RxOutlook®

1st Quarter 2025

Optum Rx®

Welcome to the 1st quarter RxOutlook Report of 2025. Optum Rx closely monitors and evaluates the drug development pipeline to identify noteworthy upcoming drug approvals and reports the essential findings here in RxOutlook.

Recap of 2024

In 2024, the FDA's Center for Drug Evaluation and Research (CDER) approved 50 novel drugs. Of the 50 approvals, 24 drugs (48%) were considered first-in-class and 33 (66%) used one or more expedited FDA programs (ie, Fast Track, Breakthrough Therapy, Priority Review, or Accelerated Approval). For the fifth year in a row, the number of novel therapies approved with Orphan Drug status exceeded non-Orphan Drugs (52% were Orphan Drugs).

In addition to these 50 novel drugs, the FDA's Center for Biologics Evaluation and Research (CBER) approved several cellular or gene therapies, including: Ryoncil® (remestemcel-L-rknd) for graft versus host disease; Kebilidi™ (eladocagene exuparvovec-tneq) for aromatic L-amino acid decarboxylase (AADC) deficiency; and Lenmeldy™ (atidarsagene autotemcel) for metachromatic leukodystrophy.

Looking Ahead to 2025

The number of novel new drugs forecasted for 2025 is expected to be similar to totals observed for 2024, and is likely to continue to emphasize treatments for rare diseases, oncology, and other conditions often treated with drugs under the specialty benefit. The final number of FDA approvals will depend on how many more new drug applications are filed with the FDA over the next several months and how many drugs are rejected by the FDA.

In this edition of RxOutlook, we will be highlighting seven drugs with an approval decision by the end of the 2nd quarter 2025. This includes two new potential indications for currently approved drugs – **Amvuttra® (vutrisiran)** and **Tremfya® (guselkumab)**. Amvuttra is under FDA review for a new indication for treatment of cardiomyopathy of transthyretin-mediated amyloidosis. Amvuttra is administered once every 3 months via subcutaneous injection and would be an alternative to orally administered transthyretin stabilizers (eg, Vyndamax™ [tafamidis]). Tremfya is under FDA review for a new indication for Crohn's disease and would be another IL-23 antagonist for the condition.

Of the five novel drugs discussed in the report, three will be used to treat rare conditions. **Sebetralstat** would potentially be the first oral therapy for on-demand or acute treatment of hereditary angioedema attacks. **Nipocalimab** would be the third anti-neonatal Fc receptor (FcRn) targeted therapy for generalized myasthenia gravis and **atrasentan** would be the second therapy targeting endothelin receptors for IgA nephropathy.

The other remaining topics in the report include **Cardamyst (etripamil)**, a novel fast acting intranasal calcium channel blocker for paroxysmal supraventricular tachycardia, a condition characterized by episodes of rapid heart rate; and **telisotuzumab vedotin**, a novel antibody-drug conjugate for patients with non-small cell lung cancer.

Key FDA approval decisions expected by the end of the 2nd quarter 2025

Drug Name	Manufacturer	Indication/Use	Expected FDA Decision Date
Amvuttra (vutrisiran)	Alnylam Pharmaceuticals	Cardiomyopathy of transthyretin-mediated amyloidosis*	March 23, 2025
Cardamyst (etripamil)	Milestone Pharmaceuticals	Paroxysmal supraventricular tachycardia	March 27, 2025
Tremfya (guselkumab)	Johnson & Johnson	Crohn's disease	April 20, 2025
Telisotuzumab vedotin	AbbVie	Non-small cell lung cancer	May 2025
Sebetralstat	KalVista Pharmaceuticals	Hereditary angioedema*	June 17, 2025
Nipocalimab	Johnson & Johnson	Generalized myasthenia gravis*	2Q 2025
Atrasentan	Novartis	IgA nephropathy	2Q 2025

* Orphan Drug Designation

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 2025.

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

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.

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 2025 may appear in future reports; however, for those who need an initial look at the larger pipeline, please refer to the Brand Pipeline Forecast Table found later in this report.

Read more

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 Drug Insights

Vutrisiran (Brand Name: Amvuttra®)

Manufacturer: Alnylam Pharmaceuticals
Regulatory designation: Orphan Drug
Expected FDA decision: March 23, 2025

Therapeutic use

Amvuttra is under review for the treatment of cardiomyopathy of transthyretin-mediated amyloidosis (ATTR-CM).

Amvuttra is currently approved for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

Transthyretin is a protein that normally transports thyroid hormone and vitamin A. In ATTR-CM, transthyretin proteins misfold and deposit in different organs of the body, including the heart. When amyloid deposits build up in the heart, it can cause dysfunction of the heart muscles (cardiomyopathy) and ultimately lead to symptoms of heart failure.

Two major forms of ATTR-CM exist. Hereditary ATTR-CM is caused by a genetic mutation in the transthyretin gene which produces transthyretin proteins that are predisposed to misfolding and deposition into muscles. Wild-type ATTR-CM is caused by the deposition of misfolded normal transthyretin through an unknown mechanism.

What you need to know:

Proposed Indication: Treatment of ATTR-CM

Mechanism: siRNA targeting transthyretin

Efficacy: Composite of death from any cause and recurrent cardiovascular events: 38% vs. 48% with placebo (28% reduction vs. placebo)

Safety: Amvuttra and placebo had similar AE profiles

Dosing: SC once every 12 weeks

Why it Matters: Novel mechanism for the treatment of ATTR-CM, alternative to once daily oral drugs (ie, Vyndamax, Attruby)

Important to Note: Lack of direct head-to-head data vs. Vyndamax, list price is significantly higher than both Vyndamax and Attruby, requires healthcare provider administration

Estimated Cost: ~$480,000 per year (based on current cost of Amvuttra)

The exact prevalence of ATTR-CM is unknown since it is underdiagnosed, but it is estimated to affect over 100,000 people in the U.S.

Clinical profile

Amvuttra is a double-stranded small interfering ribonucleic acid (siRNA) that causes degradation of mutant and wild-type transthyretin mRNA through RNA interference, which results in a reduction of serum transthyretin protein and transthyretin protein deposits in tissues.

Pivotal trial data:
The efficacy of Amvuttra was evaluated in HELIOS-B, a Phase 3, randomized, double-blind, placebo-controlled study in 655 patients with ATTR-CM. Patients were randomized to Amvuttra or placebo for up to 36 months. Patients were allowed to be on baseline therapy with tafamidis, an oral transthyretin stabilizer for ATTR-CM. The primary endpoint was a composite of death from any cause and recurrent cardiovascular events (defined as hospitalizations for cardiovascular causes or urgent visits for heart failure). The endpoints were assessed in the overall population and in the monotherapy population (patients who were not receiving tafamidis).

Vutrisiran (continued...)

Amvuttra treatment led to a lower risk of death from any cause and recurrent cardiovascular events than placebo (hazard ratio [HR] in the overall population, 0.72; 95% CI: 0.56, 0.93; p = 0.01; HR in the monotherapy population, 0.67; 95% CI: 0.49, 0.93; p = 0.02) and a lower risk of death from any cause through 42 months (HR in the overall population, 0.65; 95% CI: 0.46, 0.90; p = 0.01).

