OPTUMRx®

RxOutlook®

1st Quarter 2021

COVID-19 is expected to continue as the leading story, but the overall drug pipeline continues to be robust and the number of novel FDA approvals in 2021 could approach record high

In 2020, SARSCoV-19 (COVID-19) infection and related vaccines and treatments were the biggest story of the year, but it also saw 53 new molecular entity or novel therapy approvals, the second most from the FDA, falling just short of 2018's high mark of 59 approvals. While COVID-19 is expected to remain a leading story in 2021, this year is likely to be another with a high number of overall drug approvals, potentially coming close to or exceeding 2018.

In this edition of RxOutlook, we highlight 9 key pipeline drugs with an expected launch between April to June of 2021. Of note, several new entrants for very common conditions are expected to launch in the second quarter. We are expecting numerous new therapies for the treatment of atopic dermatitis, across different routes of administration and mechanisms of action. This includes oral Janus kinase (JAK) inhibitors (eg, abrocitinib), topical JAK inhibitors (ruxolitinib), and injectable biologics (eg, tralokinumab). These agents will not only be competing with existing branded options approved for atopic dermatitis (eg, Dupixent® [dupilumab] and Eucrisa® [crisaborole]), but also other oral JAK inhibitors that are pursuing new indications for the condition (Olumiant® [baricitinib] and Rinvoq® [upadacitinib]). In addition to atopic dermatitis, a couple new therapies are expected for highly prevalent conditions affecting woman's health. Ibrexafungerp is a novel antifungal therapy for vulvovaginal candidiasis, or vaginal yeast infection and would be an alternative to oral and topical azole antifungals. A combination oral tablet containing relugolix, estradiol, and norethindrone acetate could be the second oral drug in the class for the treatment of uterine fibroids, which are common noncancerous tumors that while benign, can cause debilitating symptoms.

Orphan drugs continue to represent a significant percentage of overall drug approvals. This review will discuss four orphan drugs, including pegcetacoplan for the ultra-rare hematologic condition, paroxysmal nocturnal hemoglobinuria. Pegcetacoplan would be a potential competitor to Alexion's Soliris® (eculizumab) and Ultomiris® (ravulizumab-cwvz), two of the most expensive drugs in the U.S.

Approval decisions for other key novel therapies are expected in the second quarter but are not reviewed here. These drugs were covered in previous editions of RxOutlook, but have experienced regulatory delays. This list includes aducanumab (Alzheimer's disease), pegunigalsidase alfa (Fabry disease), and tanezumab (osteoarthritis).

Key pipeline drugs with FDA approval decisions expected between April to June 2021

Drug Name	Manufacturer	Indication/Use	Expected FDA Decision Date
Abrocitinib	Pfizer	Atopic dermatitis	4/30/2021
Tralokinumab	Leo Pharma	Atopic dermatitis	4/2021
Ruxolitinib (topical)	Incyte	Atopic dermatitis	2Q 2021
Infigratinib	BridgeBio Pharma	Cholangiocarcinoma*	2Q 2021
Pegcetacoplan	Apellis Pharmaceuticals	Paroxysmal nocturnal hemoglobinuria*	5/14/2021
Loncastuximab tesirine	ADC Therapeutics	Diffuse large B-cell lymphoma*	5/21/2021
Ibrexafungerp	Scynexis	Vulvovaginal candidiasis	6/1/2021

Drug Name	Manufacturer	Indication/Use	Expected FDA Decision Date
Relugolix/estradiol/ norethindrone acetate	Myovant Sciences	Uterine fibroids	6/1/2021
Cyclosporine ophthalmic emulsion	Santen Pharmaceutical	Vernal keratoconjunctivitis*	6/26/2021

* Orphan Drug Designation

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

Detailed Drug Insights

This section reviews the important characteristics (eg, therapeutic use, clinical profile, competitive environment and regulatory timeline) for key pipeline drugs with potential FDA approvals by the end of the 2nd Quarter 2021.

Read more

Extended Generic Pipeline Forecast

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

Read more

Extended Brand Pipeline Forecast

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

Read more

Key Pending Indication Forecast

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

Read more

Past and future reviews

Please note that RxOutlook highlights select near-term approvals. Some drugs may not appear in this issue because they have been reviewed in previous editions of RxOutlook. Drugs of interest that are earlier in development or with expected approvals beyond 2nd Quarter 2021 may appear in future reports; however, for those who need an initial look at the full pipeline, please refer to the Brand Pipeline Forecast Table found later in this report.

Getting acquainted with pipeline forecast terms

Clinical trial phases

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

Pipeline acronyms

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

Detailed insights on key drugs

Abrocitinib (Brand Name: To be determined)

Manufacturer: Pfizer
Regulatory designations: Breakthrough Therapy
Expected FDA decision: 4/30/2021

Therapeutic use

Abrocitinib is in development for the treatment of moderate-to-severe atopic dermatitis in patients 12 years of age and older.

Atopic dermatitis, often called eczema, is a common chronic condition that causes inflammation of the skin. The most common symptoms are skin dryness and extreme itchiness. These symptoms can lead to repeated scratching which can cause thickening and hardening of the skin and can also make the skin vulnerable to infection.

Atopic dermatitis usually begins during childhood, but it can persist or occur in adults as well. It affects an estimated 9.6 million children and about 16.5 million adults in the U.S.

- Treatment of moderate-to-severe atopic dermatitis in patients 12 years of age and older

Clinical profile

Abrocitinib is an oral selective inhibitor of Janus kinase (JAK) 1. Inhibition of JAK1 is thought to modulate multiple cytokines involved in pathophysiology of atopic dermatitis, including interleukin (IL)-4, IL-13, IL-31, IL-22, and thymic stromal lymphopoietin (TSLP).

Pivotal trial data:
The efficacy of abrocitinib was evaluated in the JADE clinical program, which included JADE MONO-1, JADE MONO-2, and JADE COMPARE. JADE MONO-1 (N = 387) and JADE MONO-2 (N = 391) were similarly designed Phase 3, randomized, double-blind, placebo-controlled studies in patients 12 years or older with moderate-to-severe atopic dermatitis. Patients received abrocitinib 100 mg, abrocitinib 200 mg, or placebo. The co-primary endpoints in both studies were the proportion of patients who achieved an Investigator Global Assessment (IGA) score of clear (0) or almost clear (1) skin and two-point or greater improvement relative to baseline; and the proportion of patients who achieved at least a 75% or greater change from baseline in their Eczema Area and Severity Index (EASI) score.

In JADE MONO-1, IGA response rates at week 12 were 43.8% with abrocitinib 200 mg ($p < 0.0001$ vs. placebo), 23.7% with abrocitinib 100 mg ($p = 0.0037$ vs. placebo), and 7.9% with placebo. EASI-75 response rates at week 12 were 62.7% with abrocitinib 200 mg ($p < 0.0001$ vs. placebo), 39.7% with abrocitinib 100 mg ($p < 0.0001$ vs. placebo), and 11.8% with placebo. In JADE MONO-2, IGA response rates at week 12 were 38.1% with abrocitinib 200 mg ($p < 0.001$ vs. placebo), 28.4% with abrocitinib 100 mg ($p < 0.001$ vs. placebo), and 9.1% with placebo. EASI-75 response rates at week 12 were 61.0% abrocitinib 200 mg ($p < 0.001$ vs. placebo), 44.5% with abrocitinib 100 mg ($p < 0.001$ vs. placebo), and 10.4% with placebo.

Abrocitinib (continued...)

- Selective JAK1 inhibitor
- Oral formulation
- IGA response rate: 38% to 44% with abrocitinib 200 mg vs. 24% to 28% with abrocitinib 100 mg vs. 8% to 9% with placebo
- EASI-75 response: 61% to 63% with abrocitinib 200 mg vs. 40% to 45% with abrocitinib 100 mg vs. 10% to 12% with placebo
- Common AEs: Nausea, nasopharyngitis, headache
- Dosing: Once daily

JADE COMPARE was a Phase 3, randomized, double-blind, placebo-controlled, active-controlled study in 837 patients 18 years or older with moderate-to-severe atopic dermatitis who were also on background topical therapy. Patients received abrocitinib 100 mg or 200 mg, Dupixent® (dupilumab), or placebo. The study had the same primary endpoints as the JADE MONO-1 and JADE MONO-2 trials. Results showed that the percentage of patients achieving each co-primary endpoint at week 12 was statistically superior with both doses of abrocitinib vs. placebo. Dupixent, the active control, also demonstrated superiority to placebo at week 12. Full results with numerical differences have not yet been reported.

Safety:
The most common adverse events with abrocitinib use were nausea, nasopharyngitis, and headache.

Dosing:
In the pivotal trials, abrocitinib was administered orally once daily.

Competitive environment

Abrocitinib would offer an oral and once daily treatment option for moderate-to-severe atopic dermatitis. Current pharmacotherapy options for atopic dermatitis include topical treatments such as corticosteroids, calcineurin inhibitors, and Eucrisa® (crisaborole). Dupixent, a subcutaneously (SC) administered IL-4 monoclonal antibody, is approved for moderate-to-severe atopic dermatitis in patients whose disease is not adequately controlled with topical treatments. Oral JAK inhibitors would be competing directly with Dupixent, the current market leader in the severe atopic dermatitis subpopulation.

In the pivotal trials, abrocitinib demonstrated improvements in the clinical efficacy endpoints vs. placebo; however, there is a lack of reported data comparing abrocitinib to Dupixent. While the efficacy appears similar to Dupixent when compared indirectly, the use of oral JAK inhibitors for atopic dermatitis may be limited by their safety profile. Currently approved JAK inhibitors have boxed warnings for serious infections, malignancy, and thrombosis. These warnings are likely to apply to abrocitinib as well, since it is also a JAK inhibitor. Additionally, Pfizer recently announced the results of a post-marketing safety study for their other non-selective JAK inhibitor, Xeljanz® (tofacitinib), in patients with rheumatoid arthritis. While the study population was different, Xeljanz was associated with higher rates of major adverse cardiovascular events (MACE) and malignancies.

In addition to abrocitinib, Eli Lilly's oral JAK inhibitor Olumiant® (baricitinib), and AbbVie's Rinvoq® (upadacitinib), are also being reviewed by the FDA for atopic dermatitis. A decision for Olumiant is expected in the first or second quarter of 2021 and for Rinvoq a decision is expected in August 2021. Another treatment in the pipeline for moderate-to-severe atopic dermatitis is Leo Pharma's IL-13 monoclonal antibody, tralokinumab. Unlike some of its competitors that have been approved for other uses or indications, abrocitinib is expected to be limited to atopic dermatitis.

For reference, the Wholesale Acquisition Cost (WAC) for Dupixent is approximately $41,000 per year.

- Advantages: Oral and once daily treatment option for atopic dermatitis, large target population
- Disadvantages: Alternatives currently available and others likely to be approved in 2021 (including other oral JAK inhibitors), potential safety limitations, lack of robust head-to-head trial data vs. Dupixent, initial indication limited to 12 years of age and older (vs. 6 years and older for Dupixent)
- Reference WAC (Dupixent): ~$41,000 per year

Tralokinumab (Brand Name: To be determined)

Manufacturer: Leo Pharma
Expected FDA decision: 4/2021

Therapeutic use

Tralokinumab is in development for the treatment of adults with moderate-to-severe atopic dermatitis.

Clinical profile

Tralokinumab is a monoclonal antibody that works by neutralizing the interleukin (IL)-13 cytokine. IL-13 plays a key role in driving the underlying chronic inflammation in atopic dermatitis.

Pivotal trial data:
The efficacy of tralokinumab was evaluated in three Phase 3, randomized, double-blind, placebo-controlled studies: ECZTRA 1, ECZTRA 2 and ECZTRA 3. ECZTRA 1 and ECZTRA 2 included 802 and 794 adult patients, respectively, and evaluated tralokinumab as monotherapy in adults with moderate-to-severe atopic dermatitis. The primary endpoints were IGA score of 0 or 1 at week 16 and EASI-75 at week 16. Overall, more patients who received tralokinumab vs. placebo achieved an IGA score of 0 or 1: 15.8% vs. 7.1% in ECZTRA 1 ($p = 0.002$) and 22.2% vs. 10.9% in ECZTRA 2 ($p < 0.001$) and EASI-75: 25.0% vs. 12.7% ($p < 0.001$) and 33.2% vs. 11.4% ($p < 0.001$).

ECZTRA 3 evaluated the efficacy of tralokinumab, in combination with topical corticosteroids, in 380 adult patients with moderate-to-severe atopic dermatitis. The primary endpoints were the same as ECZTRA 1 and 2. At week 16, more tralokinumab-treated patients than placebo achieved the IGA response: 38.9% vs. 26.2% ($p = 0.015$) and EASI-75: 56.0% vs. 35.7% ($p < 0.001$).

Safety:
The most common adverse events with tralokinumab use were viral upper respiratory tract infections, conjunctivitis, headache, upper respiratory tract infection, and injection site reaction.

Dosing:
In the pivotal trials, tralokinumab was administered SC every 2 weeks.

Tralokinumab (continued...)

- Treatment of adults with moderate-to-severe atopic dermatitis
- IL-13 monoclonal antibody
- SC formulation
- GA response (monotherapy studies): 16% to 22% vs. 7% to 11% with placebo
- IGA response (in combo with topicals): 39% vs. 26% with placebo
- EASI-75 response (monotherapy studies): 25% to 33% vs. 11% to 13% with placebo
- EASI-75 response (in combo with topicals): 56% vs. 36% with placebo
- Common AEs: Viral upper respiratory tract infections, conjunctivitis, headache, upper respiratory tract infection, injection site reaction
- Dosing: Once every 2 weeks

Competitive environment

If approved, tralokinumab would offer a novel mechanism of action (MOA) for the treatment of moderate-to-severe atopic dermatitis. However, as discussed above, tralokinumab would be competing not only with existing treatment options like Dupixent, but also potentially several JAK inhibitors as well.

There is a lack of data comparing tralokinumab against any of its potential competitors for moderate-to-severe atopic dermatitis and indirectly, the efficacy does appear more modest. The proposed initial indication will be limited to adult patients which will reduce its use as atopic dermatitis is highly prevalent among children and adolescents. From a dosing perspective and in contrast to JAK inhibitors, tralokinumab requires administration via SC injection like Dupixent.

For reference, the WAC for Dupixent is approximately $41,000 per year.

- Advantages: Novel MOA for the treatment of atopic dermatitis, large target population
- Disadvantages: Alternatives currently available and others likely to be approved in 2021, lack of head-to-head data vs. competitors, initial indication limited to adults, SC formulation
- Reference WAC (Dupixent): ~$41,0000 per year

Ruxolitinib topical cream (Brand Name: To be determined)

Manufacturer: Incyte
Expected FDA decision: 2Q 2021

Therapeutic use

Ruxolitinib topical cream is in development for the treatment of mild-to-moderate atopic dermatitis in patients 12 years of age and older.

Ruxolitinib is currently available as an oral brand (Jakafi®) for the treatment of myelofibrosis, polycythemia vera, and graft vs. host disease.

- Treatment of mild-to-moderate atopic dermatitis in patients 12 years of age and older

Clinical profile

Ruxolitinib is a selective JAK1/JAK2 inhibitor.

