastinel	Allergan/ Naurex	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; Complicated UTI	IV	Phase 3; Fast track	TBD
remestemcel-L	Mesoblast	CD; Graft versus host disease	IV	Phase 3; Fast track; Orphan drug	TBD
reslizumab	Teva	Chronic rhinosinusitis	IV	Phase 3	TBD
reslizumab	Teva	Eosinophilic asthma	SC	Phase 3	TBD
respiratory syncytial virus (RSV) vaccine	Novavax	Respiratory syncitial virus (RSV) prevention (older adults)	IM	Phase 3	TBD
retagliptin	Jiangsu Hengrui Medical	T1DM; T2DM	Oral	Phase 3	TBD
retosiban	GlaxoSmithKline	Pre-term birth prevention	Oral, IV	Phase 3	TBD
revefenacin	Mylan/ Theravance	COPD	Inhalation	Phase 3	TBD
reveglucosidase alfa	Biomarin	Pompe disease (late onset)	IV	Phase 3; Orphan drug	TBD
rigerimod	Immupharma	SLE	SC	Phase 3; Fast track	TBD
rilimogene galvacirepvec/ rilimogene glafolivec	Bavarian Nordic/ Bristol-Myers Squibb	Prostate cancer	SC	Phase 3	TBD
riluzole	Biohaven	Social anxiety disorder	Oral	Phase 3	TBD
risankizumab	Abbvie/ Boehringer Ingelheim	PSO	IV, SC	Phase 3	TBD
ritonavir/ elvitegravir	Gilead	HIV	Oral	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
rituxamab (Rituxan®)	Biogen/ Genentech/ Roche	Pemphigus vulgaris; Thyroid eye disease; Nephrotic syndrome	IV	Phase 3; Breakthrough therapy	TBD
rituximab (biosimilar to Genentech's Rituxan)	Allergan/ Amgen	Granulomatosis with polyangiitis; RA; Follicular lymphoma; Non-Hodgkin's lymphoma; CLL	IV	Phase 3	TBD
rituximab (biosimilar to Genentech's Rituxan)	Archigen/ AstraZeneca/ Samsung	Granulomatosis with polyangiitis; RA; Follicular lymphoma; Non-Hodgkin's lymphoma; CLL	IV	Phase 3	TBD
rituximab (biosimilar to Genentech's Rituxan)	Pfizer	Granulomatosis with polyangiitis; RA; Follicular lymphoma; Non-Hodgkin's lymphoma; CLL	IV	Phase 3	TBD
rituximab (biosimilar to Genentech's Rituxan)	Sandoz	RA; Follicular lymphoma	IV	Phase 3	TBD
rivaroxaban (Xarelto®)	Janssen	Congestive heart failure; Coronary artery disease; Ischemic stroke; Peripheral artery disease	Oral	Phase 3	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
rovalpituzumab tesirine	Abbvie	Small cell lung cancer	IV	Phase 3; Orphan drug	TBD
roxadustat	Astellas/ Fibrogen	Anemia due to CKD	Oral	Phase 3	TBD
rucaparib (Rubraca™)	Clovis Oncology	Prostate cancer	Oral	Phase 3	TBD
sacituzumab govitecan	Immunomedics	Breast cancer	IV	Phase 3; Breakthrough therapy; Fast track	TBD
secukinumab (Cosentyx®)	Novartis	Axial spondyloarthritis; RA	SC	Phase 3	TBD
selepressin	Ferring	Sepsis-induced shock	IV	Phase 3	TBD
semaglutide	Emisphere/ Novo Nordisk	T1DM; T2DM	Oral	Phase 3	TBD
serelaxin	Novartis	Heart failure (acute)	IV	Phase 3; Breakthrough therapy; Fast track	TBD
seviprotimut-L	CK Life Sciences	Malignant melanoma	Intradermal	Phase 3	TBD
sialic acid	Ultragenyx	Hereditary inclusion body myopathy	Oral	Phase 3; Orphan drug	TBD
siponimod	Novartis	Secondary progressive MS	Oral	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
sirukumab	Eli Lilly/ GlaxoSmithKline/ Janssen	Temporal arteritis; Polymyalgia rheumatica	SC	Phase 3	TBD
sodium oxybate (Xyrem®)	Jazz	Narcolepsy with cataplexy (pediatric)	Oral	Phase 3	TBD
sorafenib tosylate (Nexavar®)	Bayer	Breast cancer	Oral	Phase 3	TBD
sotagliflozin	Lexicon/ Sanofi	T1DM; T2DM	Oral	Phase 3	TBD
stannsoporfin	Infacare/ Wellspring	Hyperbilirubinemia	IM	Phase 3	TBD
talazoparib	Medivation	Breast cancer (triple negative)	Oral	Phase 3	TBD
tanezumab	Eli Lilly/ Pfizer	Chronic back pain; Cancer pain; Osteoarthritis pain	SC	Phase 3	TBD
taselisib	Chugai/ Genentech/ Roche	Breast cancer	Oral	Phase 3	TBD
tasquinimod	Active Biotech/ Ipsen	Prostate cancer	Oral	Phase 3	TBD
TCR peptide vaccine	Immune Response Biopharma	MS	Injectable	Phase 3; Fast track; Orphan drug	TBD
tecarfarin	Armetheon	Stroke risk reduction	Oral	Phase 3	TBD
tenapanor	Ardelyx	IBS with constipation; Hyperphosphatemia	Oral	Phase 3	TBD
teplizumab	Macrogenics	T1DM; T2DM	IV	Phase 3; Orphan drug (T1DM)	TBD
terlipressin acetate	Ikaria/ Mallinckrodt	Hepatorenal syndrome	IV	Phase 3; Fast track; Orphan drug	TBD
tesevatinib	Kadmon	NSCLC	Oral	Phase 3	TBD
tezacaftor	Vertex	CF patients with CFTR gene mutations	Oral	Phase 3; Breakthrough therapy; Orphan drug	TBD
Tg-4010	Transgene/ Virax	NSCLC	Injectable	Phase 3	TBD
TGF-beta antisense	3M Innovative	NSCLC	Injectable	Phase 3; Fast track	TBD
TGR-1202	TG Therapeutics	CLL; Diffuse large B cell lymphoma	Oral	Phase 3	TBD
tildrakizumab	Merck/ Sun	PSO	SC	Phase 3	TBD
tivozanib	Aveo/ Kyowa/ Ophthotech	Kidney cancer	Oral	Phase 3	TBD
tofacitinib (Xeljanz®)	Pfizer/ Takeda	JIA; UC; PSO; PSA	Oral	Phase 3	TBD
tofogliflozin	Chugai/ Genentech/ Kowa/ Roche/ Sanofi	T1DM; T2DM	Oral	Phase 3	TBD
tozadenant	Biotie Therapies	Parkinson's disease	Oral	Phase 3	TBD