Among the patients in the overall population, 38% in the Amvuttra group and 48% in the placebo group had at least one primary endpoint event. Among the patients in the monotherapy population, 39% in the Amvuttra group and 53% in the placebo group had at least one primary endpoint event.

Safety:
In the pivotal trial, Amvuttra and placebo had similar safety profiles.

Dosing:
In the pivotal trial, Amvuttra was administered subcutaneously (SC) once every 12 weeks.

Competitive environment

If Amvuttra is approved for this new indication, it would be competing with orally administered transthyretin stabilizers – Pfizer's Vyndamax® (tafamidis) and BridgeBio's recently approved Attruby™ (acoramidis). The once every 3-month dosing of Amvuttra may be appealing to patients who are open to healthcare provider administered SC injections as an alternative to daily oral medications.

The primary endpoints were different for the trials evaluating Vyndamax, Attruby, and Amvuttra, which make indirect comparisons difficult; however, each drug has demonstrated robust improvements across a range of cardiovascular outcomes.

Transthyretin stabilizers and Amvuttra have different mechanisms of action and theoretically could be used in combination with one another for the treatment of ATTR-CM. The pivotal study for Amvuttra allowed for concomitant use of Vyndamax but there is insufficient data to asssess the benefit of combination therapy.

From a cost perspective, the Wholesale Acquisition Cost (WAC) for Amvuttra is approximately $480,000 per year, which is markedly higher than both Vyndamax ($270,000) and Attruby ($245,000).

Etripamil (Brand Name: Cardamyst)

Manufacturer: Milestone Pharmaceuticals
Expected FDA decision: March 27, 2025

Therapeutic use

Cardamyst is under review for the management of paroxysmal supraventricular tachycardia (PSVT).

PSVT is a condition in which patients experience episodes of a rapid heart rate that start in a part of the heart above the ventricles. For most adults, a normal resting heart rate is between 60 and 100 beats per minute. In patients experiencing PSVT episodes, the heart rate can commonly reach 150 to 250 beats per minute. These episodes can occur frequently and without warning. In severe episodes, patients can experience palpitations, chest discomfort, dyspnea, light-headedness, and syncope. Severe episodes may require acute treatment to convert patients to normal sinus rhythm.

Milestone Pharmaceuticals estimates that about 2 million patients have been diagnosed with PSVT and 300,000 newly diagnosed cases per year.

Clinical profile

Etripamil is a fast-acting, calcium channel blocker.

Pivotal trial data:
The efficacy of etripamil was evaluated in NODE-301, a two-part, Phase 3, randomized, double-blind, place-controlled study in adult patients with a history of PSVT.

What you need to know:

Proposed Indication: Management of paroxysmal supraventricular tachycardia

Mechanism: Calcium channel blocker

Efficacy: Conversion of PSVT to sinus rhythm: 64% vs. 31% with placebo (RAPID trial)

Common AEs: Nasal discomfort, nasal congestion, rhinorrhea

Dosing: Intranasal as needed (up to two doses for an episode)

Why it Matters: First intranasal calcium channel blocker for PSVT, may reduce the need for healthcare and emergency room visits

Important to Note: PSVT episodes are often mild and can be self-treated by non-pharmacologic techniques, modest efficacy with no difference between etripamil vs. placebo at 5 hours post-dose (primary endpoint in earlier study)

In Part 1, a medically supervised etripamil test dose was given while patients were in sinus rhythm, and then patients (n = 419) were randomized to receive etripamil or placebo. When PSVT symptoms developed, patients applied a cardiac monitor and attempted a vagal maneuver; if symptoms persisted, they self-administered blinded treatment. The primary endpoint was conversion of PSVT to sinus rhythm within 5 hours after administration. There were 156 accrued positively adjudicated PSVT events treated with etripamil or placebo. The primary endpoint was not met as the hazard ratio (HR) for the primary endpoint was 1.086 (95% CI: 0.726, 1.623; p = 0.12). Following study drug administration, the probability of conversion within the first 30 minutes was 54% for etripamil vs. 35% for placebo.

In Part 2 of the study (also called the RAPID trial), 692 patients were randomized to etripamil or placebo. Patients self-administered a first dose of etripamil or placebo and, if symptoms persisted beyond 10 minutes, a repeat dose was administered. The primary endpoint was conversion of PSVT to sinus rhythm within 30 minutes after the first dose. The conversion rates by 30 minutes were 64% with etripamil and 31% with placebo (HR 2.62, 95% CI: 1.66, 4.15; p < 0.0001). Median time to conversion was 17.2 minutes (95% CI: 13.4, 26.5) with etripamil vs. 53.5 minutes (95% CI: 38.7, 87.3) with placebo.

Etripamil (continued...)

Safety:
The most common adverse events with etripamil use were nasal discomfort, nasal congestion, and rhinorrhea.

Dosing:
In the pivotal trials, etripamil was administered intranasally as needed for PSVT episodes.

Competitive environment

Etripamil is a novel intranasally administered fast acting calcium channel blocker that would provide a self-administered treatment option for patients experiencing PSVT. PSVT episodes are generally not life threatening but can have an impact on a patient's quality of life. Patients who experience a PSVT episode can self-treat with vagal maneuvers (eg, bearing down like you're having a bowel movement). If symptoms persist, patients can require hospital visits to be treated with intravenous calcium channel blockers or adenosine. Oral calcium channel blockers and beta blockers can be used in some cases ("pill-in-pocket" approach), but these have limited efficacy.

The primary differentiator for intranasal etripamil is that it could allow patients to self-treat their PSVT episodes and thus potentially avoid seeking emergency acute care. In the pivotal study, there were lower percentages of patients seeking additional medical interventions (eg, intravenous adenosine) and emergency department visits in the etripamil group than in the placebo group, however significance was not shown.

Guselkumab (Brand Name: Tremfya®)

Manufacturer: Johnson & Johnson
Expected FDA decision: April 18, 2025

Therapeutic use

Tremfya is under review for treatment of adults with moderately to severely active Crohn's disease.

Tremfya is currently approved for plaque psoriasis, psoriatic arthritis, and ulcerative colitis.

Crohn's disease is one of two main types of inflammatory bowel disease (the other is ulcerative colitis). Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract with no known cause. Symptoms can range from mild to severe, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, and weight loss.

Inflammatory bowel disease (ulcerative colitis and Crohn's disease) affects about 3 million people in the U.S.

Clinical profile

Tremfya is a dual-acting monoclonal antibody that blocks interleukin (IL)-23 by binding to the p19 subunit of IL-23 and binding to CD64, a receptor on cells that produce IL-23. IL-23 is an important driver of the development of inflammatory diseases.