- Selective JAK1/JAK2 inhibitor
- Topical formulation

Pivotal trial data:
The efficacy of topical ruxolitinib was evaluated in two Phase 3, randomized, double-blind, vehicle-controlled studies (TRuE-AD1 and TRuE-AD2) in 1,208 patients age 12 years and older with mild-to-moderate atopic dermatitis. Patients were randomized to one of three arms for 8 weeks: ruxolitinib cream 0.75% applied twice daily, ruxolitinib cream 1.5% applied twice daily, or vehicle cream applied twice daily. The primary endpoint was the proportion of patients achieving IGA response, defined as a score of 0 (clear) or 1 (almost clear) with at least a 2-point improvement from baseline at week 8. A key secondary endpoint was EASI-75 response.

In the pooled analysis, IGA was achieved in 52.6%, 44.7%, and 11.5% of patients treated with ruxolitinib 1.5%, ruxolitinib 0.75%, and vehicle, respectively ($p < 0.0001$ for both dosages vs. placebo). EASI-75 was achieved in 62.0%, 53.8%, and 19.7% of patients treated with ruxolitinib 1.5%, ruxolitinib 0.75%, and vehicle, respectively ($p < 0.0001$ for both dosages vs. placebo).

- IGA response: 45% to 53% vs. 12% with placebo
- EASI-75 response: 53% to 62% vs. 20% with placebo

Safety:
Safety data is limited but topical ruxolitinib appeared to be well tolerated in the pivotal trials and was not associated with clinically significant application site reactions.

- No significant safety signals based on limited data

Dosing:
In the pivotal trials, ruxolitinib was administered topically twice daily.

- Dosing: Twice daily

Ruxolitinib topical cream (continued...)

Competitive environment

If approved, ruxolitinib would be the first topical JAK inhibitor for atopic dermatitis. While oral JAK inhibitors have been associated with serious adverse events, a topical formulation is expected to reduce systemic exposure and potentially reduce some of the safety concerns associated with the class. According to the data available, topical ruxolitinib appears to be well tolerated with no major safety signals.

While other atopic dermatitis drugs with potential approval in 2021 are pursuing an indication for moderate-to-severe patients, ruxolitinib was studied in mild-to-moderate patients. The mild-to-moderate subpopulation is significantly larger but is also easier to treat with topical corticosteroids and calcineurin inhibitors. In this population, ruxolitinib would also be competing with Pfizer's topical Eucrisa. The efficacy data for topical ruxolitinib appears to be more promising when compared indirectly, but Eucrisa is already approved for adult and pediatric patients 3 months of age and older.

Like the products discussed above, there are a lack of data comparing ruxolitinib against alternative agents used for atopic dermatitis.

For reference, the WAC for Eucrisa is approximately $8,000 per year.

- Advantages: Potentially the first topical JAK inhibitor for atopic dermatitis, well tolerated, large target population
- Disadvantages: Alternatives currently available and others likely to be approved in 2021, lack of head-to-head data vs. competitors, use will be limited to mild-to-moderate cases and initial indication is expected to be in patients 12 years and older
- Reference WAC (Eucrisa): ~$8,000 per year

Infigratinib (Brand Name: To be determined)

Manufacturer: BridgeBio Pharma
Regulatory designations: Orphan Drug, Fast Track
Expected FDA decision: 2Q 2021 *(being reviewed under the Real-Time Oncology Review pilot program)*

Therapeutic use

Infigratinib is in development for the treatment of patients with unresectable locally advanced or metastatic cholangiocarcinoma with *fibroblast growth factor receptor 2 (FGFR2)* gene fusions or translocations.

Cholangiocarcinoma is a cancer of the bile duct. This includes both intrahepatic and extrahepatic bile duct cancers. It's a relatively rare cancer in the U.S. with an estimated 8,000 new cases per year but the actual number is likely higher, because these cancers can be hard to diagnose, and some might be misclassified as other types of cancer. *FGFR* mutations are present in 13% to 17% of intrahepatic cholangiocarcinomas. The 5-year relative survival rate in patients with intrahepatic forms of the cancer is about 10%.

- Treatment of patients with unresectable locally advanced or metastatic cholangiocarcinoma FGFR2 gene fusions or translocations

Clinical profile

Infigratinib is a FGFR1-3 tyrosine kinase inhibitor. Alterations in *FGFR* genes, which regulate cell proliferation and survival, can promote aberrant FGF pathway activation and tumorigenesis.

- FGFR1-3 tyrosine kinase inhibitor
- Oral formulation
- ORR: 26.9%
- Median PFS: 6.8 months
- Median OS: 12.5 months
- Common AEs: Hyperphosphatemia, fatigue, stomatitis, alopecia, constipation
- Dosing: Once daily

<u>Pivotal trial data:</u>
The efficacy of infigratinib was evaluated in a Phase 2, single arm, open label study in 71 patients with cholangiocarcinoma and *FGFR2* fusions/translocations. Patients received infigratinib for 21 days of 28-day cycles until unacceptable toxicity, disease progression, investigator discretion, or withdrawal of consent. The primary endpoint was the investigator-assessed confirmed overall response rate (cORR). Secondary endpoints included progression-free survival (PFS) and overall survival (OS).

The cORR was 26.9% (95% CI: 16.8, 39.1). For patients who had received one or fewer prior treatment regimens, the cORR was 39.3%, whereas patients who had received two or more treatment regimens had a cORR of 17.9%. Median PFS was 6.8 months (95% CI: 5.3, 7.6) and median OS was 12.5 months (95% CI: 9.9, 16.6 months).

<u>Safety:</u>
The most common adverse events with infigratinib use were hyperphosphatemia, fatigue, stomatitis, alopecia, and constipation.

<u>Dosing:</u>
In the pivotal trial, infigratinib was administered orally once daily.

Infigratinib (continued...)

Competitive environment

Infigratinib would provide an additional treatment option in patients with cholangiocarcinoma and *FGFR2* fusions or rearrangements. There is a significant unmet need as limited treatment options are available for this type of cancer and patients have poor prognosis.

For patients with unresectable or metastatic disease, first-line treatment is chemotherapy, but response rates are low. Incyte's FGFR inhibitor, Pemazyme® (pemigatinib), was approved in April 2020 and so infigratinib would be the second to market for this specific niche of patients. While it is difficult to compare across clinical trials, the efficacy of Pemazyme and infigratinib appear similar.

Infigratinib is being evaluated in earlier settings of cholangiocarcinoma, urothelial carcinoma, and achondroplasia, a rare bone growth condition in children.

For reference, the WAC for Pemazyre is approximately $17,000 per 21-day cycle.

- Advantages: High unmet need, oral and once daily, potential expanded uses
- Disadvantages: Second-to-market drug in the class, narrow initial indication
- Reference WAC (Pemazyre): ~$17,000 per 21-day cycle

Pegcetacoplan (Brand Name: To be determined)

Manufacturer: Apellis Pharmaceuticals
Regulatory designations: Orphan Drug, Fast Track
Expected FDA decision: 5/14/2021

Therapeutic use

Pegcetacoplan is in development for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).

PNH is a rare acquired hematopoietic stem cell disorder in which patients develop hemolytic anemia due to red blood cell (RBCs) prematurely breaking down. Patients can experience symptoms such as fatigue, jaundice, hemoglobinuria, and difficulty breathing. Thrombosis (blood clots), occurs in 15% to 30% of patients with PNH and it is the leading cause of death.

The prevalence is estimated to be between 0.5 to 1.5 per million people in the general population. The disorder can affect any age group and the median age at diagnosis is during the 30s.

- Treatment of adults with PNH

Clinical profile

Pegcetacoplan is a targeted C3 inhibitor. The complement cascade is a part of the immune system that is responsible for recognizing and eliminating pathogens and damaged cells in the blood. In PNH, blood cells lack complement regulatory proteins, so the body recognizes healthy RBCs as damaged and this leads to uncontrolled activation of the complement cascade, initiated at C3, and results in the destruction of RBCs.

- Targeted C3 inhibitor
- SC formulation
- Adjusted mean hemoglobin difference of 3.8 g/dL vs. Soliris
- Common AEs: Injection site reactions, diarrhea, infections
- Dosing: Twice a week

<u>Pivotal trial data:</u>
The efficacy of pegcetacoplan was evaluated in PEGASUS, a Phase 3, randomized, open-label, active-comparator controlled study in 80 adults with PNH. Patients must have been on Soliris® (eculizumab), a C5 inhibitor used for PNH, for at least 3 months, with a hemoglobin level of < 10.5 g/dL at the screening visit. During a 4-week run-in period, patients received pegcetacoplan in addition to their current dose of Soliris. During the 16-week randomized, controlled period, patients were randomized to receive either monotherapy pegcetacoplan or Soliris. The primary endpoint was change in hemoglobin level from baseline (start of run-in period) to week 16. A key secondary endpoint was blood transfusion avoidance.

Pegcetacoplan met the study's primary endpoint for efficacy, demonstrating superiority to Soliris with a statistically significant improvement in adjusted mean hemoglobin at week 16. The least-squares (LS) mean changes in hemoglobin were 2.37 g/dL with pegcetacoplan vs. -1.47 g/dL with Soliris (difference of 3.8 g/dL vs. Soliris; $p < 0.0001$). Overall, 85% of pegcetacoplan-treated patients were transfusion-free over 16 weeks vs. 15% of Soliris-treated patients.

Pegcetacoplan (continued...)

Safety:
The most common adverse events with pegcetacoplan use were injection site reactions, diarrhea, and infections.

Dosing:
In the pivotal trial, pegcetacoplan was administered SC twice a week.

Competitive environment

If approved, pegcetacoplan would be the first C3 targeted therapy for the treatment of PNH. The only curative treatment for PNH is allogeneic hematopoietic cell transplantation, but this is generally reserved for patients with severe complications associated with PNH. Since 2007, Alexion's C5 inhibitor, Soliris, has been the standard of care for the treatment of PNH. In 2018, Alexion's next-generation C5 inhibitor, Ultomiris® (ravulizumab), was approved based on non-inferiority data to Soliris. While pegcetacoplan is administered via SC injection, both Soliris and Ultomiris require IV administration. Ultomiris is given every 8 weeks and Soliris is given every 2 weeks.

In the head-to-head trial vs. Soliris, the improvements in hemoglobin and significant reductions in transfusion dependence were promising with pegcetacoplan. However, pegcetacoplan was associated with higher rates of adverse events such as diarrhea and injection site reactions; there were also 3 discontinuations due to adverse events with pegcetacoplan vs. none with Soliris.

Pegcetacoplan would be a late market entry and its use would be initially limited to PNH, which is an ultra-rare condition. In contrast, Alexion's C5 inhibitors have been available for nearly 15 years and are approved for additional indications, including atypical hemolytic uremic syndrome, generalized myasthenia gravis, and neuromyelitis optica spectrum disorder.

For reference, the WAC for Ultomiris is approximately $458,000 per year.

- Advantages: Novel MOA for the treatment of PNH, promising head-to-head efficacy data vs. Soliris, SC administration vs. existing IV administered treatments
- Disadvantages: Late market entry, higher discontinuation rate vs. Soliris, twice weekly injections
- Reference WAC (Ultomiris): ~$458,000 per year

Loncastuximab tesirine (Brand Name: To be determined)

Manufacturer: ADC Therapeutics
Regulatory designations: Orphan Drug
Expected FDA decision: 5/21/2021

Therapeutic use

Loncastuximab tesirine is in development for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL).

DLBCL is an aggressive and common form of non-Hodgkin's lymphoma (NHL). The rate of new cases of DLBCL was 5.6 per 100,000 per year based on 2013 to 2017 cases. While this is a fast-growing cancer, approximately 60% of patients with DLBCL can be effectively treated with first-line chemoimmunotherapies. The 5-year relative survival rate for DLBCL is 63.8%.

- Treatment of relapsed or refractory DLBCL

Clinical profile

Loncastuximab tesirine is an antibody-drug conjugate comprising a humanized anti-CD19 monoclonal antibody conjugated to a pyrrolobenzodiazepine dimer cytotoxin.

CD19 is a target for immunotherapy in DLBCL as it is normally expressed during B-cell development. Once bound to a CD19-expressing cell, loncastuximab tesirine is designed to be internalized by the cell, where it metabolized by enzymes that release the cytotoxic component.

- Antibody-drug conjugate (CD19 monoclonal antibody)
- IV formulation
- ORR: 48.3%
- ORR (FL): 40% to 50%
- Common AEs: Neutropenia, thrombocytopenia, increased GGT, anemia
- Dosing: Once every 3 weeks

<u>Pivotal trial data:</u>
The efficacy of loncastuximab tesirine was evaluated in LOTIS 2, a Phase 2, open-label, single-arm study in 145 patients with relapsed or refractory DLBCL following at least 2 lines of prior systemic therapy. Patients had received a median of 3 prior lines of therapy. The primary endpoint was overall response rate (ORR). Loncastuximab tesirine achieved an ORR of 48.3%. As of the last data cut-off, the median duration of response (DOR) was 10.25 months.

<u>Safety:</u>
The most common adverse events with loncastuximab tesirine use were neutropenia with low incidence of febrile neutropenia, thrombocytopenia, increased gamma-glutamyl transferase (GGT), and anemia.

<u>Dosing:</u>
In the pivotal trial, loncastuximab tesirine was administered intravenously (IV) once every 3 weeks for up to one year or until disease progression, unacceptable toxicity, or other discontinuation criteria, whichever occurred first.

Loncastuximab tesirine (continued...)

Competitive environment

Loncastuximab tesirine would offer a novel chemotherapy-free treatment option for relapsed/refractory DLBCL. While treatment options were historically limited in this setting, several products have been approved in the last couple years. Like loncastuximab tesirine, Genentech's CD79b-directed antibody-drug conjugate, Polivy® (polatuzumab vedotin-piiq), was approved in June 2019 in the third-line relapsed/refractory DLBCL setting. Unlike loncastuximab tesirine, Polivy requires use in combination with chemotherapy. MorphoSys' CD19 monoclonal antibody, Monjuvi® (tafasitamab-cxix), was approved in July 2020 for relapsed/refractory DLBCL in combination with Revlimid® (lenalidomide). Finally, highly effective chimeric antigen receptor (CAR) T cell therapies were also recently approved for DLBCL (eg, Yescarta® [axicabtagene ciloleucel]).

Since it can be used as monotherapy, loncastuximab tesirine appears to be relatively well tolerated and could be an alternative to CAR T cell therapies, which are costly and have delays in therapy due to the long production process.

The lack of late stage trial data and the narrow initial indication for loncastuximab tesirine will limit its early use but additional studies are ongoing that could expand the use of loncastuximab tesirine in the future, including in earlier settings of DLBCL.

For reference, the WAC for Polivy is approximately $15,000 per cycle.

- Advantages: Novel chemotherapy-free treatment option for DLBCL, potential future use in earlier settings of DLBCL
- Disadvantages: Alternatives available, narrow initial indication, lack of late stage trial data, IV administration
- Reference WAC (Polivy): ~$15,000 per cycle

Ibrexafungerp (Brand Name: To be determined)

Manufacturer: Scynexis
Regulatory designations: Fast Track
Expected FDA decision: 6/1/2021

Therapeutic use

Ibrexafungerp is in development for the treatment of vulvovaginal candidiasis (VVC).