PIPELINE DRUG LIST continued

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
tralokinumab	AstraZeneca/ LEO/ Medimmune	Asthma	SC	Phase 3	TBD
tramiprosate	Alzheon	Alzheimer's disease (mild-moderate)	Oral	Phase 3	TBD
trastuzumab (biosimilar to Genentech's Herceptin)	Celltrion/ Teva	Gastroesophageal junction cancer; Gastric cancer; Breast cancer (HER2+)	IV	Phase 3	TBD
trastuzumab (biosimilar to Genentech's Herceptin)	Pfizer	Gastroesophageal junction cancer; Gastric cancer; Breast cancer (HER2+)	IV	Phase 3	TBD
trelagliptin succinate	Takeda	T1DM; T2DM	Oral	Phase 3	TBD
tremelimumab	AstraZeneca/ MedImmune	SCCHN	IV	Phase 3	TBD
triamcinolone acetonide	Clearside Biomedical	Macular edema	Ophthalmic	Phase 3	TBD
trifluridine/ tipiracil (Lonsurf®)	Otsuka/ Taiho	Gastric cancer	Oral	Phase 3	TBD
turgenpumatucel-L	Newlink Genetics	NSCLC	Injectable	Phase 3	TBD
ubrogepant	Allergan	Migraine	Oral	Phase 3	TBD
upadacinitib	Abbvie	RA	Oral	Phase 3	TBD
ustekinumab (Stelara®)	Janssen	AS; UC	IV, SC	Phase 3	TBD
vadadustat	Akebia Therapeutics	Anemia due to CKD	Oral	Phase 3	TBD
valnivudine	Contravir	Herpes zoster (shingles) treatment	Injectable	Phase 3	TBD
varicella-zoster virus vaccine	Merck	Herpes zoster (shingles) prevention	SC	Phase 3	TBD
vepoloxamer	Mast Therapeutics	Sickle cell disease vaso-occlusive crisis	IV	Phase 3	TBD
vericiguat	Bayer/ Merck	Heart failure	Oral	Phase 3	TBD
vildagliptin	Novartis	T1DM; T2DM	Oral	Phase 3	TBD
vocimagene amiretrorepvec/ flucytosine	Tocagen	Glioblastoma multiforme; Anaplastic astrocytoma	Oral	Phase 3	TBD
voclosporin	Aurinia	Lupus nephritis	Oral	Phase 3	TBD
voglibose/ metformin	CJ Corp	T1DM; T2DM	Oral	Phase 3	TBD
vonapanitase	Proteon Therapeutics	Prevention of arteriovenous fistula and arteriovenous graft failure in CKD	IV	Phase 3; Fast track	TBD
zanamivir	GlaxoSmithKline	Influenza treatment (ages ≥7 years)	IV	Phase 3	TBD
zoptarelin doxorubicin	Aeterna Zentaris	Endometrial cancer	IV	Phase 3	TBD