Pivotal trial data:
The efficacy of Tremfya was evaluated in GALAXI 2 and GALAXI 3, two identical Phase 3, randomized, double-blind, placebo-controlled, active-controlled studies in patients with moderately to severely active Crohn's disease with inadequate response/intolerance to conventional therapies (corticosteroids or immunomodulators) and/or biologics (tumor necrosis factor [TNF] antagonists or Entyvio® [vedolizumab]). Patients were randomized to one of the following groups: Tremfya intravenous (IV) induction followed by Tremfya SC maintenance (200 mg every 4 weeks or 100 mg every 8 weeks); Stelara IV induction followed by Stelara SC maintenance; or placebo. The co-primary endpoints were (1) clinical response at Week 12 and clinical remission at Week 48, and (2) clinical response at Week 12 and endoscopic response at Week 48. The primary analysis compared Tremfya vs. placebo. Secondary analysis included comparisons of Tremfya vs. Stelara.

In GALAXI 2, clinical response at Week 12 and clinical remission at Week 48 was achieved in 49.0% to 54.8% of patients with Tremfya vs. 11.8% with placebo ($p < 0.001$ for both Tremfya doses). Clinical response at Week 12 and endoscopic response at Week 48 was achieved in 38.4% to 39.2% of patients with Tremfya vs. 5.3% with placebo ($p < 0.001$ for both Tremfya doses). In GALAXI 3, clinical response at Week 12 and clinical remission at Week 48 was achieved in 46.9% to 48.0% of patients with Tremfya vs. 12.5% with placebo ($p < 0.001$ for both Tremfya doses). Clinical response at Week 12 and endoscopic response at Week 48 was achieved in 33.6% to 36.0% of patients with Tremfya vs. 5.6% with placebo ($p < 0.001$ for both Tremfya doses).

What you need to know:

Proposed Indication: Treatment of adults with moderately to severely active Crohn's disease

Mechanism: IL-23 antagonist

Efficacy:

- GALAXI 2 and 3 (pooled analysis): Clinical and endoscopic remission at Week 48: 41.6% to 47.3% with Tremfya vs. 33.7% with Stelara
- GRAVITI: Clinical remission at Week 12: 56.1% with Tremfya SC vs. 21.4% with placebo; Endoscopic response at Week 12: 41.3% with Tremfya vs. 21.4% with placebo

Safety: Consistent with the known safety profile of Tremfya across its currently approved indications

Dosing: IV or SC induction therapy; SC maintenance therapy every 4 to 8 weeks

Why it Matters: Demonstrated superiority vs. Stelara for endoscopic endpoints, flexibility of IV or SC induction therapy (other biologics may require IV induction)

Important to Note: Alternatives available including within class (eg, Omvoh, Skyrizi), biosimilar competition (eg, Humira, Stelara)

Estimated Cost: ~$14,000 per dose (based on current pricing for Tremfya)

Guselkumab (continued...)

At Week 48, Tremfya also demonstrated statistical superiority vs. Stelara across key secondary endpoints. In a pooled analysis of GALAXI 2 and 3, endoscopic response at Week 48 was achieved in 47.9% to 52.7% of patients with Tremfya vs. 37.1% of patients with Stelara. Clinical remission with endoscopic remission was achieved in 41.6% to 47.3% of patients with Tremfya vs. 33.7% with Stelara.

The efficacy of Tremfya was also evaluated in GRAVITI, a Phase 3, randomized, double-blind, placebo-controlled study in a similar Crohn's disease population as the GALAXI trials. The main difference in this study was that patients received induction therapy with SC Tremfya instead of IV. Patients were randomized to Tremfya SC 400 mg every 4 weeks followed by Tremfya 200 mg SC every 4 weeks or Tremya 100 mg SC every 8 weeks, or placebo. The co-primary endpoints were clinical remission and endoscopic response at Week 12.

At Week 12, clinical remission was achieved in 56.1% of patients with Tremfya vs. 21.4% of patients with placebo ($p < 0.001$). Endoscopic response was achieved in 41.3% of patients with Tremfya vs. 21.4% of patient with placebo ($p < 0.001$). Both doses of Tremfya also demonstrated superiority vs. placebo for the key secondary endpoints at Week 48 (clinical remission and endoscopic response).

Safety:
The safety findings in the Crohn's disease studies were consistent with the known safety profile of Tremfya across its currently approved indications.

Dosing:
In the pivotal trials, Tremfya was administered via SC injection or IV infusion for induction, followed by maintenance SC therapy every 4 to 8 weeks.

Competitive environment

Tremfya is Johnson & Johnson's selective IL-23 antagonist and their successor to Stelara (an IL-12/IL-23 antagonist) which faces biosimilar competition in 2025. If approved for Crohn's disease, Tremfya will have mirroring adult indications to Stelara. The two differentiators for Tremfya include promising head-to-head trial data vs. Stelara demonstrating improvements in endoscopic endpoints and the flexibility to use a SC or IV formulation for induction therapy.

Tremfya will be a late market entry for the treatment of Crohn's disease, a disease state that has become increasingly competitive, with the availability of multiple drugs across different mechanisms of action. Within the same class of selective IL-23 antagonists, Tremfya will be competing with Eli Lilly's Omvoh™ (mirikizumab-mrkz) and AbbVie's Skyrizi® (risankizumab-rzaa). Additionally, there is biosimilar competition with Stelara and Humira (adalimumab) (a TNF blocker), both of which are approved for Crohn's disease.

The WAC for Tremfya is approximately $14,000 per dose.

Telisotuzumab vedotin (Brand Name: To be determined)

Manufacturer: AbbVie
Regulatory designation: Breakthrough Therapy
Expected FDA decision: May 2025 *(accelerated approval decision)*

Therapeutic use

Telisotuzumab vedotin is under review for the treatment of adult patients with previously treated, locally advanced or metastatic epidermal growth factor receptor (EGFR) wild type, nonsquamous non-small cell lung cancer (NSCLC) with c-Met protein overexpression.

Lung cancer is a common cancer in both men and women, with about 234,580 new cases expected in 2024 in the U.S. NSCLC is the most common type of lung cancer, affecting about 80% of cases, and 70% of NSCLC tumors are of nonsquamous histology. The c-Met protein is a receptor tyrosine kinase found to be overexpressed in approximately 25% of advanced EGFR wild type, nonsquamous NSCLC patients and is associated with a poor prognosis.

Clinical profile

Telisotuzumab is a c-Met protein directed antibody-drug conjugate designed to target c-Met overexpressing tumors.

Pivotal trial data:
The efficacy of telisotuzumab was evaluated in LUMINOSITY, a Phase 2, open-label study in 172 patients with previously treated c-Met-overexpressing non-squamous EGFR wildtype advanced NSCLC. The primary endpoint was the overall response rate (ORR).

The ORR was 34.6% (c-Met high overexpression), 22.9% (c-Met intermediate overexpression), and 28.6% (overall population). The median duration of response was 9.0 months (c-Met high overexpression), 7.2 months (c-Met intermediate overexpression), and 8.3 months (overall population).

Safety:
The most common adverse events with telisotuzumab use were peripheral sensory neuropathy, peripheral edema, and fatigue.

Dosing:
In the pivotal trial, telisotuzumab was administered via IV infusion every 14 days.