VVC, also known as vaginal yeast infection caused by *Candida*, is the second most common type of vaginal infection after bacterial vaginal infections. Although most VVC cases are mild, some women can develop severe infections involving redness, swelling, and cracks in the wall of the vagina.

While the exact number of VVC cases is unknown, an estimated 1.4 million outpatient visits occur annually in the U.S. An estimated 75% of women will have at least one episode of VVC in their lifetime, and 40% to 45% will have two or more episodes.

- Treatment of VVC

Clinical profile

Ibrexafungerp is a novel glucan synthase inhibitor. It has demonstrated broad spectrum antifungal activity, in vitro and in vivo, against multidrug-resistant pathogens, including azole- and echinocandin-resistant strains.

- Glucan synthase inhibitor
- Oral formulation
- Clinical cure rate: 51% vs. 29% with placebo in VANISH-303; 63% vs. 44% with placebo in VANISH-306
- Common AEs: Gastrointestinal events (diarrhea/loose stool, nausea, abdominal pain)
- Dosing: Two doses 12 hours apart (one-day course)

Pivotal trial data:
The efficacy of ibrexafungerp was evaluated in two identical, Phase 3, randomized, double-blind, placebo-controlled studies (VANISH-303 and VANISH-306) in patients presenting with an acute episode of VVC. VANISH-303 enrolled 376 patients and VANISH-306 enrolled 455 patients. Patients received a one-day course of ibrexafungerp or placebo. Primary efficacy analyses were conducted in the modified-intent-to-treat (mITT) population, comprised of patients with culture confirmed *Candida spp*. infection at baseline. The primary endpoint of the trials was clinical cure rate, defined as the complete resolution of all signs and symptoms at the Test-of-Cure (TOC) visit (day 10).

In VANISH-303, the clinical cure rate was 50.5% and 28.6% for ibrexafungerp and placebo, respectfully ($p < 0.001$). In VANISH-306, the clinical cure rate was 63.3% and 44.0% for ibrexafungerp and placebo, respectfully ($p < 0.01$).

Safety:
The most common adverse events with ibrexafungerp use were gastrointestinal events (diarrhea/loose stool, nausea and abdominal pain).

Dosing:
In the pivotal trials, ibrexafungerp was administered orally as a one-day course (two doses 12 hours apart).

Ibrexafungerp (continued...)

Competitive environment

Ibrexafungerp would offer a novel MOA for the treatment of VVC. The current standard of care are azole antifungals, including topical products (typically over-the-counter) and oral fluconazole (available as generics). While the majority of patients are treatable with existing therapies that are available generically, many women also have recurrent infections or have resistant strains of *Candida*. Ibrexafungerp has broad-spectrum antifungal activity and provides an additional treatment option, particularly in difficult-to-treat patients. An earlier Phase 2 study found that ibrexafungerp may provide some benefit vs. fluconazole for persistent antifungal activity, but the trial was not powered for statistical significance. Based on the available evidence from preclinical studies in animals, ibrexafungerp may be safer in pregnancy vs. fluconazole, which is not recommended in pregnancy.

The initial target population for ibrexafungerp as a treatment for VVC is large given the high prevalence of infections, and its use could be further expanded as ibrexafungerp is being evaluated in the CANDLE study vs. fluconazole as a preventative treatment for recurrent VVC. Results are expected in the second half of 2021. Additionally, ibrexafungerp is being evaluated for invasive fungal infections which is an area of high unmet need but limited to the hospital setting.

- Advantages: Novel MOA, large target population, potentially safer in pregnancy vs. azole antifungals, also in development for additional uses
- Disadvantages: Generic alternatives available, lack of robust head-to-head trial data vs. fluconazole

Relugolix/estradiol/norethindrone acetate (Brand Name: To be determined)

Manufacturer: Myovant Sciences
Expected FDA decision: 6/1/2021

Therapeutic use

- Treatment of women with heavy menstrual bleeding associated with uterine fibroids

Relugolix/estradiol/norethindrone (relugolix combination therapy) is in development for the treatment of women with heavy menstrual bleeding associated with uterine fibroids.

Uterine fibroids (or leiomyomas) are noncancerous tumors that develop in or on the muscular walls of the uterus. Although uterine fibroids are benign, they can cause debilitating symptoms such as heavy menstrual bleeding, pain, increased abdominal symptoms, urinary frequency or retention, constipation, pregnancy loss, and, in some cases, infertility.

Fibroids are most common in women aged 30 to 40 years, but they can occur at any age. They can be detected in up to 80% of women by 50 years of age and an estimated 5 million women in the U.S. suffer from symptoms of uterine fibroids.

Relugolix is currently available as a single-ingredient tablet formulation under the brand name Orgovyx™ for the treatment of prostate cancer.

Clinical profile

- GnRH receptor antagonist, estrogen, and progestin combination therapy
- Oral formulation
- Response rate: 71% to 73% vs. 15% to 19% with placebo
- Common AEs: Hot flush, menorrhagia, headache
- Dosing: Once daily

Relugolix is a gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces ovarian estradiol, a hormone known to stimulate the growth of uterine fibroids and endometriosis.

GnRH receptor antagonists can cause bone loss due to reduced levels of circulating estrogen. Exogenous estradiol is included in the combination to increase bone resorption and reduce the resultant bone loss. Norethindrone acetate may protect the uterus from the potential adverse endometrial effects of unopposed estrogen.

Pivotal trial data:
The efficacy of relugolix combination therapy was evaluated in two identical, Phase 3, randomized, double-blind, placebo-controlled studies (LIBERTY 1 and LIBERTY 2) in in women with uterine fibroids and heavy menstrual bleeding. LIBERTY 1 enrolled 388 women and LIBERTY 2 enrolled 382 women. Patients were randomized to one of three groups: relugolix in combination with estradiol and norethindrone acetate (relugolix combination therapy) for 24 weeks, relugolix monotherapy for 12 weeks followed by relugolix combination therapy for an additional 12 weeks, or placebo for 24 weeks. The primary endpoint was the response rate, defined as a menstrual blood loss volume of less than 80 mL and a 50% or greater reduction from baseline in menstrual blood loss volume during the last 35 days of the 24-week treatment period.

LIBERTY 1 and 2 met the primary endpoint ($p < 0.0001$) with 73.4% and 71.2% of women receiving relugolix combination therapy for 24 weeks meeting the criteria for response compared with 18.9% and 14.7% of women receiving placebo at 24 weeks, respectively. On average, women receiving relugolix combination therapy in both studies experienced an 84.3% reduction in menstrual blood loss from baseline ($p < 0.0001$).

Relugolix/estradiol/norethindrone acetate (continued...)

Safety:
The most common adverse events with relugolix combination therapy were hot flush, menorrhagia, and headache.

Dosing:
In the pivotal trials, relugolix combination therapy was administered orally once daily.

Competitive environment

If approved, relugolix combination therapy would be the second oral GnRH antagonist for the treatment of uterine fibroids. AbbVie's GnRH antagonist combination therapy, Oriahnn® (elagolix/ estradiol/norethindrone acetate), was approved in May 2020. Like Oriahnn, relugolix would be competing with other treatment modalities for uterine fibroids. Management is generally tailored to the size and location of fibroids, the patient's age, symptoms, and desire to maintain fertility. Medical therapies include hormonal contraceptives, tranexamic acid, nonsteroidal anti-inflammatory drugs (NSAIDs), injectable GnRH agonists, and progestin-releasing intrauterine devices (IUDs). Surgical treatment, such as hysterectomy and myomectomy, is also an option in some women.

Compared indirectly to Oriahnn, relugolix appears to be similarly effective in reducing menstrual bleeding. Oriahnn has a boxed warning for increased risk of vascular events and thrombotic or thromboembolic disorders and may cause bone loss over time which may not be reversible. Most of these warnings are likely class-wide but relugolix combination therapy may not be associated with the same severity of bone loss as Oriahnn. In the pivotal trials, bone mineral density changes for relugolix combination therapy were comparable to placebo.

For reference, the WAC for Oriahnn is approximately $12,700 per year.

- Advantages: Additional oral GnRH antagonist treatment for uterine fibroids, large target population, also in development for endometriosis
- Disadvantages: Alternative treatments available (including AbbVie's GnRH combination - Oriahnn), lack of robust head-to-head trial data vs. competitors
- Reference WAC (Oriahnn): ~$12,700 per year

Cyclosporine (Brand Name: Verkazia)

Manufacturer: Santen Pharmaceutical
Regulatory designations: Orphan Drug
Expected FDA decision: 6/26/2021

Therapeutic use

Cyclosporine topical ophthalmic emulsion, 0.1% is in development for the treatment of severe vernal keratoconjunctivitis (VKC) in patients ages 4 to 18.

VKC is a chronic, non-contagious allergic eye disorder with seasonal recurrences usually appearing during the spring or warm weather. VKC symptoms include inflammation of the outer membrane of the eye which causes redness, blurred vision, and itchiness. In very severe cases, VKC can cause scarring of the cornea, or clouding of the lens (cataract), leading to temporary or permanent vision loss.

Onset of VKC typically occurs at about 11 years of age but can range from 3 to 25 years of age. The prevalence of VKC varies widely depending on the region and climate but is less frequent in areas such as Northern Europe and North America compared to global rates. As an example, one study found a prevalence of 3.2 per 10,000 in the European Union.

- Treatment of severe VKC in patients ages 4 to 18

Clinical profile

Cyclosporine is a calcineurin inhibitor thought to work by inhibiting T helper type 2 (Th2) proliferation and interleukin 2 production and by reducing levels of immune cells and mediators acting on the ocular surface and conjunctiva.

- Calcineurin inhibitor
- Ophthalmic emulsion

<u>Pivotal trial data:</u>
The efficacy of cyclosporine was evaluated in the VEKTIS trial, a Phase 3, double-masked, vehicle-controlled study in 169 pediatric patients (4 to younger than 18 years) with active severe VKC and severe keratitis. Patients were randomized to cyclosporine 0.1% eye drops 4 times daily (high dose), cyclosporine twice daily (low dose) plus vehicle twice daily, or vehicle 4 times daily for 4 months. The primary endpoint was a mean composite score that reflected keratitis as measured by corneal fluorescein staining (CFS), rescue medication use (dexamethasone), and corneal ulceration over the 4 months. A positive value in the patient composite efficacy score indicates improvement.

- Mean composite score: statistically significant difference for both the high-dose (0.76) and the low-dose (0.67) cyclosporine groups vs. vehicle
- Common AEs: Instillation site pain
- Dosing: Two to four times daily

Differences in least-squares means vs. vehicle for the primary endpoint were statistically significant for both the high-dose (0.76; $p = 0.007$) and the low-dose (0.67; $p = 0.010$) groups, with treatment effect mainly driven by CFS score. Significant differences were found between both active treatment groups and vehicle for use of rescue medication.

Cyclosporine (continued...)

Safety:
The most common adverse reaction with cyclosporine use was instillation site pain.

Dosing:
In the pivotal trial, cyclosporine was administered as one drop into each eye two or four times a day.

Competitive environment

If approved, cyclosporine ophthalmic emulsion, 0.1% would provide an additional treatment option for VKC. Patients with mild forms of VKC can be treated with non-pharmacological treatments such as cool compresses or ophthalmic antihistamines. Mast-cell stabilizers (eg, lodoxamide tromethamine) can prevent flare-ups and are the only approved treatments for VKC but they have little impact on the symptoms of the condition. Patients with more severe forms of the disease have more limited treatment options. Topical steroid preparations are the most effective therapy, but their use is limited by long-term adverse events (eg, glaucoma). Currently available cyclosporine ophthalmic formulations, Restasis® and Cequa®, are available but there is limited data for their use in VKC and they contain lower concentrations of cyclosporine (0.05% and 0.09%, respectively) vs 0.1% for Verkazia.

However, this formulation of cyclosporine would have a narrow indication as VKC is a rare condition and its use will likely be limited to severe patients since it was only studied in that patient population. The primary place in therapy will likely be as a corticosteroid-sparing agent in these patients.

- Advantages: Additional approved treatment for VKC, limited options for severe cases of the disease
- Disadvantages: Likely to be used after other non-pharmacological and pharmacological treatments have failed, small target population

1st Quarter 2021

Extended generic pipeline forecast

OptumRx generic pipeline forecast

Brand name	Generic name	Brand manufacturer	Dosage form	Strengths available as generic	Possible launch date
2021 Possible launch date					
BEPREVE	bepotastine	Bausch Health	Ophthalmic	All	2021
THALOMID	thalidomide	Celgene	Capsule	All	2021
PRESTALIA	perindopril/amlodipine	Symplmed	Tablet	All	2021
DALIRESP	roflumilast	AstraZeneca	Tablet	All	2021
ULTRAVATE	halobetasol	Sun	Lotion	All	2021
DEXILANT	dexlansoprazole	Takeda	Capsule, delayed-release	All	2021
DORYX MPC	doxycycline hyclate	Mayne	Tablet, delayed-release	All	2021
RESTASIS	cyclosporine	Allergan	Ophthalmic	All	2021
BYETTA	exenatide	AstraZeneca	Subcutaneous	All	2021
DUREZOL	difluprednate	Alcon	Ophthalmic	All	2021
TOVIAZ	fesoterodine	Pfizer	Tablet, extended-release	All	2021
SUPRENZA	phentermine	Citius/Akrimax	Tablet, orally disintegrating	All	2021
CHANTIX	varenicline	Pfizer	Tablet	All	1H-2021
OSMOPREP	sodium biphosphate/sodium phosphate	Bausch Health	Tablet	All	1Q-2021
OMNARIS	ciclesonide	Covis	Intranasal	All	1Q-2021
SYNDROS	dronabinol	Insys Therapeutics	Oral solution	All	1Q-2021
ABSORICA	isotretinoin	Sun	Capsule	All	1Q-2021
CUVPOSA	glycopyrrolate	Merz	Oral solution	All	1Q-2021
GLUCAGON	glucagon	Eli Lilly	Injection	All	1Q-2021
CRIXIVAN	indinavir	Merck	Capsule	All	02-2021
NORTHERA	droxidopa	H. Lundbeck	Capsule	All	02-2021
MYALEPT	metreleptin	Aegerion	Subcutaneous	All	02-2021
FORTICAL	calcitonin salmon recombinant	Upsher-Smith	Intranasal	All	02-2021
IMPAVIDO	miltefosine	Knight Therapeutics	Capsule	All	03-2021
ACTOPLUS MET XR	pioglitazone/metformin	Takeda	Tablet, extended-release	All	03-2021