PIPELINE DRUG LIST continued

Complete Response Letter (CRL) / Withdrawn Drugs

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	EXPECTED FDA APPROVAL
acetaminophen/ hydrocodone/ promethazine	Charlestone Labs/ Daiichi Sankyo	Symptoms associated with acute opioid withdrawal	Oral	CRL	TBD
acetaminophen/ hydrocodone/ promethazine	Charlestone Labs/ Daiichi Sankyo	Osteoarthritis	Oral	CRL	TBD
ataluren	PTC Therapeutics	CF with CFTR gene mutations; Becker muscular dystrophy	Oral	Withdrawn	N/A
buparlisib	Novartis	Breast cancer; Glioblastoma multiforme; Colorectal cancer; Prostate cancer; NSCLC; Non-Hodgkin's lymphoma; Squamous cell carcinoma	Oral	Withdrawn	N/A
clonidine	Biodelivery Sciences	Diabetic peripheral neuropathic pain	Topical	Withdrawn	N/A
encenicline HCl	Forum/ Mitsubishi Tanabe	Alzheimer's disease; Schizophrenia-related cognitive decline	Oral	Withdrawn	N/A
idalopirdine	H. Lundbeck A-S/ Otsuka	Alzheimer's disease (mild to moderate)	Oral	Withdrawn	N/A
lutetium lu 177 dotatate	Advanced Accelerator Applications/ Fujifilm	Neuroendocrine tumors (NET)	IV	CRL	TBD
naloxone	Amphastar	Opioid overdose	Intranasal	CRL	TBD
omarigliptin	Merck	T1DM; T2DM	Oral	Withdrawn	N/A
pradigastat	Novartis	Familial chylomicronemia syndrome; Hyperlipoproteinemia; Hypertriglyceridemia; T1DM; T2DM; Coronary artery disease	Oral	Withdrawn	N/A
rolapitant	OPKO Health/ Tesaro	Chemotherapy induced nausea and vomiting (CINV)	IV	CRL	TBD
sodium zirconium cyclosilicate	AstraZeneca/ ZS	Hyperkalemia	Oral	CRL	TBD
verubecestat	Merck	Alzheimer's disease (prodromal)	Oral	Withdrawn	N/A

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

CF Cystic Fibrosis

CKD Chronic Kidney Disease

COPD Chronic Obstructive Pulmonary Disease

CRL Complete Response Letter

CV Cardiovascular

CVD Cardiovascular Disease

FDA Food and Drug Administration

ER Extended-release

GI Gastrointestinal

GLP-1 Glucagon-like Peptide-1

H Half

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

NSCLC Non-Small Cell Lung Cancer

PCI Percutaneous Coronary Intervention

PDUFA Prescription Drug User Fee Act

PSA Psoriatic Arthritis

PSO Plaque Psoriasis

PTCA Percutaneous Transluminal Coronary Angioplasty

Q Quarter

RA Rheumatoid Arthritis

sBLA Supplemental Biologics License Application

SC Subcutaneous

SCCHN Squamous Cell Cancer of the Head and Neck

SLE Systemic Lupus Erythematosus

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

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