What you need to know:

Proposed Indication: Treatment of adult patients with previously treated, locally advanced or metastatic EGFR wild type, nonsquamous NSCLC with c-Met protein overexpression

Mechanism: Antibody-drug conjugate targeting c-Met

Efficacy: ORR (overall population): 28.6%

Common AEs: Peripheral sensory neuropathy, peripheral edema, fatigue

Dosing: IV once every 14 days

Why it Matters: First-in-class antibody-drug conjugate, first targeted therapy for this subpopulation of NSCLC patients (c-Met overexpression)

Important to Note: Lack of robust overall survival data (confirmatory trial ongoing with completion expected in March 2028), safety concern for pneumonitis and bronchopulmonary hemorrhage

Estimated Cost: ~$315,000 per year (based on pricing for Tepmetko)

Telisotuzumab vedotin (continued...)

Competitive environment

There are currently no FDA approved therapies specifically for c-Met overexpression in NSCLC and telisotuzumab would be a first-in-class therapy for this population. The Phase 2 trial data are promising given the unmet need in this population and the results could support an accelerated approval. Telisotuzumab is also being evaluated in a larger confirmatory, Phase 3, head-to-head trial vs. chemotherapy with docetaxel. That study is expected to complete in March 2028 and will provide more robust data on the potential survival benefit with telisotuzumab.

There were important safety signals in the pivotal study, most notably rare but serious adverse events like pneumonitis and bronchopulmonary hemorrhage. If telisotuzumab is approved, these serious adverse events will require close monitoring.

For reference, the WAC for Tepmetko® (tepotinib), a kinase inhibitor that targets MET, is approximately $315,000 per year.

Sebetralstat (Brand Name: To be determined)

Manufacturer: KalVista Pharmaceuticals
Regulatory designations: Orphan Drug, Fast Track
Expected FDA decision: June 17, 2025

Therapeutic use

Sebetralstat is under review for the on-demand treatment of hereditary angioedema (HAE) attacks in adult and pediatric patients aged 12 years and older.

HAE is an inherited disorder characterized by recurrent episodes of the accumulation of fluids outside of the blood vessels, causing rapid swelling of tissues in the hands, feet, limbs, face, intestinal tract, or airway. Swelling of the airway may lead to obstruction, a potentially very serious complication. The severity of the disease varies greatly among affected individuals.

HAE affects about 1 in every 50,000 individuals and the estimated prevalence in the U.S. is about 6,500 to 8,000 in the U.S.

Clinical profile

Sebetralstat is a plasma kallikrein inhibitor. Inhibition of plasma kallikrein reduces bradykinin, a potent vasodilator that increases vascular permeability resulting in swelling and pain associated with HAE.

What you need to know:

Proposed Indication: On-demand treatment of HAE attacks in adult and pediatric patients aged 12 years and older

Mechanism: Plasma kallikrein inhibitor

Efficacy: Median time to the beginning of symptom relief: 1.61 to 1.79 hours vs. 6.72 hours with placebo

Safety: Sebetralstat and placebo had similar AE profiles

Dosing: Oral as needed (up to two doses for an acute attack)

Why it Matters: Potentially the first oral therapy for on-demand treatment of HAE and alternative to injectable SC and IV options

Important to Note: Lack of head-to-head trial data vs. current standard of care, alternatives available including generic icatibant

Pivotal trial data:
The efficacy of sebetralstat was evaluated in KONFIDENT, a Phase 3, randomized, double-blind, event-driven study in 136 patients at least 12 years of age with HAE. Patients self-administered each eligible HAE attack with up to two doses of study drug (sebetralstat 300 mg, sebetralstat 600 mg, or placebo), and each patient could treat up to three HAE attacks over the course of the study. The primary endpoint, assessed in a time-to-event analysis, was the beginning of symptom relief, defined as a rating of “a little better” on the Patient Global Impression of Change scale (ratings range from “much worse” to “much better”) at two or more consecutive time points within 12 hours after the first administration of the study drug.

The time to the beginning of symptom relief with the sebetralstat 300 mg dose and the sebetralstat 600 mg dose was faster than with placebo ($p < 0.001$ and $p = 0.001$ for the two comparisons, respectively), with median times of 1.61 hours (interquartile range, 0.78 to 7.04), 1.79 hours (1.02 to 3.79), and 6.72 hours (1.34 to >12), respectively. The time to reduction in the attack severity with the 300 mg dose and the 600 mg dose was faster than with placebo ($p = 0.004$ and $p = 0.003$), with median times of 9.27 hours (interquartile range, 1.53 to >12), 7.75 hours (2.19 to >12), and more than 12 hours (6.23 to >12). The percentage of attacks with complete resolution within 24 hours was 42.5% with the 300 mg dose, 49.5% with the 600 mg dose, and 27.4% with placebo.

Sebetralstat (continued...)

Safety:
In the pivotal trial, sebetralstat and placebo had similar safety profiles.

Dosing:
In the pivotal trial, sebetralstat was administered orally after an HAE attack and could be used for up to two doses.

Competitive environment

Treatment for HAE includes both prophylaxis and on-demand therapies for acute attacks. If approved, sebetralstat would be the first oral on-demand treatment and a competitor to the current SC and IV options (eg, Ruconest®, Berinert®, Kalbitor®, Firazyr®). Except for Firazyr, which is available generically (icatibant), the other drugs are currently only available as branded products.

Oral administration is the main differentiator for sebetralstat since it would be easier to transport, store, and administer compared to injectable therapies. Reducing the burden for treatment may help reduce treatment delays for acute attacks.

The efficacy and safety profile of sebetralstat appear promising relative to placebo; however, there is no head-to-head study comparing it against any of the current standard of care options. Since sebetralstat is administered as an oral tablet, there may be some caution or reluctance to prescribe it over injectable therapies in patients at high risk for laryngeal attacks (which can be severe). KalVista is developing an orally disintegrating tablet formulation which may alleviate this concern in the future.

Nipocalimab (Brand Name: To be determined)

Manufacturer: Johnson & Johnson
Regulatory designations: Orphan Drug, Fast Track
Expected FDA decision: 2Q 2025

Therapeutic use

Nipocalimab is under review for treatment of generalized myasthenia gravis (gMG).

MG is a neuromuscular, autoimmune disorder characterized by weakness and fatigue affecting multiple muscle groups. Symptoms can include, but are not limited to weakness of eye muscles, impaired speech, difficulties swallowing, and weakness of the upper arms and legs. In very severe cases, patients can experience life-threatening complications due to involvement of muscles used during breathing.

In patients with the condition, the body's immune system attacks muscle receptors by producing anti-receptor antibodies (eg, anti-acetylcholine receptor [AChR]) that can block or destroy these muscle receptors, preventing signals from transferring from nerves to muscle.

gMG affects approximately 100,000 people in the U.S. Symptom onset most commonly peaks in females during their 20s or 30s and in males in their 50s or 60s.