Brand name	Generic name	Brand manufacturer	Dosage form	Strengths available as generic	Possible launch date
NEUPRO	rotigotine	UCB	Transdermal patch	All	03-2021
POMALYST	pomalidomide	Celgene	Capsule	All	2Q-2021
VELPHORO	sucroferric oxyhydroxide	Vifor Fresenius Medical Care Renal Pharma (VFMCRP)	Tablet, chewable	All	2Q-2021
LYRICA CR	pregabalin	Pfizer	Tablet, extended-release	All	04-2021
ERAXIS	anidulafungin	Pfizer	Intravenous	All	04-2021
FORTEO	teriparatide	Eli Lilly	Injection	All	04-2021
PERFOROMIST	formoterol fumarate	Mylan	Inhalation	All	06-2021
INTELENCE	etravirine	Janssen	Tablet	All	06-2021
NARCAN	naloxone	Emergent BioSolutions	Intranasal	All	2H-2021
FERAHEME	ferumoxytol	AMAG Pharmaceuticals	Intravenous	All	07-2021
RESCULA	unoprostone isopropyl	R-Tech Ueno	Ophthalmic	All	07-2021
EPIDUO FORTE	adapalene/benzoyl peroxide	Galderma	Gel	All	07-2021
BALCOLTRA	levonorgestrel/ethinyl estradiol/ferrous bisglycinate	Avion	Tablet	All	08-2021
SUTENT	sunitinib	Pfizer	Capsule	All	08-2021
JEVTANA KIT	cabazitaxel	Sanofi	Intravenous	All	09-2021
BYSTOLIC	nebivolol	Allergan	Tablet	All	09-2021
LUCENTIS	ranibizumab	Roche	Intravitreal	All	09-2021
PRADAXA	dabigatran etexilate mesylate	Boehringer Ingelheim	Capsule	All	4Q-2021
INNOPRAN XL	propranolol	Ani Pharmaceuticals	Capsule, extended-release	All	10-2021
MIRCERA	methoxy polyethylene glycol-epoetin beta	Roche/Royalty Pharma	Subcutaneous	All	11-2021
BROVANA	arformoterol	Sunovion	Inhalation	All	11-2021
ONEXTON	clindamycin/benzoyl peroxide	Bausch Health	Gel	All	12-2021
EPANED KIT	enalapril	Silvergate	Oral solution	All	12-2021
CAYSTON	aztreonam lysine	Gilead	Inhalation	All	12-2021
MYTESI	crofelemer	Napo	Tablet, delayed-release	All	12-2021
EXPAREL	bupivacaine	Pacira	Injection	All	12-2021
SUPREP BOWEL PREP KIT	magnesium sulfate anhydrous/potassium sulfate / sodium sulfate	Braintree	Oral solution	All	12-2021
AFINITOR DISPERZ	everolimus	Novartis	Oral suspension	All	12-2021
2022 Possible launch date					

Brand name	Generic name	Brand manufacturer	Dosage form	Strengths available as generic	Possible launch date
PREZISTA	darunavir	Janssen	Tablet	75 mg, 150 mg, 300 mg	2022
DULERA	formoterol fumarate/mometasone furoate	Merck	Inhalation	All	2022
FLOVENT HFA	fluticasone propionate	GlaxoSmithKline	Inhalation	All	2022
NATPARA	parathyroid hormone 1-84	NPS/Nycomed	Subcutaneous	All	01-2022
NPLATE	romiplostim	Amgen	Subcutaneous	All	01-2022
OXAYDO	oxycodone	Egalet	Tablet	All	01-2022
SELZENTRY	maraviroc	ViiV Healthcare	Tablet	All	02-2022
VIMPAT	lacosamide	UCB	Intravenous; tablet; oral solution	All	03-2022
ZIPSOR	diclofenac potassium	Depomed	Capsule	All	03-2022
CHOLBAM	cholic acid	Retrophin	Capsule	All	03-2022
ABRAXANE	paclitaxel	Celgene/Abraxis	Injection	All	03-2022
REVLIMID	lenalidomide	Bristol-Myers Squibb/Celgene	Capsule	All	03-2022
ARESTIN	minocycline hydrochloride	Bausch Health	Subgingival, sustained-release	All	03-2022
MAVENCLAD	cladribine	Serono	Tablet	All	03-2022
LEXISCAN	regadenoson	Astellas	Intravenous	All	04-2022
COMBIGAN	brimonidine/timolol	Allergan	Ophthalmic	All	04-2022
TEFLARO	ceftaroline fosamil	Allergan	Intravenous	All	04-2022
ZOLADEX	goserelin	TerSera Therapeutics	Subcutaneous	All	04-2022
ALIMTA	pemetrexed disodium	Eli Lilly	Intravenous	All	05-2022
VELCADE	bortezomib	Takeda	Intravenous	All	05-2022
TARGINIQ ER	oxycodone/naloxone	Purdue	Tablet, extended-release	All	05-2022
CAPRELSA	vandetanib	Genzyme/Sanofi	Tablet	All	06-2022
VIIBRYD	vilazodone	Forest/Allergan	Tablet	All	06-2022
ELESTRIN	estradiol	Mylan	Gel	All	06-2022
QBRELIS	lisinopril	Silvergate	Oral solution	All	06-2022
IRESSA	gefitinib	AstraZeneca	Tablet	All	07-2022
ACTEMRA	tocilizumab	Roche/Chugai	Intravenous; subcutaneous	All	07-2022
EVAMIST	estradiol	Perrigo/Elan	Transdermal solution	All	07-2022
IXEMPRA Kit	ixabepilone	R-Pharm	Intravenous	All	07-2022
VOSEVI	sofosbuvir/velpatasvir/voxilaprevir	Gilead	Tablet	All	07-2022

Brand name	Generic name	Brand manufacturer	Dosage form	Strengths available as generic	Possible launch date
VIBATIV	telavancin	Theravance	Intravenous	All	08-2022
KEVEYIS	dichlorphenamide	Strongbridge Biopharma	Tablet	All	08-2022
ORAVIG	miconazole	Midatech/R-Pharm	Tablet, buccal	All	09-2022
BIJUVA	estradiol/progesterone	TherapeuticsMD	Capsule	All	09-2022
HALFLYTELY with BISACODYL	bisacodyl / polyethylene glycol 3350, potassium chloride, sodium bicarbonate, sodium chloride	Braintree	Tablet/oral solution	All	10-2022
ORENCIA	abatacept	Bristol-Myers Squibb	Intravenous; subcutaneous	All	11-2022
XERESE	acyclovir/hydrocortisone	Bausch Health	Cream	All	11-2022
NAGLAZYME	galsulfase	BioMarin	Intravenous	All	11-2022
FOLOTYN	pralatrexate	Acrotech/Aurobindo	Intravenous	All	11-2022
GLOPERBA	colchicine	Avion Pharmaceuticals	Oral solution	All	11-2022
NASCOBAL	cyanocobalamin	Par/Endo	Intranasal	All	12-2022
MYRBETRIQ	mirabegron	Astellas	Tablet, extended-release	All	12-2022
DYLOJECT	diclofenac	Hospira/Pfizer/Javelin	Intravenous	All	12-2022
RAYOS	prednisone	Horizon	Tablet, delayed-release	All	12-2022
TREANDA	bendamustine	Cephalon/Teva	Intravenous	All	12-2022
ZIOPTAN	tafluprost	Akorn	Ophthalmic	All	12-2022
2023 Possible launch date					
ALPHAGAN P	brimonidine	Allergan	Ophthalmic	All	2023
KOMBIGLYZE XR	saxagliptin/metform	Astra Zeneca	Tablet, extended-release	All	1H-2023
ONGLYZA	saxagliptin	AstraZeneca	Tablet	All	1H-2023
AMZEEQ	minocycline	Foamix	Foam	All	1Q-2023
FIRVANQ KIT	vancomycin	Azurity	Oral solution	All	1Q-2023
NOXAFIL	posaconazole	Merck	Intravenous	All	01-2023
HUMIRA	adalimumab	AbbVie	Subcutaneous	All	01-2023
PROLENSA	bromfenac	Bausch Health	Ophthalmic	All	01-2023
APIDRA	insulin glulisine recombinant	Sanofi	Subcutaneous	All	01-2023
DUEXIS	ibuprofen/famotidine	Horizon Pharma	Tablet	All	01-2023
XYREM	sodium oxybate	Jazz	Oral solution	All	01-2023
CAMBIA	diclofenac potassium	Depomed	Oral solution	All	01-2023
TROKENDI XR	topiramate	Supernus	Capsule, extended-release	All	01-2023

Brand name	Generic name	Brand manufacturer	Dosage form	Strengths available as generic	Possible launch date
DUOBRII	halobetasol propionate/tazarotene	Bausch Health	Lotion	All	01-2023
LUMIZYME	alglucosidase alfa	Genzyme	Intravenous	All	02-2023
LATUDA	lurasidone	Sunovion	Tablet	All	02-2023
GATTEX	teduglutide recombinant	Takeda	Subcutaneous	All	03-2023
AGGRASTAT	tirofiban	Medicure	Intravenous	All	03-2023
AUBAGIO	teriflunomide	Sanofi/Genzyme	Tablet	All	03-2023
DEFITELIO	defibrotide	Jazz	Intravenous	All	03-2023
PROVAYBLUE	methylene blue	Provepharm/American Regent	Intravenous	All	04-2023
KEPIVANCE	palifermin	Swedish Orphan Biovitrum	Intravenous	All	04-2023
CLINDESSE	clindamycin phosphate	Perrigo	Vaginal cream	All	04-2023
CORLANOR	ivabradine	Amgen	Tablet	All	04-2023
DALVANCE	dalbavancin	Amgen	Intravenous	All	05-2023
LIVALO	pitavastatin	Eli Lilly/Kowa Pharmaceuticals	Tablet	All	05-2023
EYLEA	aflibercept	Regeneron	Intraocular	All	06-2023
TOLAK	fluorouracil	Pierre Fabre	Cream	All	07-2023
MOZOBIL	plerixafor	Sanofi/Genzyme	Subcutaneous	All	07-2023
EGRIFTA	tesamorelin	Theratechnologies	Subcutaneous		08-2023
CYSTADROPS	cysteamine	Recordati	Ophthalmic	All	08-2023
VYVANSE	lisdexamfetamine	Shire/Takeda	Capsule, extended-release; tablet, chewable	All	08-2023
TEMODAR	temozolomide	Merck	Injection	All	09-2023
STELARA	ustekinumab	Janssen	Subcutaneous	All	09-2023
OZURDEX	dexamethasone	Allergan	Ophthalmic	All	11-2023
AMTURNIDE	aliskiren/amlodipine/ hydrochlorothiazide	Novartis	Tablet	All	11-2023
VESICARE LS	solifenacin	Astellas	Oral suspension	All	11-2023
KOGENATE FS	octocog alpha	Bayer	Intravenous	All	11-2023
HELIXATE FS	antihemophilic factor VIII	CSL Behring/Bayer	Intravenous	All	11-2023
VICTOZA	liraglutide recombinant	Novo Nordisk	Subcutaneous	All	12-2023
MULTAQ	dronedarone	Sanofi	Tablet	All	12-2023
GIAZO	balsalazide disodium	Bausch Health	Tablet	All	12-2023
KALBITOR	ecallantide	Dyax	Subcutaneous	All	12-2023

Brand name	Generic name	Brand manufacturer	Dosage form	Strengths available as generic	Possible launch date
GILENYA	fingolimod	Novartis	Capsule	0.5 mg	12-2023

Extended brand pipeline forecast

OptumRx Brand Pipeline Forecast

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
2021 Possible launch date									
SRP-4045	casimersen	Sarepta	morpholino antisense oligonucleotide	Duchenne muscular dystrophy	IV	Filed BLA	2/25/2021	Yes	Yes
Ygalo (Melflufen)	melphalan-flufenamide	Oncopeptides AB	alkylating agent/ DNA synthesis inhibitor	Multiple myeloma	IV	Filed NDA	2/28/2021	No	Yes
Neutrolin (CRMD-003, CRMD-004)	citrate/ taurolidine/ heparin	CorMedix	antimicrobial agent/ anticoagulant	Catheter-related infections	IV	Filed NDA	2/28/2021	No	No
CPP-1X/ sulindac (DFMO)	eflornithine/ sulindac	Cancer Prevention Pharma	ornithine decarboxylase inhibitor/ non-steroidal anti-inflammatory drug (NSAID)	Familial adenomatous polyposis	PO	Filed NDA	2/28/2021	Yes	Yes
Zydena	udenafil	Mezzion Pharma	phosphodiesterase type 5 (PDE5) inhibitor	Congenital single ventricle heart disease	PO	Filed NDA	2/28/2021	No	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
HM30181A/paclitaxel	paclitaxel and encequidar	Athenex	P-glycoprotein pump inhibitor/ taxane	Breast cancer	PO	Filed NDA	2/28/2021	Yes	No
KP-415	D-threo-methylphenidate controlled-release	KemPharm	CNS stimulant	Attention deficit hyperactivity disorder	PO	Filed NDA	3/2/2021	No	No
ropeginterferon alfa-2b	ropeginterferon alfa-2b	PharmaEssentia	interferon	Polycythemia vera	SC	Filed BLA	3/13/2021	Yes	Yes
arimoclomol	arimoclomol	Orphazyme	cytoprotectives	Niemann-Pick disease	PO	Filed NDA	3/17/2021	Yes	Yes
RG-3477 (ACT-128800)	ponesimod	Johnson & Johnson	sphingosine 1 phosphate receptor agonist	Multiple sclerosis	PO	Filed NDA	3/18/2021	Yes	No
FG-4592 (ASP-1517)	roxadustat	FibroGen/ AstraZeneca	hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor	Anemia	PO	Filed NDA	3/20/2021	Yes	No
bb-2121	idecabtagene vicluecel	Bristol-Myers Squibb/ bluebird Bio	chimeric antigen receptor (CAR) T cell therapy	Multiple myeloma	IV	Filed BLA	3/27/2021	Yes	Yes
ZP-4207 (ZP-GA-1)	dasiglucagon	Zealand Pharma	glucagon analog	Diabetes mellitus	SC	Filed NDA	3/27/2021	No	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Myrbetriq (oral suspension)	mirabegron	Astellas	beta-3 adrenoceptor agonist	Neurogenic detrusor overactivity	PO	Filed NDA	3/28/2021	No	No
Leukotac	inolimomab	ElsaLys Biotech	IL-2 monoclonal antibody	Graft vs. host disease	IM	Filed BLA	1Q2021	Yes	Yes
SPI-2012	eflapegrastim	Spectrum	granulocyte colony-stimulating factor (GCSF)	Chemotherapy-induced neutropenia	SC	Filed BLA	1Q2021	Yes	No
Hydexor	promethazine/ hydrocodone/ acetaminophen	Charleston Laboratories	anti-emetic/ opioid/ analgesic	Nausea/ Vomiting/ Pain	PO	Filed NDA	1Q2021	No	No
Tivopath (AV-951, KRN-951, ASP-4130)	tivozanib	AVEO Oncology	VEGF inhibitor	Renal cell cancer	PO	Filed NDA	3/31/2021	Yes	No
CMX-001	brincidofovir	Chimerix	DNA-directed DNA polymerase inhibitor	Smallpox	PO	Filed NDA	4/7/2021	No	Yes
cyclic pyranopterin monophosphate (ALXN-1101)	fosdenopterin	BridgeBio Pharma/ Origin Biosciences	molybdenum cofactor stimulant	Molybdenum cofactor deficiency	IV	Filed NDA	4/11/2021	Yes	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Estelle	estetrol/ drospirenone	Mayne Pharma/ Mithra Pharmaceuticals	estrogen receptor agonist	Pregnancy prevention	PO	Filed NDA	4/16/2021	No	No
S5G4T-1 (DER-45-EV)	benzoyl peroxide	Sol-Gel Technologies	benzoyl peroxide	Rosacea	TOP	Filed NDA	4/26/2021	No	No
PRX-102	pegunigalsidase alfa	Protalix	enzyme replacement	Fabry disease	IV	Filed BLA	4/27/2021	Yes	No
PF-04965842	abrocitinib	Pfizer	janus kinase 1 (JAK-1) inhibitor	Atopic dermatitis	PO	Filed NDA	4/30/2021	Yes	No
CAT-354	tralokinumab	Leo Pharma	interleukin-13 (IL-13) inhibitor	Atopic dermatitis	SC	Filed BLA	4/2021	Yes	No
HTX-011	bupivacaine/ meloxicam	Heron Therapeutics	anesthetic/ Nonsteroidal Anti-inflammatory Drug (NSAID)	Pain	Instillation	Filed NDA	5/13/2021	No	No
APL-2	pegcetacoplan	Apellis Pharmaceuticals	complement C3 inhibitor	Paroxysmal nocturnal hemoglobinuria	SC	Filed NDA	5/14/2021	Yes	Yes
GZ-402666 (NeoGAA)	avalglucosidase alfa	Sanofi	enzyme replacement therapy	Pompe disease	IV	Filed BLA	5/18/2021	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
ADCT-402	loncastuximab tesirine	ADC Therapeutics	antibody drug conjugate	Diffuse large B-cell lymphoma	IV	Filed BLA	5/21/2021	Yes	Yes
FP-001 (LMIS)	leuprolide mesylate	Foresee	gonadotropin-releasing hormone (GnRH) analog	Prostate cancer	SC	Filed NDA	5/27/2021	Yes	No
DS-100	dehydrated alcohol	Eton	undisclosed	Methanol poisoning	SC	Filed NDA	5/27/2021	No	Yes
ET-104	zonisamide	Eton	anticonvulsant	Seizures	PO	Filed NDA	5/29/2021	No	No
KD-025	belumosudil	Kadmon	Rho-associated coiled-coil kinase 2 (ROCK2) inhibitor	Graft vs. Host disease	PO	Filed NDA	5/30/2021	Yes	Yes
BGJ-398	infigratinib	BridgeBio	FGFR1-3 selective inhibitor	Cholangiocarcinoma	PO	Filed NDA	5/2021 - 6/2021	Yes	Yes
SCY-078 (MK-3118)	ibrexafungerp	Scynexis	glucan synthase inhibitor	Vulvovaginal candidiasis	PO	Filed NDA	6/1/2021	No	Yes
ALKS-3831	olanzapine/ samidorphan	Alkermes	dopamine receptor antagonist/ opioid receptor antagonist	Schizophrenia/ Bipolar disorder	PO	Filed NDA	6/1/2021	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
relugolix/ estradiol/ norethindrone acetate	relugolix/ estradiol/ norethindrone acetate	Myovant Sciences	gonadotropin-releasing hormone (GnRH) receptor antagonist	Uterine fibroids	PO	Filed NDA	6/1/2021	No	No
Ryplazim	human plasminogen	Liminal BioSciences	plasminogen	Plasminogen deficiency	IV	Filed BLA	6/5/2021	Yes	Yes
BIIB-037	aducanumab	Biogen	amyloid beta-protein inhibitor	Alzheimer's disease	IV	Filed BLA	6/7/2021	Yes	No
StrataGraft Skin Tissue	StrataGraft Skin Tissue	Mallinckrodt	autologous skin tissue	Burn injury	TOP	Filed BLA	6/8/2021	Yes	Yes
TAK-721 (SHP-621)	budesonide	Takeda	corticosteroid	Eosinophilic esophagitis	PO	Filed NDA	6/15/2021	Yes	Yes
ACP-001 (TransCon Growth Hormone)	lonapegsomatropin	Ascendis Pharma	growth hormone prodrug	Short stature/ growth hormone deficiency	SC	Filed BLA	6/25/2021	Yes	Yes
Verkazia	cyclosporine	Santen Pharmaceutical	immunosuppressant	Vernal keratoconjunctivitis	OPH	Filed NDA	6/26/2021	No	Yes
NexoBrid	bromelain	Vericel	peptide hydrolase replacement agent	Burns/ Skin injury	TOP	Filed BLA	6/29/2021	No	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
PF-06482077	multivalent group B streptococcus vaccine	Pfizer	vaccine	Bacterial infection	IM	Filed BLA	6/2021	Yes	No
tanezumab	tanezumab	Pfizer/ Eli Lilly	nerve growth factor (NGF) inhibitor	Osteoarthritis	SC	Filed BLA	2Q2021	Yes	No
INC-424	ruxolitinib	Incyte	janus kinase (JAK) inhibitor	Atopic dermatitis	TOP	Filed NDA	1H2021	Yes	No
TSR-042	dostarlimab	GlaxoSmithKline	PD-1 checkpoint inhibitor	Endometrial cancer	IV	Filed BLA	1H2021	Yes	No
JZP-458 (PF-743)	recombinant crisantaspase	Jazz Pharmaceuticals	asparaginase	Acute lymphoblastic leukemia	IM/IV	InTrial	Mid-2021	Yes	No
CLS-1001	triamcinolone acetonide	Clearside	corticosteroid	Macular edema	intraocular/ subretinal	CRL	Mid-2021	Yes	No
RT-002 (Daxi)	daxibotulinumtoxinA	Revance Therapeutics	botulinum toxins	Glabellar lines (frown lines)	IM	Filed BLA	Mid-2021	Yes	No
PRV-031	teplizumab	Provention Bio/ MacroGenics	CD3 antigen inhibitor	Diabetes mellitus	IV	Filed BLA	7/2/2021	Yes	Yes
MEDI-546	anifrolumab	AstraZeneca/ BMS	interferon receptor antagonist	Systemic lupus erythematosus	IV	Filed BLA	7/5/2021	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
CCX-168	avacopan	ChemoCentryx	C5a receptor (C5aR) antagonist	Vasculitis	PO	Filed NDA	7/7/2021	Yes	Yes
BAY-948862	finerenone	Bayer	mineralocorticoid receptor antagonist	Diabetic nephropathy	PO	Filed NDA	7/9/2021	No	No
OMS-721	narsoplimab	Omeros	anti-MASP-2 monoclonal antibody	Hematopoietic stem cell transplant-associated thrombotic microangiopathy	IV/SC	Filed BLA	7/17/2021	Yes	Yes
V-114	pneumococcal conjugate vaccine	Merck	vaccine	Bacterial infection	IM	Filed BLA	7/18/2021	Yes	No
odevixibat	odevixibat	Albireo Pharma	ileal bile acid transporter inhibitor	Progressive familial intrahepatic cholestasis	PO	Filed NDA	7/20/2021	Yes	Yes
MGA-012	retifanlimab	Incyte	programmed cell death protein 1 (PD-1) inhibitor	Anal cancer	IV	Filed BLA	7/25/2021	Yes	Yes
sulopenem	sulopenem	Iterum Therapeutics	carbapenem	Urinary tract infections	PO	Filed NDA	7/25/2021	No	No
UCB-4940 (CDP-4940)	bimekizumab	UCB	interleukin-17 (IL-17) receptor inhibitor	Plaque psoriasis	IV	Filed BLA	7/2021	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Uptravi (IV)	selexipag	Janssen	non-prostanoid prostacyclin agonist	Pulmonary arterial hypertension	IV	Filed NDA	7/30/2021	Yes	Yes
TWIN (S6G5T-1; S6G5T-3)	benzoyl peroxide/ tretinoin	Sol-Gel Technologies	retinoid	Acne vulgaris	TOP	Filed NDA	8/1/2021	No	No
JNJ-6372	amivantamab	Johnson & Johnson	EGFR and cMET antibody	Non-small cell lung cancer	IV	Filed BLA	8/3/2021	Yes	No
ET-101	topiramate	Eton	undisclosed	Seizure disorders	PO	Filed NDA	8/6/2021	No	No
AMG-510	sotorasib	Amgen	KRAS inhibitor	Non-small cell lung cancer	PO	Filed NDA	8/16/2021	Yes	Yes
BMN-111	vosoritide	BioMarin	C-type natriuretic peptide (CNP) analog	Achondroplasia	SC	Filed NDA	8/20/2021	Yes	Yes
Vicinium (VB-4-845)	oportuzumab monatox	Sesen Bio	anti-ECAM exotoxin A fusion protein	Bladder cancer	Intravesical	Filed BLA	8/21/2021	Yes	No
CR-845	difelikefalin	Cara Therapeutics	opioid receptor agonist	Pruritus	IV/PO	Filed NDA	8/28/2021	No	No
SPN-812	viloxazine	Supernus Pharmaceuticals	selective norepinephrine reuptake inhibitor	Attention deficit hyperactivity disorder	PO	Filed NDA	8/2021	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
paliperidone palmitate (6-month)	paliperidone palmitate	Johnson & Johnson	atypical antipsychotic	Schizophrenia	IM	Filed NDA	9/2/2021	Yes	No
Kyzatrex	testosterone undecanoate	Marius Pharmaceuticals	testosterone replacement therapy	Hypogonadism	PO	Filed NDA	9/5/2021	No	No
INP-104	POD-dihydroergotamine mesylate (POD-DHE)	Impel NeuroPharma	ergot derivative	Acute migraines	Intranasal	Filed NDA	9/6/2021	No	No
ARGX-113	efgartigimod	Argenx	neonatal Fc receptor (FcRn) antibody	Myasthenia gravis	IV	Filed BLA	9/9/2021	Yes	Yes
Doria	risperidone	Laboratorios Farmacéuticos Rovi	atypical antipsychotic	Schizophrenia	IM	Filed NDA	9/24/2021	Yes	No
JNJ-4528 (LCAR-B38M)	ciltacabtagene autoleucel	Legend Biotech/ Janssen	chimeric antigen receptor (CAR) T cell therapy	Multiple myeloma	IV	InTrial	3Q2021	Yes	Yes
AB-103	reltecimod	Atox Bio	CD-28 co-stimulatory receptor modulator	Necrotizing soft tissue infections	IV	Filed NDA	9/30/2021	Yes	Yes
MK-8031	atogepant	AbbVie	calcitonin gene-related peptide (CGRP) receptor antagonist	Migraine prophylaxis	PO	Filed NDA	3Q2021	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
SHP-625 (LUM-001)	maralixibat	Mirum Pharmaceuticals	apical sodium-dependent bile acid transporter (ABST) inhibitor	Alagille syndrome	PO	Filed NDA	10/2/2021	Yes	Yes
FT-218	sodium oxybate extended-release	Avadel	dopamine receptor agonist	Narcolepsy	PO	Filed NDA	10/16/2021	Yes	Yes
OS-01 nasal spray	varenicline	Oyster Point Pharma	nicotinic acetylcholine receptor (nAChR) agonist	Dry eye disease	Intranasal	Filed NDA	10/18/2021	No	No
MOD-401	somatrogon	Pfizer/ Opko	human growth hormone	Growth hormone deficiency	SC	Filed BLA	10/2021	Yes	Yes
DE-117	omidenepag isopropyl	Santen Pharmaceutical	Prostaglandin E Receptor 2 (PTGER2) agonist	Glaucoma	OPH	Filed NDA	11/19/2021	No	No
Sci-B-Vac	hepatitis B vaccine	VBI Vaccines	vaccine	Hepatitis B	IM	Filed BLA	11/30/2021	No	No
MTP-131 (SS-31)	elamipretide	Stealth Biotherapeutics	mitochondrial permeability transition pore inhibitor	Barth syndrome	IV/PO/SC	InTrial	4Q2021	Yes	Yes
PL-56	budesonide	Calliditas	corticosteroid	Nephropathy	PO	InTrial	4Q2021	No	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
TAK-788	mobocertinib	Takeda	tyrosine kinase inhibitor	Non-small cell lung cancer	PO	InTrial	4Q2021	Yes	Yes
RTA-402	bardoxolone methyl	Reata Pharmaceuticals/ AbbVie	Nrf2 activator	Alport syndrome	PO	InTrial	4Q2021	Yes	Yes
AT-GAA	cipaglucosidase alfa	Amicus	enzyme therapy	Pompe disease	IV	InTrial	4Q2021	Yes	Yes
ublituximab (LFB-R603, TG20, TGTX-1101, TG-1101, Utuxin)	ublituximab	TG Therapeutics	CD-20 monoclonal antibody	Chronic lymphocytic leukemia; multiple sclerosis	IV	InTrial	4Q2021	Yes	Yes
BBI-608	napabucasin	Sumitomo Dainippon	stem cell inhibitor	Colorectal cancer	PO	InTrial	4Q2021	Yes	No
131I-8H9	omburtamab	Y-mAbs Therapeutics	B7-H3 antagonist	Brain cancer	Intrathecal	InTrial	4Q2021	Yes	Yes
TAK-609	idursulfase-IT	Takeda	enzyme replacement	Hunter syndrome	Intrathecal	InTrial	4Q2021	Yes	Yes
Purified Cortrophin Gel	corticotropin	ANI Pharmaceuticals	adrenocorticotropic hormone (ACTH)	Multiple sclerosis/ rheumatoid arthritis/ systemic lupus	IV	InTrial	4Q2021	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
				erythematosus/ ulcerative colitis					
Filsuvez (AP-101)	episalvan	Amryt Pharma	triterpene	Epidermolysis bullosa	TOP	Not Approved	4Q2021	No	Yes
TAK-003	Dengue fever vaccine	Takeda	vaccine	Dengue fever	SC	InTrial	4Q2021	Yes	No
SYD-985	[vic-] trastuzumab duocarmazine	Synthon	HER2-targeting antibody-drug conjugate	Breast cancer	IV	InTrial	4Q2021	Yes	No
HMPL-012	surufatinib	Hutchison China MediTech	angio-immunokinase inhibitor	Neuroendocrine tumors	PO	InTrial	4Q2021	Yes	Yes
Taclantis	paclitaxel injection concentrate for suspension	Sun Pharma Advanced Research Company (SPARC)	taxane	Breast cancer; lung cancer; pancreatic cancer	IV	CRL	2H2021	No	No
CAM-2038	buprenorphine	Braeburn	opioid receptor agonist (partial)	Opioid use disorder/ Pain	SC	CRL	2H2021	Yes	No
tramadol	tramadol	Avenue Therapeutics	opioid receptor agonist	Pain	IV	CRL	2H2021	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
BIVV-009 (TNT-009)	sutimlimab	Sanofi	complement C1s subcomponent inhibitor	Cold agglutinin disease	IV	CRL	2H2021	Yes	Yes
Contepo	fosfomycin	Nabriva Therapeutics	cell wall inhibitor	Bacterial infections	IV	CRL	2H2021	Yes	No
ALN-PCSsc (PCSK9si)	inclisiran	Novartis	RNA interfering therapeutic targetting proprotein convertase subtilisin–kexin type 9 (PCSK9)	Hyperlipidemia	SC	CRL	2H2021	Yes	Yes
VP-102	VP-102	Verrica	antiviral	Molluscum	TOP	CRL	2H2021	No	No
LIQ-861	treprostinil	Liquidia Technologies	prostacyclin analog	Pulmonary arterial hypertension	INH	CRL	2H2021	Yes	No
ISIS 304801 (ISIS-APOCIIIRx)	volanesorsen	Ionis	antisense drug	Familial chylomicronemia syndrome	SC	CRL	2H2021	Yes	Yes
Libervant	diazepam	Aquestive Therapeutics	benzodiazepine	Seizures	PO	CRL	2H2021	No	Yes
ET-105	lamotrigine	Eton	anticonvulsant	Epilepsy	PO	CRL	2021	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
BNT-162 (BNT162b2, PF-07302048)	coronavirus vaccine	Pfizer/ BioNTech	vaccine	Novel coronavirus disease 2019 (COVID-19)	IM	InTrial	2021	No	No
mRNA-1273	coronavirus vaccine	Moderna	vaccine	Novel coronavirus disease 2019 (COVID-19)	undisclosed	InTrial	2021	No	No
MYK-461 (SAR-439152)	mavacamten	MyoKardia	cardiac myosin allosteric modulator	Cardiomyopathy	PO	InTrial	Late 2021	Yes	Yes
HuMax-TF ADC	tisotumab vedotin	Seagen/ Genmab	tissue factor antibody	Cervical cancer	IV	InTrial	Late 2021	Yes	No
AXS-05	dextromethorphan/ bupropion	Axsome	N-methyl-D-aspartate (NMDA) antagonist/ antidepressant	Treatment-resistant depression	PO	InTrial	Late 2021	No	No
TadFin	tadalafil and finasteride	Veru	phosphodiesterase type 5 inhibitor /5-alpha-reductase inhibitor	Benign prostatic hyperplasia	PO	InTrial	Late 2021	No	No
LN-145	LN-145	Iovance Biotherapeutics	tumor infiltrating lymphocyte	Cervical Cancer	IV	InTrial	Late 2021	Yes	No
AGEN-2034	balstilimab	Agenus	PD-1 antagonist	Cervical cancer	IV	InTrial	Late 2021	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Trevyent	treprostinil	United Therapeutics	prostacyclin analog	Pulmonary arterial hypertension	SC	CRL	Late 2021	Yes	Yes
ALN-TTRsc02	vutrisiran	Alnylam	siRNA/RNAi	Transthyretin-mediated amyloidosis	SC	InTrial	Late 2021	Yes	Yes
Zimhi	naloxone	Adamis	opioid antagonist	Opioid overdose	IM	CRL	Late 2021	No	No
Rizaport (VersaFilm)	rizatriptan	IntelGenx	triptans	Acute migraines	PO	CRL	4Q2021	No	No
AGIL-AADC	AGIL-AADC	PTC Therapeutics	gene therapy	Aromatic L-amino acid decarboxylase deficiency	Intracerebral	InTrial	Late 2021	Yes	Yes
ABI-009	sirolimus and albumin	Aadi Bioscience	mTOR kinase inhibitor	Epithelioid cell caricnoma	IV	InTrial	Late 2021	Yes	Yes
FT-2102	olutasidenib	Forma Therapeutics	dehydrogenase 1 (IDH1) inhibitor	Acute myeloid leukemia	PO	InTrial	Late 2021	Yes	Yes
pacritinib	pacritinib	CTI BioPharma	janus associated kinase-2 (JAK2) inhibitor	Myelofibrosis	PO	InTrial	Late 2021	Yes	Yes
SHP-620	maribavir	Shire	benzimidazole	Cytomegalovirus	PO	InTrial	Late 2021	No	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
PRO-140	leronlimab	CytoDyn	C-C chemokine receptor 5 (CCR5) antagonist	HIV	SC	InTrial	Late 2021	Yes	No
AGEN-1884	zalifrelimab	Agenus	immune checkpoint modulator (CPM) antibody	Cervical cancer	IV	InTrial	Late 2021	Yes	No
NPI-2358	plinabulin	BeyondSpring	tumor vascular disrupting agent (tVDA)	Neutropenia/ non-small cell lung cancer	IV	InTrial	Late 2021	Yes	No
SGX-301	synthetic hypericin	Access Pharmaceuticals	synthetic hypericin	Cutaneous T-cell lymphoma	TOP	InTrial	Late 2021	Yes	Yes
R-667 (RG-667)	palovarotene	Ipsen	selective retinoic acid receptor (RAR-gamma) agonist	Fibrodysplasia ossificans progressiva (FOP)	PO	InTrial	Late 2021	Yes	Yes
Translarna	ataluren	PTC Therapeutics	gene transcription modulator	Duchenne muscular dystrophy	PO	CRL	Late 2021	Yes	Yes
PDS-1.0	ranibizumab	Roche/ Genentech	Anti-VEGF (vascular endothelial growth factor)	Wet age-related macular degeneration	Intravitreal implant	InTrial	Late 2021	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Adstiladrin	nadofaragene firadenovec	FerGene	gene therapy	Bladder cancer	Intravesical	CRL	Late 2021	Yes	No
BXCL-501	dexmedetomidine	BioXcel Therapeutics	selective alpha 2a receptor agonist	Schizophrenia and bipolar disorder	PO	InTrial	Late 2021	No	No
2022 Possible launch date									
ACT-541468	daridorexant	Idorsia Pharmaceuticals	orexin receptor antagonist	Insomnia	PO	Filed NDA	1/8/2022	No	No
Tlando	testosterone	Lipocine	androgen	Hypogonadism	PO	Tentative Approval	3/27/2022	No	No
AKB-6548	vadadustat	Akebia Therapeutics/ Vifor Pharma/ Otsuka	hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor	Anemia	PO	InTrial	1Q2022	Yes	No
IDP-124	pimecrolimus	Bausch Health	calcineurin Inhibitor	Atopic dermatitis	TOP	InTrial	1Q2022	No	No
AG-348	mitapivat	Agios	pyruvate kinase-R (PKR) activator	Pyruvate kinase deficiency	PO	InTrial	1Q2022	Yes	Yes
IDP-120	tretinoin/ benzoyl peroxide	Bausch	retinoid	Acne	TOP	InTrial	1Q2022	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
glatiramer acetate depot	glatiramer acetate long-acting	Mylan	immunosuppressant	Multiple sclerosis	IM	InTrial	1Q2022	Yes	No
AXS-07	meloxicam/ rizatriptan	Axsome Therapeutics	non-steroidal anti-inflammatory drug/triptan	Migraine	PO	InTrial	1Q2022	No	No
NX-1207 (NYM-4805, REC 0482)	fexapotide triflutate	Nymox	pro-apoptotic	Benign prostatic hyperplasia	Intratumoral	InTrial	1Q2022	Yes	No
OBE-2109 (KLH-2109)	linzagolix	ObsEva	gonadotropin-releasing hormone (GnRH) antagonist	Uterine fibroids	PO	InTrial	1Q2022	No	No
EBV-CTL (ATA-129)	tabelecleucel	Atara Biotherapeutics	cell therapy	Lymphoproliferative disorder	IV	InTrial	1Q2022	Yes	Yes
ABL-001	asciminib	Novartis	allosteric Bcr-Abl inhibitor	Chronic myeloid leukemia	PO	InTrial	1Q2022	Yes	Yes
COR-003	levoketoconazole	Strongbridge Biopharma	azole antifungal	Cushing's syndrome	PO	InTrial	1Q2022	No	Yes
SB-206	SB-206	Novan Therapeutics	nitric oxide-releasing compound	Molluscum contagiosum	TOP	InTrial	2Q2022	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Zynteglo (LentiGlobin)	betibeglogene autotemcel	Bluebird Bio	gene therapy	Beta-thalassemia; sickle cell disease	IV	InTrial	2Q2022	Yes	Yes
177Lu-PSMA-617	Lutetium	Novartis	Radiopharmaceutical	Prostate cancer	IV	InTrial	1H2022	Yes	No
HM781-36B	poziotinib	Spectrum Pharmaceuticals	pan-HER inhibitor	Non-small cell lung cancer	PO	InTrial	1H2022	Yes	No
MLN-4924 (TAK-92)	pevonedistat	Ligand	Nedd 8 Activating Enzyme (NAE) antagonist	Myelodysplastic syndrome	IV	InTrial	1H2022	Yes	No
Sativex	nabiximols	GW Pharmaceuticals/ Otsuka	cannabinoid product	Spasticity	SL/ SPR	InTrial	1H2022	No	No
Lenti-D	elivaldogene tavalentivec	Bluebird Bio	gene therapy	Adrenomyeloneuropathy	IV	InTrial	1H2022	Yes	Yes
S-265744 LAP (S/GSK-1265744 LAP; GSK-744 LA)	cabotegravir	ViiV Healthcare	HIV integrase inhibitor	HIV pre-exposure prophylaxis	IM	InTrial	1H2022	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
VT-1161	oteseconazole	Mycovia Pharmaceuticals	lanosterol demethylase (CYP51) inhibitor	Fungal infections	PO	InTrial	1H2022	No	No
AmnioFix	dehydrated human amnion/chorion membrane (dHACM)	MiMedx	amniotic tissue membrane	Plantar fasciitis/ achilles tendonitis	INJ	InTrial	1H2022	Yes	No
AGN-190584	pilocarpine	Allergan	cholinergic muscarinic receptor agonist	Presbyopia	OPH	InTrial	1H2022	No	No
CUTX-101	copper histidinate	Fortress Biotech	copper replacement	Menkes Disease	SC	InTrial	1H2022	Yes	Yes
DARE-BV1	clindamycin	Daré Bioscience	lincosamide	Bacterial vaginosis	Intravaginal	InTrial	1H2022	No	No
Botulax	botulinum toxin type A	Hugel Pharma	botulinum toxins	Wrinkles	IM	InTrial	1H2022	Yes	No
dovitinib	dovitinib	Oncology Venture	fibroblast growth factor receptor 3 (FGFR3) inhibitor	Renal cell carcinoma	PO	InTrial	1H2022	Yes	No
AMG-157 (MEDI-9929)	tezepelumab	AstraZeneca/ Amgen	thymic stromal lymphopoietin antagonist	Asthma	IV/SC	InTrial	1H2022	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
Iomab-B	iodine I 131 monoclonal antibody BC8	Actinium	anti-CD45 monoclonal antibody	Acute myeloid leukemia/ Myelodysplastic syndrome	IV	InTrial	1H2022	Yes	Yes
CERC-801	CERC-801	Cerecor	D-galactose	Phosphoglucomutase 1 (PGM1) deficiency	PO	InTrial	1H2022	Yes	Yes
ACER-001	sodium phenylbutyrate	Acer Therapeutics	BCKDC kinase inhibitor	Urea cycle disorders	PO	InTrial	1H2022	No	No
GZ-402665	olipudase alfa	Sanofi	sphingomyelinase	Acid sphingomyelinase deficiency	IV	InTrial	Mid-2022	Yes	Yes
IMGN-853 (M-9346A-sulfo-SPDB-DM4)	mirvetuximab soravtansine	ImmunoGen	folate receptor-1 antagonist	Ovarian cancer	IV	InTrial	Mid-2022	Yes	Yes
Otividex	dexamethasone sustained-release	Otonomy	corticosteroid	Meniere's disease	Intratympanic	InTrial	Mid-2022	Yes	No
WTX-101	bis-choline tetrathiomolybdate (TTM)	Alexion	chelating agent	Wilson's disease	PO	InTrial	Mid-2022	Yes	Yes
AMT-061	etranacogene dezaparvovec	CSL Behring/ uniQure	gene therapy	Hemophilia B	IV	InTrial	Mid-2022	Yes	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
ERY-ASP (ERY-001)	L-asparaginase (eryaspase)	Erytech/ Recordati	L-asparaginase	Pancreatic cancer	IV	InTrial	Mid-2022	Yes	Yes
CCD-1042	ganaxolone	Marinus Pharmaceuticals	allopregnanolone analog	Seizures	PO	InTrial	Mid-2022	No	Yes
GS-010	GS-010	GenSight Biologics	gene therapy	Optic neuropathy	Intraocular	InTrial	Mid-2022	Yes	Yes
MIN-102	hydroxypioglitazone	Minoryx Therapeutics	PPAR gamma agonist	Adrenomyeloneuropathy	Undisclosed	InTrial	Mid-2022	Yes	Yes
PF-06838435 (SPK-9001)	fidanacogene elaparvovec	Pfizer/ Spark Therapeutics	gene therapy	Hemophilia B	IV	InTrial	Mid-2022	Yes	Yes
Roctavian	valoctocogene roxaparvovec	BioMarin	gene therapy	Hemophilia A	IV	CRL	Mid-2022	Yes	Yes
OTL-200 (GSK-2696274)	OTL-200 (GSK-2696274)	Orchard Therapeutics	gene therapy	Leukodystrophy	IV	InTrial	Mid-2022	Yes	Yes
FCX-007 (GM-HDF-COL7, INXN-3002)	FCX-007 (GM-HDF-COL7, INXN-3002)	Castle Creek Pharmaceutical	gene-modified autologous fibroblast	Epidermolysis bullosa	Intradermal	InTrial	Mid-2022	Yes	Yes
DCCR	diazoxide choline controlled-release	Soleno Therapeutics	vasodilator	Prader-Willi syndrome	PO	InTrial	Mid-2022	Yes	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
M-7824	bintrafusp alfa	GlaxoSmithKline	PD-L1 / TGF-beta immunoinhibition	Biliary tract cancer	IV	InTrial	Mid-2022	Yes	Yes
Ultomiris SC	ravulizumab-cwvz	Alexion	C5 complement inhibitor	paroxysmal nocturnal hemoglobinuria; Hemolytic uremic syndrome	SC	InTrial	Mid-2022	Yes	Yes
PT-027	budesonide/ albuterol	AstraZeneca	Glucocorticoid/beta agonist	Asthma	Inh	InTrial	Mid-2022	No	No
IMC-gp100	tebentafusp	Immunocore	anti-CD3 antibody	Uveal melanoma	IV	InTrial	Mid-2022	Yes	Yes
SPR-994	tebipenem	Spero Therapeutics	carbapenem	Urinary tract infections	PO	InTrial	Mid-2022	No	No
JS-001	toripalimab	Coherus BioSciences	anti-PD-1 monoclonal antibody	Nasopharyngeal carcinoma	IV	InTrial	Mid-2022	Yes	Yes
MRTX-849	adagrasib	Mirati Therapeutics	KRAS inhibitor	Non-small cell lung cancer	PO	InTrial	Mid-2022	Yes	No
RG-7828	mosunetuzumab	Roche	anti-CD20/CD3 monoclonal antibody	Follicular lymphoma	IV/SC	InTrial	Mid-2022	Yes	Yes
DJ-927	tesetaxel	Odonate Therapeutics	Microtubules (tubulin) inhibitor	Breast cancer	PO	InTrial	Mid-2022	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
GS-CA1 (GS-6207)	lenacapavir	Gilead	HIV capsid inhibitor	HIV-1	SC	InTrial	Mid-2022	No	No
DCR-PHXC	nedosiran	Dicerna/ Alnylam	glycolate oxidase antagonist	hyperoxaluria	SC	InTrial	Mid-2022	Yes	Yes
KB-103	beremagene geperpavec	Krystal Biotech	gene therapy	Epidermolysis bullosa	Topical	InTrial	Mid-2022	Yes	Yes
AT-007	AT-007	Applied Therapeutics	aldose reductase inhibitor	Galactosemia	undisclosed	InTrial	Mid-2022	Yes	Yes
REGN-2477	garetosmab	Regeneron	Activin A antibody	Fibrodysplasia ossificans progressiva	IV/SC	InTrial	Mid-2022	Yes	Yes
OTL-103 (GSK-2696275)	OTL-103 (GSK-2696275)	Orchard Therapeutics	gene therapy	Wiskott-Aldrich syndrome	IV	InTrial	Mid-2022	Yes	Yes
NiCord	omidubicel	Gamida	cellular therapy	Hematological cancers	IV	InTrial	3Q2022	Yes	Yes
ONS-5010	bevacizumab-vikg	Outlook Therapeutics	anti-VEGF antibody	Wet age-related macular degeneration	Intravitreal	InTrial	4Q2022	Yes	No
BHV-3500	vazegepant	Biohaven	calcitonin gene-related peptide (CGRP) receptor antagonist	Migraine	Intranasal	InTrial	4Q2022	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
RG-7440 (GDC-0068)	ipatasertib	Roche	pan-Akt inhibitor	Prostate cancer	PO	InTrial	2H2022	Yes	No
AAI-101	cefepime/enmetazobactam	Allecra	beta-lactam/b-lactamase inhibitor	Urinary tract infection	IV	InTrial	2H2022	No	No
CDZ-173	leniolisib	Pharming/ Novartis	phosphatidylinositol-3-4-5-trisphosphate (PIP3) inhibitor	Primary immunodeficiencies	PO	InTrial	2H2022	Yes	Yes
PDP-716	brimonidine	Sun Pharma Advanced Research Company (SPARC)	alpha-2 agonist	Glaucoma	OPH	InTrial	2H2022	No	No
RG-7716 (RO-6867461)	faricimab	Roche/ Chugai	bispecific VEGF-A/ angiopoietin-2 antagonist	Diabetic macular edema; age-related macular degeneration	Intravitreal	InTrial	2H2022	Yes	No
LY-686017	tradipitant	Vanda Pharmaceuticals	neurokinin 1 receptor (NK-1R) antagonist	Motion sickness/ gastroparesis	PO	InTrial	2H2022	No	No
MBG-453	MBG-453	Novartis	anti-TIM-3	Myelodysplastic syndrome	IV	InTrial	2H2022	Yes	No
Oxabact (IxOC-3)	oxalobacter	OxThera	probiotic	Hyperoxaluria	PO	InTrial	2H2022	No	Yes