What you need to know:

Proposed Indication: Treatment of gMG

Mechanism: anti-FcRn monoclonal antibody

Efficacy: Change in MG-ADL: –4.70 vs. –3.25 with placebo

Common AEs: Diarrhea, headache, nasopharyngitis

Dosing: IV once every 2 weeks

Why it Matters: Additional competitor for gMG with potential broad indication, also in development for multiple other conditions (eg, autoimmune hemolytic anemia, chronic inflammatory demyelinating polyneuropathy)

Important to Note: Highly competitive category including competition within the FcRn class, no head-to-head trial data, requires IV administration

Estimated Cost: ~$400,000 per year (based on average pricing for gMG drugs)

Clinical profile

Nipocalimab is an anti-neonatal Fc receptor (FcRn) monoclonal antibody. Inhibition of FcRn reduces circulating IgG antibodies, which are involved in the pathogenesis of gMG.

Pivotal trial data:
The efficacy of nipocalimab was evaluated in Vivacity-MG3, a Phase 3, randomized, double-blind, placebo-controlled study in patients with gMG. Patients were randomized to nipocalimab plus standard of care (SOC) or placebo plus SOC. The primary endpoint was the mean change in Myasthenia Gravis – Activities of Daily Living (MG-ADL) score from baseline to Week 24 in the 153 antibody positive patients. MG-ADL is an assessment of symptoms impacting activities of daily living, with a total score range of 0 to 24; a higher score indicates greater symptom severity.

Patients receiving nipocalimab plus SOC improved by 4.70 points on the MG-ADL score vs. 3.25 points with placebo plus SOC (difference of least squares means –1.45, p = 0.002).

Nipocalimab (continued...)

Safety:
The most common adverse events with nipocalimab use were diarrhea, headache, and nasopharyngitis.

Dosing:
In the pivotal trial, nipocalimab was administered via IV infusion every 2 weeks.

Competitive environment

The current standard of care for gMG includes acetylcholinesterase inhibitors (eg, pyridostigmine), steroids, and nonsteroidal immunosuppressants (such as azathioprine, tacrolimus, mycophenolate mofetil). For patients who require additional steroid-sparing treatment, complement inhibitors (ie, Ultomiris®, Soliris®, Zilbrysq®) and other FcRN targeted therapies are also available (ie, Vyvgart® and Rystiggo®).

Nipocalimab would be the third FcRN targeted therapy and a competitor to both complement inhibitors and other FcRN targeted therapies. All these therapies are high cost and do not have generic/biosimilar alternatives; however, Soliris is expected to have biosimilar competition later this year. Nipocalimab was not compared head-to-head against existing treatment options, and cross trial comparisons are difficult due to differences in study populations. A potential differentiator for nipocalimab is that it was studied in a broad population, including patients with anti-acetylcholine receptor (AChR), anti-muscle-specific tyrosine kinase (MuSK), and/or anti-low density lipoprotein-related protein 4 (LRP4) antibodies. There is currently no FDA approved therapy for patients with LRP4 antibodies.

Like many of the other drugs approved in this category, nipocalimab is being studied for a wide range of conditions, including hemolytic disease of the fetus and newborn, warm autoimmune hemolytic anemia, and chronic inflammatory demyelinating polyneuropathy. If data is positive for these other disease states, that will significantly increase the market potential for nipocalimab.

For reference, the average WAC for gMG drugs is approximately $400,000 per year.

Atrasentan (Brand Name: To be determined)

Manufacturer: Novartis
Expected FDA decision: 2Q 2025 *(accelerated approval decision)*

Therapeutic use

Atrasentan is under review for treatment of immunoglobulin A (IgA) nephropathy.

IgA nephropathy, also known as Berger's disease, is a kidney disease that occurs when IgA deposits build up in the kidneys, causing inflammation that damages kidney tissues. As a result, the kidneys begin to let substances such as blood and protein leak into the urine. Over time, IgA nephropathy can lead to end-stage kidney disease (ESKD) and the need for dialysis. The condition can occur at any age, although the first evidence of kidney disease most frequently appears when people are in their teens to late 30s.

IgA nephropathy is one of the most common kidney diseases, other than those caused by diabetes or high blood pressure. The disease affects over 100,000 people in the U.S.

What you need to know:

Proposed Indication: Treatment of IgA nephropathy

Mechanism: Endothelin receptor inhibitor

Efficacy: Change in urinary protein-to-creatinine ratio at Week 36: –38.1% vs. –3.1% with placebo

Safety: Similar rates of AEs compared to placebo

Dosing: Oral once daily

Why it Matters: Promising interim efficacy data, favorable safety profile

Important to Note: First-line treatments include generically available renin–angiotensin system inhibitors (ACE inhibitors) and corticosteroids, alternative second-and third-line options available (ie, Filspari, Fabhalta), lack of kidney function data

Estimated Cost: ~$119,000 per year (based on pricing for Filspari)

Clinical profile

Atrasentan is a selective inhibitor of the endothelin type A receptor. Endothelin-1 is implicated in the pathophysiology of IgA nephropathy. Binding of endothelin-1 to the endothelin type A receptor in the kidney causes cellular damage and tubular inflammation.

Pivotal trial data:
The efficacy of atrasentan was evaluated in ALIGN, a Phase 3, randomized, double-blind, placebo-controlled study in adults with biopsy-proven IgA nephropathy. Patients were randomized to receive atrasentan or placebo for 132 weeks. The primary endpoint, assessed at a prespecified interim analysis of data from the first 270 patients in the main stratum, was the change in the 24-hour urinary protein-to-creatinine ratio from baseline to Week 36.

The geometric mean percentage change in the urinary protein-to-creatinine ratio relative to baseline was significantly greater with atrasentan (–38.1%) than with placebo (–3.1%), with a geometric mean between-group difference of –36.1 percentage points (95% CI: –44.6, –26.4; $p < 0.001$).

Atrasentan (continued...)

Safety:
In the pivotal trial, the percentage of patients with adverse events did not differ substantially between the atrasentan and placebo groups.

Dosing:
In the pivotal trial, atrasentan was administered orally once daily.

Competitive environment

Historically, the standard of care for IgA nephropathy included renin–angiotensin system inhibitors (eg, angiotensin-converting enzyme [ACE] inhibitors) and corticosteroids. Since 2023, the FDA approved two novel therapies for IgA nephropathy: Travere Therapeutics' Filspari® (sparsentan), a dual blocker of endothelin receptor and angiotensin receptor, and Novartis' Fabhalta® (iptacopan), a complement factor B inhibitor. Atrasentan would be a direct competitor to Filspari and provide another add-on therapy option in patients who need multitargeted regimens.

The interim data from the ALIGN trial for atrasentan are promising with significant improvements in proteinuria; however, this is a surrogate endpoint for the disease and would only provide support for an accelerated approval. The final, long-term analysis of ALIGN will evaluate the effects of atrasentan on kidney function (using the estimated glomerular filtration rate) and if positive, would support a full approval.

For reference, the WAC for Filspari is approximately $119,000 per year.