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
ALT-803	nogapendekin alfa inbakicept	ImmunityBio	interleukin-15 (IL-15) super agonist/ IL-15R alpha-Fc fusion complex	Bladder cancer	Intravesical	InTrial	2H2022	Yes	No
GLPG-0634	filgotinib	Gilead/ Galapagos	janus associated kinase-1 (JAK) inhibitor	Rheumatoid arthritis	PO	CRL	2H2022	Yes	No
PAX-101	suramin	PaxMedica	unknown	trypanosomiasis	IV	InTrial	2H2022	No	No
VBP-15	vamorolone	Santhera	corticosteroid	Duchenne muscular dystrophy	PO	InTrial	2H2022	Yes	Yes
ABBV-951	levodopa/carbidopa	AbbVie	aromatic amino acid/aromatic amino acid decarboxylation inhibitor	Parkinson's disease	SC	InTrial	2H2022	Yes	No
OTL-101	ADA-transduced autologous stem cell therapy	Orchard Therapeutics	gene therapy	Adenosine deaminase-deficient severe combined immunodeficiency	Undisclosed	InTrial	2022	Yes	Yes
OPNT-003	nalmefene	Opiant	opioid receptor antagonist	Opioid overdose	Intranasal	InTrial	2022	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
ADV-7103	tripotassium citrate monohydrate/ potassium hydrogen carbonate	Advicenne	undisclosed	Distal rental tubular acidosis	PO	InTrial	2022	Yes	No
Entyvio (SC formulation)	vedolizumab	Takeda	integrin receptor antagonist	Ulcerative colitis/ Crohn's disease	SC	CRL	2022	Yes	No
CNTX-4975	CNTX-4975	Centrexion Therapeutics	TRPV1 agonist	Osteoarthritis	Intra-articular	InTrial	2022	Yes	No
RGN-259 (GBT-201; RGN-352)	timbetasin	RegeneRx	actin regulating peptide	Dry eye disease	OPH	InTrial	2022	No	Yes
pentoxifylline	pentoxifylline	Eton	phosphodiesterase inhibitor	Peyronie's disease	PO	InTrial	2022	No	No
HY-01	minocycline	Hovione	tetracycline	Rosacea	TOP	InTrial	2022	No	No
CERC-802	CERC-802	Cerecor	D-mannose	Mannose-phosphate isomerase deficiency	PO	InTrial	2022	Yes	Yes
obeticholic acid	obeticholic acid	Intercept Pharmaceuticals	farnesoid X receptor (FXR) agonist	Nonalcoholic steatohepatitis	PO	CRL	2022	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
KN-046	KN-046	Alphamab Oncology	PD-L1/CTLA-4 bispecific monoclonal antibody	Thymic cancer	IV	InTrial	2022	Yes	Yes
BGB-A317 (BGB-A-317)	tislelizumab	Celgene/ BeiGene	programmed death-1 (PD-1) inhibitor	Hepatocellular cancer	IV	InTrial	2022	Yes	No
ADP-A2M4 (MAGE-A4)	ADP-A2M4 (MAGE-A4)	Adaptimmune	SPEAR T-cell therapy	Sarcoma	IV	InTrial	2022	Yes	Yes
Nanoflu	influenza vaccine	Novavax	vaccine	Influenza	IM	InTrial	2022	No	No
GSK-2894512 (WBI-1001)	tapinarof	Dermavant Sciences	therapeutic aryl hydrocarbon receptor modulating agent (TAMA)	Plaque psoriasis	TOP	InTrial	2022	Yes	No
SPN-830	apomorphine	Supernus Pharmaceuticals	non-ergoline dopamine agonist	Parkinson’s disease	SC infusion	InTrial	2022	Yes	No
VGX-3100	VGX-3100	Inovio	vaccine	Cervical cancer/dysplasia	IM	InTrial	2022	Yes	No
IBI-308	sintilimab	Eli Lilly	programmed death-1 receptor (PD-1) inhibitor	Non-small cell lung cancer	IV	InTrial	2022	Yes	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
scCeftriaxone	ceftriaxone	scPharmaceuticals	Penicillin binding protein inhibitor	Bacterial infections	SC	InTrial	2022	No	No
LN-144	lifileucel	Iovance Biotherapeutics	tumor infiltrating lymphocyte	Melanoma	IV	InTrial	2022	Yes	Yes
DBV-712 (Viaskin Peanut)	DBV-712	DBV Technologies	Immunotherapy	Peanut allergy	TOP	CRL	2022	No	No
REGN-475 (SAR-164877)	fasinumab	Regeneron/ Sanofi-Aventis/ Teva	selective anti-nerve growth factor (NGF) monoclonal antibody	Osteoarthritis	IV/SC	InTrial	2022	Yes	No
iDose travoprost	travoprost	Glaukos Corporation	prostaglandin analog	Glaucoma/ Ocular hypertension	Intraocular	InTrial	2022	No	No
NNZ-2566	trofinetide	Neuren	insulin-like growth factor 1 derivative	Rett syndrome	IV/PO	InTrial	2022	Yes	Yes
POL-6326	balixafortide	Polyphor	chemokine antagonist	Breast cancer	IV	InTrial	2022	Yes	No
LY-3298176	tirzepatide	Eli Lilly	glucose-dependent insulinotropic polypeptide/glucagon-like peptide-1 receptor agonist	Diabetes mellitus	SC	InTrial	Late 2022	No	No

Drug name	Generic name	Company	Drug class	Therapeutic use	Route of administration	Regulatory status	Estimated release date	Specialty drug	Orphan drug
RP-L102	RP-L102	Rocket Pharmaceuticals	gene therapy	Fanconi anemia	IV	InTrial	Late 2022	Yes	Yes
ARQ-151	roflumilast	Arcutis Biotherapeutics	Phosphodiesterase-4 inhibitor	Plaque psoriasis	TOP	InTrial	Late 2022	No	No
MT-7117	MT-7117	Mitsubishi Tanabe Pharma	Undisclosed	Erythropoietic protoporphyria	PO	InTrial	Late 2022	Yes	No
R-1658 (RG-1658, JTT-705, RO-4607381)	dalcetrapib	DalCor	cholesteryl ester transfer protein inhibitor	Acute coronary syndrome	PO	InTrial	Late 2022	Yes	No
Hepcludex	bulevirtide	Gilead	HBV receptor binder	Hepatitis delta virus	SC	InTrial	2H2022	No	Yes
NS-2	reproxalap	Aldeyra Therapeutics	aldehyde antagonist	Dry eye disease	OPH	InTrial	Late 2022	No	No
GSK-2140944	gepotidacin	GlaxoSmithKline	bacterial Type II topoisomerase inhibitor	Bacterial infections	PO/IV	InTrial	Late 2022	No	No
RG-7433 (ABT-263)	navitoclax	AbbVie	Bcl-2 inhibitor	Myelofibrosis	PO	InTrial	Late 2022	Yes	Yes

IM = intramuscular, INH = inhalation, INJ = injection, IUD = intrauterine device, IV = intravenous, OPH = ophthalmic, PO = oral, SC = subcutaneous, TOP = topical

Key pending indication forecast

OptumRx Key Pending Indication Forecast

Brand name	Generic name	Company	Drug class	Therapeutic use	Proposed new indication	Route of administration	Estimated approval date
Libtayo	cemiplimab-rwlc	Sanofi	programmed death ligand-1 (PD-L1) inhibitor	Non-small cell lung cancer	Treatment of patients with first-line locally advanced or metastatic non-small cell lung cancer (NSCLC) with ≥ 50% PD-L1 expression	IV	2/28/2021
Yescarta	axicabtagene ciloleucel	Kite/ Gilead	chimeric antigen receptor (CAR) T cell therapy	non-Hodgkin lymphoma	Treatment of relapsed or refractory follicular lymphoma and marginal zone lymphoma after two or more prior lines of systemic therapy.	IV	3/4/2021
Olumiant	baricitinib	Eli Lilly	janus associated kinase 1/2 (JAK1/2) inhibitor	Atopic dermatitis	Treatment of adults with moderate-to-severe atopic dermatitis	PO	3/15/2021
Arcalyst	rilonacept	Kiniksa	interleukin-1 inhibitor	Pericarditis	Treatment of recurrent pericarditis	SC	3/21/2021
Exparel	bupivacaine (liposomal suspension)	Pacira	local anesthetic	Analgesia	Single-dose infiltration in adults and pediatric patients 6 years and over, to produce postsurgical local analgesia and as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia	INJ	3/22/2021
Keytruda	pembrolizumab	Merck	anti-PD-1 inhibitor	Breast cancer	Treatment of patients with high-risk early-stage TNBC, in combination with chemotherapy as neoadjuvant	IV	3/29/2021

Brand name	Generic name	Company	Drug class	Therapeutic use	Proposed new indication	Route of administration	Estimated approval date
					treatment, and then as a single agent as adjuvant treatment after surgery		
Rinvoq	upadacitinib	AbbVie	janus associated kinase (JAK) inhibitor	Psoriatic arthritis	Treatment of adult patients with active psoriatic arthritis	PO	4/1/2021
Nuplazid	pimavanserin	Acadia	5-HT-2A receptor agonist	Dementia-related psychosis	Treatment of hallucinations and delusions associated with dementia-related psychosis (DRP)	PO	4/3/2021
Praluent	alirocumab	Sanofi/ Regeneron	PCSK9 inhibitor	Hyperlipidemia	Treatment of LDL-C reduction in adult patients with homozygous familial hypercholesterolemia (HoFH)	SC	4/4/2021
Keytruda	pembrolizumab	Merck	anti-PD-1 inhibitor	Esophageal cancer	In combination with platinum and fluoropyrimidine based chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the esophagus and gastroesophageal junction (GEJ).	IV	4/13/2021
Farxiga	dapagliflozin	AstraZeneca	sodium glucose cotransporter-2 (SGLT-2) inhibitor	Chronic kidney disease	Treatment of new or worsening chronic kidney disease (CKD) in adults with and without type-2 diabetes (T2D)	PO	4/15/2021
Tyvaso	treprostinil	United Therapeutics	prostacyclin analog	Pulmonary hypertension	Treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD).	INH	4/17/2021

Brand name	Generic name	Company	Drug class	Therapeutic use	Proposed new indication	Route of administration	Estimated approval date
Ibsrela	tenapanor	Ardelyx	sodium-hydrogen exchanger-3 (NHE-3) inhibitor	Hyperphosphatemia	To control serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis	PO	4/29/2021
Lorbrena	lorlatinib	Pfizer	kinase inhibitor	Non-small cell lung cancer	First-line treatment for people with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)	PO	4/30/2021
Xtandi	enzalutamide	Astellas	androgen receptor inhibitor	Prostate cancer	Label update to include overall survival data from the phase 3 PROSPER study in nonmetastatic castration-resistant prostate cancer	PO	4/30/2021
Jardiance	empagliflozin	Boehringer Ingelheim/ Eli Lilly	sodium-dependent glucose transporter 2 (SGLT-2) inhibitor	Heart failure	To reduce the risk of cardiovascular death and hospitalization for heart failure and to slow kidney function decline in adults with chronic heart failure with reduced ejection fraction, including those with and without type 2 diabetes	PO	5/1/2021
Aubagio	teriflunomide	Sanofi	pyrimidine synthesis inhibitor	Pediatric multiple sclerosis	Treatment of relapsing multiple sclerosis in pediatric patients	PO	5/2/2021
Xeljanz	tofacitinib	Pfizer	Janus associated kinase (JAK) inhibitor	Axial spondyloarthritis	Treatment of axial spondyloarthritis	PO	5/15/2021
Opdivo	nivolumab	Bristol-Myers Squibb	anti-PD-1 antibody; T lymphocyte stimulator; protein kinase B (PKB/Akt) inhibitor	Esophageal cancer	Treatment of patients with resected esophageal or gastroesophageal junction (GEJ) cancer in the adjuvant setting, after neoadjuvant chemoradiation therapy (CRT)	IV	5/20/2021