Extended brand pipeline forecast

Optum Rx brand pipeline forecast

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
2025 Possible launch date									
Hernicore (SI-6603)	condoliase	Seikagaku	glycosaminoglycan-degrading enzyme	Pain	Intrathecal	Filed BLA	03/14/2025	Yes	No
NT-501	revakinagene tarotcel	Neurotech Pharmaceuticals	cellular therapy	Macular telangiectasia type 2	Intraocular	Filed BLA	03/18/2025	Yes	Yes
YN-96D1	rivoceranib	Elevar Therapeutics	vascular endothelial growth factor receptor antagonist	Hepatocellular carcinoma	PO	Filed NDA	03/23/2025	Yes	Yes
SHR-1210	camrelizumab	Elevar Therapeutics	programmed death receptor-1-blocking antibody	Hepatocellular carcinoma	IV	Filed BLA	03/23/2025	Yes	Yes
GSK-2140944	gepotidacin	GlaxoSmithKline	bacterial Type II topoisomerase inhibitor	Bacterial infections	PO	Filed NDA	03/26/2025	No	No
MSP-2017	etripamil	Milestone	calcium channel blocker	Arrhythmia	Intranasal	Filed NDA	03/26/2025	No	No
DCCR	diazoxide choline controlled-release	Soleno Therapeutics	vasodilator	Prader-Willi syndrome	PO	Filed NDA	03/27/2025	Yes	Yes

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
ALN-APC (ALN-AT3)	fitusiran	Sanofi	RNAi therapeutic	Hemophilia A and B	SC	Filed BLA	03/28/2025	Yes	Yes
chenodeoxycholic acid	chenodeoxycholic acid	Mirum Pharmaceuticals	farnesoid X receptor agonist	Cerebrotendinous xanthomatosis	PO	Filed NDA	03/28/2025	Yes	Yes
PB-2452	bentracimab	SFJ Pharmaceuticals	antiplatelet monoclonal antibody	Antiplatelet drug toxicity	IV	Filed BLA	1Q2025	No	No
Subvenite	lamotrigine	OWP Pharmaceuticals	anticonvulsant	Epilepsy/ bipolar disorder	PO	Filed NDA	1Q2025	No	No
Irinotecan liposome	irinotecan liposome	CSPC Pharmaceutical	topoisomerase-I inhibitor	Pancreatic cancer	IV	Filed NDA	1Q2025	Yes	No
NS-2 (ALDX-1E1, ADX-102)	reproxalap	Aldeyra Therapeutics	aldehyde antagonist	Dry eye disease	OPH	Filed NDA	04/02/2025	No	No
MTP-131 (SS-31)	elamipretide	Stealth Biotherapeutics	mitochondrial permeability transition pore inhibitor	Barth syndrome	SC	Filed NDA	04/29/2025	Yes	Yes
M-281	nipocalimab	J&J	FcRn antagonist	Generalized myasthenia gravis	IV	Filed BLA	04/29/2025	Yes	Yes
EB-101	prademagene zamikeracel	Abeona Therapeutics	gene therapy	Epidermolysis Bullosa	TOP	Filed BLA	04/29/2025	Yes	Yes
STS-101	dihydroergotamine	Satsuma Pharmaceuticals	ergotamine	Migraine	Intranasal	Filed NDA	04/30/2025	No	No

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
AEB-1102	pegzilarginase	Aeglea BioTherapeutics	enzyme replacement/ arginase-I stimulator	Arginase 1 deficiency	IV	Filed BLA	05/05/2025	Yes	Yes
Dihydroergotamine autoinjector	dihydroergotamine	Amneal Pharmaceuticals	ergot derivative	Migraine	SC	Filed NDA	05/21/2025	No	No
LIQ-861	treprostinil	Liquidia Technologies	prostacyclin analog	Pulmonary arterial hypertension; interstitial lung disease	INH	Tentative Approval	05/23/2025	Yes	No
ABBV-399	telisotuzumab	AbbVie	antibody (anti-c-Met)-drug conjugate	Non-small cell lung cancer	IV	Filed BLA	05/27/2025	Yes	No
SL-1009	sodium dichloroacetate	Saol Therapeutics	pyruvate dehydrogenase kinase inhibitor	Pyruvate dehydrogenase complex deficiency	PO	Filed NDA	05/27/2025	Yes	Yes
ET-400	hydrocortisone	Eton Pharmaceuticals	glucocorticoid	Endocrine disorders	PO	Filed NDA	05/28/2025	No	No
AR-15512	AR-15512	Aerie Pharmaceuticals	TRPM8 agonist	Dry eye disease	OPH	Filed NDA	05/30/2025	No	No
mRNA-1283	COVID-19 vaccine, mRNA	Moderna	messanger RNA	COVID-19 prevention	IM	Filed BLA	05/31/2025	No	No
GMRx2	telmisartan/ amlodipine/ indapamide	George Medicines	angiotensin II receptor blocker/ calcium channel blocker/ diuretic	Hypertension	PO	Filed NDA	06/06/2025	No	No
NP-001	sodium chlorite	Neuvivo	neuroprotective agent	Amyotrophic lateral sclerosis	IV	Filed NDA	06/07/2025	Yes	Yes

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
MK-1654	clesrovimab	Merck	RSV targeted monoclonal antibody	Respiratory syncytial virus	IM	Filed BLA	06/10/2025	No	No
UGN-102	mitomycin	UroGen	alkylating drug	Bladder cancer	Intravesical	Filed NDA	06/13/2025	Yes	No
KVD-900	sebetralstat	KalVista Pharmaceuticals	plasma kallikrein inhibitor	Hereditary angioedema	PO	Filed NDA	06/17/2025	Yes	Yes
AB-106	taletrectinib	Nuvation Bio	ROS1/NTRK tyrosine kinase inhibitor	Non-small cell lung cancer	PO	Filed NDA	06/23/2025	Yes	Yes
Xinlay	atrasentan	Novartis	selective endothelin-A receptor antagonist	IgA nephropathy	PO	Filed NDA	06/2025	Yes	No
SPI-014	oxylanthanum carbonate	Unicycive	phosphate binder	Hyperphosphatemia	PO	Filed NDA	06/28/2025	No	No
CUTX-101	copper histidinate	Fortress Biotech	copper replacement	Menkes Disease	SC	Filed NDA	06/30/2025	Yes	Yes
VS-6063	defactinib	Verastem	focal adhesion kinase inhibitor	Ovarian cancer	PO	Filed NDA	06/30/2025	Yes	Yes
VS-6766	avutometinib	Verastem	RAF/MEK clamp	Ovarian cancer	PO	Filed NDA	06/30/2025	Yes	No
PDP-716	brimonidine	Visiox Pharma	alpha-2 agonist	Glaucoma	OPH	Not Approved	1H2025	No	No
S-217622	ensitrelvir fumaric acid	Shionogi	Protease inhibitor	COVID-19 treatment	PO	InTrial	1H2025	No	No