Brand name	Generic name	Company	Drug class	Therapeutic use	Proposed new indication	Route of administration	Estimated approval date
Opdivo	nivolumab	Bristol-Myers Squibb	anti-PD-1 antibody; T lymphocyte stimulator; protein kinase B (PKB/Akt) inhibitor	Gastric cancer	In combination with fluoropyrimidine- and platinum-containing chemotherapy, for the treatment of patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer or esophageal adenocarcinoma	IV	5/25/2021
Zeposia	ozanimod	Bristol Myers Squibb	sphingosine-1-phosphate (S1P) receptor modulator	Ulcerative colitis	Treatment of adults with moderately to severely active ulcerative colitis (UC)	PO	5/30/2021
Nuzyra	omadacycline	Paratek	tetracycline	Community-acquired pneumonia	Oral-only dosing for the treatment of community-acquired pneumonia	PO	5/31/2021
Esbriet	pirfenidone	Genentech	dual TGF-beta synthesis and TNG-alpha synthesis inhibitor	Unclassifiable interstitial lung disease	Treatment of unclassifiable interstitial lung disease (UILD)	PO	5/31/2021
Nurtec ODT	rimegepant	Biohaven	calcitonin gene-related peptide (CGRP) inhibitor	Migraine prophylaxis	Preventive treatment of migraine in both episodic and chronic migraine patients	PO	6/1/2021
Ozempic	semaglutide	Novo Nordisk	glucagon-like peptide-1 (GLP-1) receptor agonist	Obesity	Treatment of adults with obesity (BMI ≥ 30 kg/m2) or overweight (BMI ≥ 27 kg/m2) with at least one weight-related comorbidity, as an adjunct to reduced-calorie diet and increased physical activity.	SC	6/4/2021
Trikafta	elexacaftor/tezacaftor/ivacaftor; ivacaftor	Vertex	cystic fibrosis transmembrane conductance	Cystic fibrosis	Treatment of children with CF ages 6 to 11 years who have two F508del mutations and in children who have	PO	6/8/2021

Brand name	Generic name	Company	Drug class	Therapeutic use	Proposed new indication	Route of administration	Estimated approval date
			regulator (CFTR) modulators		one F508del mutation and one minimal function mutation		
Nucala	mepolizumab	GlaxoSmithKline	IL-5 antagonist monoclonal antibody	Nasal polyps	Treatment of chronic rhinosinusitis with nasal polyposis	SC	6/15/2021
Shingrix	zoster vaccine recombinant, adjuvanted	GlaxoSmithKline	vaccine	Herpes zoster	Prevention of herpes zoster in adults aged 18 years and older at increased risk of herpes zoster	IM	6/15/2021
Ayvakit	avapritinib	Blueprint Medicines	selective KIT and PDGFRa inhibitor	Systemic mastocytosis	Treatment of adult patients with advanced systemic mastocytosis (SM)	PO	6/17/2021
Rinvoq	upadacitinib	AbbVie	janus associated kinase (JAK) inhibitor	Ankylosing spondylitis	Treatment of adult patients with active ankylosing spondylitis	PO	6/25/2021
Cosentyx	secukinumab	Novartis	IL-17 receptor antagonist	Pediatric psoriasis	Treatment of pediatric psoriasis	SC	6/27/2021
Solosec	secnidazole	Lupin Pharmaceuticals	nitroimidazole antimicrobial	Trichomoniasis	Treatment of trichomoniasis in adults and adolescents	PO	6/30/2021
Dupixent	dupilumab	Sanofi/ Regeneron	interleukin-4/13 (IL-4/IL-13) inhibitor	Asthma	Add-on maintenance treatment in patients with moderate-to-severe asthma aged 6 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma	SC	7/1/2021
Rinvoq	upadacitinib	AbbVie	janus associated kinase (JAK) inhibitor	Atopic dermatitis	Treatment of adults and adolescents with moderate to severe atopic dermatitis	PO	8/19/2021

Brand name	Generic name	Company	Drug class	Therapeutic use	Proposed new indication	Route of administration	Estimated approval date
Xarelto	rivaroxaban	Janssen	factor Xa inhibitor	Peripheral arterial disease	Reduce the risk of major thrombotic vascular events such as heart attack, stroke and amputation in patients after recent lower-extremity revascularization in patients with peripheral arterial disease (PAD)	PO	8/26/2021
Keytruda	pembrolizumab	Merck	anti-PD-1 inhibitor	Cutaneous squamous cell carcinoma	Treatment of patients with locally advanced cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation	IV	9/9/2021
Darzalex Faspro	daratumumab and hyaluronidase-fihj	Janssen/ Halozyme Therapeutics	humanized anti-CD38 monoclonal antibody	Multiple myeloma	In combination with pomalidomide and dexamethasone (D-Pd) for the treatment of patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy	SC	9/12/2021
Verzenio	abemaciclib	Eli Lilly	cyclin-dependent kinase 4 and 6 (CKD4/6) inhiibitor	Early breast cancer	Treatment of hormone receptor positive, HER2 negative, early breast cancer	PO	9/15/2021
Andexxa	coagulation factor Xa (recombinant), inactivated-zhzo	Alexion	recombinant Factor Xa inhibitor antidote	Drug toxicity	In patients presenting with acute intracranial hemorrhage while taking an oral Factor Xa inhibitor	IV	10/31/2021
Jakafi	ruxolitinib	Incyte	janus associated kinase (JAK) inhibitors	Graft-versus-host disease (GVHD)	Treatment of patients with chronic graft-versus-host disease (GVHD)	PO	11/11/2021

IM = intramuscular, INH = inhaled, IV = intravenous, OPH = ophthalmic, PO = oral, SC = subcutaneous, TOP = topical

References:

ADC Therapeutics Press Release. ADC Therapeutics Web site. ADC Therapeutics announces FDA accepts Biologics License Application and grants priority review for loncastuximab tesirine for treatment of relapsed or refractory diffuse large B-cell lymphoma. https://ir.adctherapeutics.com/press-releases/press-release-details/2020/ADC-Therapeutics-Announces-FDA-Accepts-Biologics-License-Application-and-Grants-Priority-Review-for-Loncastuximab-Tesirine-for-Treatment-of-Relapsed-or-Refractory-Diffuse-Large-B-cell-Lymphoma/default.aspx. November 20, 2020. Accessed January 13, 2021.

ADC Therapeutics Press Release. ADC Therapeutics Web site. ADC Therapeutics announces maturing data from pivotal Phase 2 clinical trial and Phase 1/2 combination clinical trial of loncastuximab tesirine (Lonca) in patients with relapsed or refractory diffuse large B-cell lymphoma. https://ir.adctherapeutics.com/press-releases/press-release-details/2020/ADC-Therapeutics-Announces-Maturing-Data-from-Pivotal-Phase-2-Clinical-Trial-and-Phase-12-Combination-Clinical-Trial-of-Loncastuximab-Tesirine-Lonca-in-Patients-with-Relapsed-or-Refractory-Diffuse-Large-B-cell-Lymphoma/default.aspx. June 12, 2020. Accessed January 13, 2021.

American Cancer Society. Bile duct cancer. American Cancer Society Web site. https://www.cancer.org/cancer/bile-duct-cancer.html. January 21, 2021.

American Cancer Society. Non-Hodgkin lymphoma. American Cancer Society Web site. https://www.cancer.org/cancer/non-hodgkin-lymphoma. Accessed January 13, 2021.

American College of Obstetricians and Gynecologists (ACOG). Uterine fibroids FAQs. ACOG Web site. https://www.acog.org/womens-health/faqs/uterine-fibroids. Accessed January 19, 2021.

Apellis Pharmaceuticals Press Release. Apellis Pharmaceuticals Web site. Apellis announces FDA acceptance and priority review of the New Drug Application for pegcetacoplan for the treatment of PNH. https://investors.apellis.com/news-releases/news-release-details/apellis-announces-fda-acceptance-and-priority-review-new-drug. November 16, 2021. Accessed January 12, 2021.

Apellis Pharmaceuticals Press Release. Apellis Pharmaceuticals Web site. New pivotal data demonstrate superiority of Apellis' pegcetacoplan to eculizumab in improving hemoglobin levels, independent of prior transfusions, in PNH. https://investors.apellis.com/news-releases/news-release-details/new-pivotal-data-demonstrate-superiority-apellis-pegcetacoplan. June 20, 2020. Accessed January 12, 2021.

BioMedTracker Drug Intelligence Platform. BioMedTracker Web site. http://www.biomedtracker.com/

BridgeBio Pharma Press Release. BridgeBio Pharma Web site. BridgeBio Pharma and affiliate QED Therapeutics announce FDA acceptance of New Drug Application for infigratinib for the treatment of cholangiocarcinoma. https://bridgebio.com/news/bridgebio-pharma-and-affiliate-qed-therapeutics-announce-fda-acceptance-of-new-drug-application-for-infigratinib-for-the-treatment-of-cholangiocarcinoma. December 1, 2020. Accessed January 21, 2021.

Centers for Disease Control and Prevention (CDC). 2015 sexually transmitted diseases treatment guidelines: vulvovaginal candidiasis. CDC Web site. https://www.cdc.gov/std/tg2015/candidiasis.htm. Last reviewed June 4, 2015. Accessed February 5, 2021.

ClinicalTrials.gov. Study to evaluate efficacy and safety of PF-04965842 in subjects aged 12 years and older with moderate to severe atopic dermatitis (JADE Mono-1). https://clinicaltrials.gov/ct2/show/NCT03349060. Accessed January 7, 2021.

De La Cruz MS, Buchanan EM. Uterine fibroids: diagnosis and treatment. Am Fam Physician. 2017;95(2):100-107.

Hamadani M, Radford J, Carlo-Stella C, et al. Final results of a Phase 1 study of loncastuximab tesirine in relapsed/refractory B-cell non-Hodgkin lymphoma. Blood. 2020. Epub ahead of print.

Incyte Press Release. Incyte Web site. https://investor.incyte.com/press-releases/press-releases/2020/Pooled-Results-from-Incytes-TRuE-AD1-and-TRuE-AD2-Atopic-Dermatitis-Studies-of-Ruxolitinib-Cream-Show-Clinically-Meaningful-Improvements-in-Patient-Reported-Quality-of-Life-Assessments/default.aspx. October 29, 2020. Accessed February 5, 2021.

Javle M, Lowery M, Shroff RT, et al. Phase II study of BGJ398 in patients with FGFR-altered advanced cholangiocarcinoma. J Clin Oncol. 2018;36(3):276-282.

Leonardi A, Doan S, Amrane M, et al; VEKTIS Study Group. A randomized, controlled trial of cyclosporine A cationic emulsion in pediatric vernal keratoconjunctivitis: the VEKTIS study. Ophthalmology. 2019;126(5):671-681.

Myovant Sciences Press Release. Myovant Sciences Web site. Myovant Sciences announces FDA acceptance of New Drug Application for once-daily relugolix combination tablet for uterine fibroids. https://investors.myovant.com/news-releases/news-release-details/myovant-sciences-announces-fda-acceptance-new-drug-application. August 17, 2020. Accessed January 19, 2021.

National Eczema Association. Atopic dermatitis. National Eczema Association Web site. https://nationaleczema.org/eczema/types-of-eczema/atopic-dermatitis/. Accessed January 7, 2021.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). Atopic dermatitis. NIAMS Web site. https://www.niams.nih.gov/health-topics/atopic-dermatitis. Accessed January 7, 2021.

National Organization for Rare Disorders (NORD). Vernal keratoconjunctivitis. NORD Web site. https://rarediseases.org/rare-diseases/vernal-keratonconjunctivitis. Accessed January 20, 2021.

Pfizer Press Release. Pfizer Web site. FDA grants priority review and EMA accepts regulatory submission for Pfizer's abrocitinib, an oral once-daily JAK1 inhibitor, for patients 12 and up with moderate to severe atopic dermatitis. https://www.pfizer.com/news/press-release/press-release-detail/fda-grants-priority-review-and-ema-accepts-regulatory. October 27, 2020. Accessed January 7, 2021.

Pfizer Press Release. Pfizer Web site. Pfizer announces positive top-line results from third Phase 3 trial of abrocitinib for moderate to severe atopic dermatitis, which showed improvements in skin clearance, disease extent and severity, and itch. https://www.pfizer.com/news/press-release/press-release-detail/pfizer_announces_positive_top_line_results_from_third_phase_3_trial_of_abrocitinib_for_moderate_to_severe_atopic_dermatitis_which_showed_improvements_in_skin_clearance_disease_extent_and_severity_and_itch. March 18, 2020. Accessed January 7, 2021.

Santen Pharmaceutical Press Release. Santen Pharmaceutical Web site. Santen announces U.S. FDA filling acceptance of New Drug Application (NDA) for cyclosporine topical ophthalmic emulsion, 0.1% in the treatment of severe vernal keratoconjunctivitis in patients ages 4-18. https://www.santen.com/en/news/20201026.pdf. October 26, 2020. Accessed January 20, 2021.

Scynexis Press Release. Scynexis Web site. Scynexis announces FDA acceptance and priority review of New Drug Application for oral ibrexafungerp for the treatment of vaginal yeast infections. https://www.scynexis.com/news-media/press-releases/detail/225/scynexis-announces-fda-acceptance-and-priority-review-of. December 7, 2020. Accessed January 13, 2021.

Scynexis Press Release. Scynexis Web site. Scynexis reports positive top-line results from first Phase 3 registration study of oral ibrexafungerp in vulvovaginal candidiasis (VANISH-303). https://www.scynexis.com/news-media/press-releases/detail/193/scynexis-reports-positive-top-line-results-from-first-phase. November 7, 2019. Accessed January 13, 2021.

Scynexis Press Release. Scynexis Web site. Scynexis announces positive top-line results from its second pivotal Phase 3 study (VANISH-306) of oral ibrexafungerp for the treatment of vulvovaginal candidiasis (vaginal yeast infection). https://www.scynexis.com/news-media/press-releases/detail/207/scynexis-announces-positive-top-line-results-from-its. April 21, 2020. Accessed January 13, 2021.

Scynexis Press Release. Scynexis Web site. Scynexis announces the presentation of SCY-078 data at the Teratology Society 58th Annual Meeting. https://www.scynexis.com/news-media/press-releases/detail/154/scynexis-announces-the-presentation-of-scy-078-data-at-the. June 27, 2018. Accessed February 5, 2021.

Silverberg JI, Simpson EL, Thyssen JP, et al. Efficacy and safety of abrocitinib in patients with moderate-to-severe atopic dermatitis: a randomized clinical trial. JAMA Dermatol. 2020;156(8):863-873.

Silverberg JI, Toth D, Bieber T, et al. Tralokinumab plus topical corticosteroids for the treatment of moderate-to-severe atopic dermatitis: results from the double-blind, randomized, multicentre, placebo-controlled phase III ECZTRA 3 trial. Br J Dermatol. 2020. Epub ahead of print.

Simpson EL, Sinclair R, Forman S, et al. Efficacy and safety of abrocitinib in adults and adolescents with moderate-to-severe atopic dermatitis (JADE MONO-1): a multicentre, double-blind, randomised, placebo-controlled, phase 3 trial. Lancet. 2020;396(10246):255-266.

UpToDate Database. https://www.uptodate.com.

Wollenberg A, Blauvelt A, Guttman-Yassky; ECZTRA 1 and ECZTRA 2 study investigators. Tralokinumab for moderate-to-severe atopic dermatitis: results from two 52-week, randomized, double-blind, multicentre, placebo-controlled phase III trials (ECZTRA 1 and ECZTRA 2). Br J Dermatol. 2020. Epub ahead of print.

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