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
DZD-9008	sunvozertinib	Dizal	EGFR inhibitor	Non-small cell lung cancer	PO	Filed NDA	07/08/2025	Yes	No
REGN-5458	linvoseltamab	Regeneron	BCMA and CD3 bispecific antibody inhibitor	Multiple myeloma	IV	Filed BLA	07/10/2025	Yes	No
RP-1	vusolimogene oderparepvec	Replimune	oncolytic immunotherapy	Melanoma	Intratumoral	Filed BLA	07/22/2025	Yes	No
LEO-124249	delgocitinib	LEO Pharma	Janus kinase inhibitor	Chronic hand eczema	TOP	Filed NDA	07/23/2025	No	No
PTC-923	sepiapterin	PTC Therapeutics	phenylalanine hydroxylase activator	Phenylketonuria	PO	Filed NDA	07/29/2025	Yes	Yes
LNZ-100	aceclidine	Lenz Therapeutics	acetylcholine receptor agonist	Treatment of presbyopia	OPH	Filed NDA	08/08/2025	No	No
BAY-342	elinzanetant	Bayer	neurokinin-1,3 receptor antagonist	Vasomotor symptoms	PO	Filed NDA	08/09/2025	No	No
BHV-4157	troriluzole	Biohaven	glutamate modulator	Spinocerebellar ataxia	PO	Filed NDA	08/11/2025	Yes	Yes
INS-1007	brensocatib	Insmed	dipeptidyl peptidase 1 inhibitor	Bronchiectasis	PO	Filed NDA	08/12/2025	No	No
TNX-102	cyclobenzaprine	Tonix	muscle relaxant	Fibromyalgia	PO	Filed NDA	08/15/2025	No	No
PTC-743	vatiquinone	PTC Therapeutics	undisclosed	Friedreich's ataxia	PO	Filed NDA	08/19/2025	Yes	Yes

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
UX-111 (ABO-102)	UX-111	Ultragenyx Pharmaceutical	gene therapy	Sanfilippo syndrome type A	IV	Filed BLA	08/19/2025	Yes	Yes
IONIS-PKK-LRx (ISIS-721744)	donidalorsen	Ionis	antisense drug	Hereditary angioedema	SC	Filed NDA	08/21/2025	Yes	Yes
PRN-1008	rilzabrutinib	Sanofi	BTK inhibitor	Chronic immune thrombocytopenia	PO	Filed NDA	08/29/2025	No	Yes
ONC-201	dordaviprone	Chimerix	dopamine receptor antagonist	Brain cancer	PO	Filed NDA	08/30/2025	Yes	Yes
PRGN-2012	PRGN-2012	Precigen	immunotherapy	Respiratory papillomatosis	SC	Filed BLA	08/30/2025	Yes	Yes
Leqembi SC	lecanemab	Eisai/Biogen	beta-amyloid targeted therapy	Alzheimer's disease	SC	Filed BLA	08/31/2025	Yes	No
CAP-1002	deramiocel	Capricor Therapeutics	cellular therapy	Duchenne muscular dystrophy	IV	Filed BLA	09/02/2025	Yes	Yes
RSQ-777	bumetanide	Corstasis Therapeutics	diuretic	Edema	Intranasal	Filed NDA	09/14/2025	No	No
CRN-00808	paltusotine	Crinetics Pharmaceuticals	somatostatin receptor 2 agonist	Acromegaly	PO	Filed NDA	09/25/2025	Yes	Yes
CK-274	aficamten	Cytokinetics	cardiac myosin inhibitor	Obstructive hypertrophic cardiomyopathy	PO	Filed NDA	09/26/2025	Yes	Yes

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
N-115	sodium pyruvate	EmphyCorp	IL-6 inhibitor	Idiopathic pulmonary fibrosis	Intranasal	Filed NDA	09/2025	Yes	No
SRK-015	apitegromab	Scholar Rock	myostatin activation inhibitor	Spinal muscular atrophy	IV	Filed BLA	09/30/2025	Yes	Yes
Translarna	ataluren	PTC Therapeutics	gene transcription modulator	Duchenne muscular dystrophy	PO	Filed NDA	3Q2025	Yes	Yes
RP-L102 (RPL-102)	RP-L102	Rocket Pharmaceuticals	gene therapy	Fanconi anemia	IV	InTrial	3Q2025	Yes	Yes
Nuvaxovid	Novavax COVID-19 2024-2025 formula	Novavax/Sanofi	mRNA	Prevention of COVID-19	IM	Filed BLA	3Q2025	No	No
OMS-721	narsoplimab	Omeros	anti-MASP-2 monoclonal antibody	Hematopoietic stem cell transplant-associated thrombotic microangiopathy	IV	CRL	3Q2025	Yes	Yes
ONS-5010	bevacizumab-vikg	Outlook Therapeutics	anti-VEGF antibody	Wet age-related macular degeneration	Intravitreal	CRL	3Q2025	Yes	No
MT-1621	deoxythymidine/ deoxycytidine	UCB	deoxynucleoside	Thymidine kinase 2 deficiency	PO	InTrial	3Q2025	Yes	Yes
TAR-200	gemcitabine	J&J	nucleoside metabolic inhibitor	Bladder cancer	Intravesical	Filed NDA	11/16/2025	Yes	No

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
ARO-APOC3	plozasiran	Arrowhead Pharmaceuticals	RNAi targeting apolipoprotein C-III	Familial chylomicronemia syndrome	SC	Filed BLA	11/18/2025	Yes	Yes
LIB-003	lerodalcibep	LIB Therapeutics	PCSK9 inhibitor	Hypocholesteremia	SC	Filed BLA	12/12/2025	No	No
CORT-125134	relacorilant	Corcept Therapeutics	glucocorticoid receptor II antagonist	Cushing's syndrome	PO	Filed NDA	12/30/2025	Yes	Yes
Molgradex	molgramostim	Savara	granulocyte macrophage-colony stimulating factor	Pulmonary alveolar proteinosis	INH	InTrial	4Q2025	Yes	Yes
SAR-442168	tolebrutinib	Sanofi	Bruton’s tyrosine kinase inhibitor	Multiple sclerosis	PO	Filed NDA	4Q2025	Yes	No
GSK-3511294	depemokimab	GlaxoSmithKline	interleukin-5 antagonist	Eosinophilic asthma	SC	InTrial	4Q2025	Yes	No
LY-3484356	imlunestrant	Eli Lilly	selective estrogen receptor degrader	Breast cancer	PO	Filed NDA	4Q2025	Yes	No
Donesta	estetrol	Mithra Pharmaceuticals	estrogen	Vasomotor symptoms	PO	InTrial	4Q2025	No	No
MCO-010	sonpiretigene isteparvovec	Nanoscope Therapeutics	gene therapy	Retinitis pigmentosa	Intravitreal	InTrial	4Q2025	Yes	Yes
LAI-287	insulin icodec	Novo Nordisk	ultra-long-acting basal insulin	Diabetes mellitus	SC	CRL	2H2025	No	No
PAX-101	suramin	PaxMedica	unknown	trypanosomiasis	IV	InTrial	2H2025	No	No

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
ND-0612H	levodopa/ carbidopa	Mitsubishi Tanabe	dopamine precursor/ dopa-decarboxylase inhibitor	Parkinson's disease	SC	CRL	2H2025	Yes	No
SPR-001	tildacerfont	Spruce Biosciences	corticotropin-releasing factor type-1 receptor antagonist	Congenital adrenal hyperplasia	PO	InTrial	2H2025	Yes	Yes
LY-686017	tradipitant	Vanda Pharmaceuticals	neurokinin 1 receptor antagonist	Motion sickness; gastroparesis	PO	CRL	2H2025	No	No
SDN-037	difluprednate	Visiox	corticosteroid	Ocular inflammation/pain	OPH	InTrial	2H2025	No	No
NRX-101 (Cyclurad)	d-cycloserine/ lurasidone	NeuroRx	N-methyl-D-aspartate receptor modulator/ 5-HT2A receptor antagonist	Bipolar disorder	PO	InTrial	2H2025	No	No
OX-124	naloxone	Orexo	opioid antagonist	Opioid overdose	Intranasal	CRL	2H2025	No	No
K-127	pyridostigmine	Amneal	cholinesterase inhibitor	Myasthenia gravis	PO	InTrial	2H2025	No	No
NRX-100	ketamine	NeuroRx	NMDA antagonist	Depression	PO	InTrial	2H2025	No	No
AXS-14	S-reboxetine	Axsome Therapeutics	selective noradrenaline reuptake inhibitor	Fibromyalgia	PO	InTrial	2H2025	No	No
SLS-001 (WT-1)	galinpepimut-S	Sellas Life Sciences Group	vaccine	Acute myeloid leukemia	SC	InTrial	2H2025	Yes	Yes

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
Revascor	rexlemestrocel-L	Mesoblast	allogeneic autologous mesenchymal precursor cell	Heart failure	IV	InTrial	2H2025	Yes	Yes
SEL-212	SVP-rapamycin/ pegsiticase	Selecta Biosciences/ 3SBio	synthetic vaccine particle/ enzyme combination	Gout	IV	InTrial	2H2025	Yes	No
CSL-312	garadacimab	CSL Limited	anti-factor XIIa monoclonal antibody	Hereditary angioedema	SC	CRL	2H2025	Yes	Yes
GSK-2330672	linerixibat	GlaxoSmithKline	ileal bile acid transfer inhibitor	Primary biliary cholangitis	PO	InTrial	2H2025	Yes	Yes
RP-L201	marnetegragene autotemcel	Rocket Pharmaceuticals	gene therapy	Leukocyte adhesion deficiency-I	IV	CRL	2H2025	Yes	Yes
RGX-121	RGX-121	Regenxbio	gene therapy	Mucopolysaccharidosis Type II	Intracisternal	InTrial	2H2025	Yes	Yes
CPI-0610	pelabresib	MorphoSys	BET inhibitor	Myelofibrosis	PO	InTrial	2H2025	Yes	Yes
D-PLEX100	doxycycline	PolyPid	tetracycline	Surgical site infections	IMPLANT	InTrial	2H2025	No	No
XEN-1101	XEN-1101	Xenon Pharmaceuticals	Kv7 potassium channel opener	Focal epilepsy	PO	InTrial	2H2025	TBD	No
ANB-019	imsidolimab	AnaptysBio	interleukin-36 receptor antagonist	Generalized pustular psoriasis	IV	InTrial	2H2025	Yes	Yes

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
CAM-2029	octreotide	Camurus	somatostatin analogue	Acromegaly	SC	CRL	2H2025	Yes	Yes
AGEN-1181	botensilimab	Agenus	anti-CTLA-4 antibody	Colorectal cancer	IV	InTrial	2H2025	Yes	No
ICP-022	orelabrutinib	InnoCare	Bruton's tyrosine kinase inhibitor	Mantle cell lymphoma	PO	InTrial	2H2025	Yes	Yes
Rybrevant SC	amivantamab-vmjw/ hyaluronidase	Johnson & Johnson	bispecific EGF receptor-directed and MET receptor-directed antibody	Non-small cell lung cancer	SC	CRL	2H2025	Yes	No
Keytruda SC	pembrolizumab	Merck	programmed death receptor-1-blocking antibody	Various cancers	SC	InTrial	2H2025	Yes	No
BNT161+ BNT162b2	influenza and COVID-19 vaccine	Pfizer/BioNTech	mRNA	Prevention of influenza and COVID-19 infection	IM	InTrial	2025	No	No
AT-007	govorestat	Applied Therapeutics	aldose reductase inhibitor	Galactosemia	PO	CRL	2025	Yes	Yes
Hepcludex	bulevirtide	Gilead	HBV receptor binder	Hepatitis delta virus	SC	CRL	2025	Yes	Yes
VNRX-5133	cefepime/ taniborbactam	VenatoRx Pharmaceuticals	cephalosporin/ beta-lactamase inhibitor	Bacterial infections	IV	CRL	2025	No	No
Mino-Lok	minocycline-EDTA-ETOH	Citrus	tetracyclines	Bacterial infection	Intracatheter	InTrial	2025	No	No

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
Dasynoc	dasatinib	Xspray Pharma	kinase inhibitor	Chronic myeloid leukemia	PO	CRL	2025	Yes	Yes
F-901318	olorofim	F2G	orotomide antifungal	Aspergillosis	PO/IV	CRL	2025	No	Yes
Sarconeos	BIO-101	Biophytis	MAS G-protein coupled receptor agonist	COVID-19 treatment	PO	InTrial	2025	No	No
Lydolyte	lidocaine	MEDRx	anesthetic agent	Neuropathic pain	TOP	CRL	2025	No	No
HER3-DXd	patritumab deruxtecan	Daiichi Sankyo/ Merck	antibody drug conjugate	Non-small cell lung cancer	IV	CRL	2025	Yes	No
mRNA-1010	mRNA-1010	Moderna	vaccine	Influenza	IM	InTrial	2025	No	No
AZD-0914	zoliflodacin	Innoviva	DNA gyrase inhibitor	Gonorrhea	PO	InTrial	Late 2025	No	No
AXS-12	reboxetine	Axsome Therapeutics	norepinephrine reuptake inhibitor	Narcolepsy	PO	InTrial	Late 2025	Yes	Yes
EB-1020	centanafadine	Otsuka	norepinephrine, dopamine and serotonin reuptake inhibitor	Attention deficit hyperactivity disorder	PO	InTrial	Late 2025	No	No
ALZ-801	valiltramiprosate	Alzheon	amyloid beta-protein inhibitor	Alzheimer's disease	PO	InTrial	Late 2025	Yes	No
ANX-005	ANX-005	Annexon	C1q inhibitor	Guillain-Barré syndrome	IV	InTrial	Late 2025	Yes	Yes

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
RG-6058	tiragolumab	Roche	TIGIT monoclonal antibody	Non-small cell lung cancer/ esophageal cancer	IV	InTrial	Late 2025	Yes	No
AQST-109	epinephrine	Aquestive Therapeutics	non-selective alpha/ beta-adrenergic receptor agonist	Anaphylaxis	PO	InTrial	Late 2025	No	No
BI-1015550	nerandomilast	Boehringer Ingelheim	phosphodiesterase 4b inhibitor	Idiopathic pulmonary fibrosis/ interstitial lung disease	PO	InTrial	Late 2025	Yes	Yes
DNL-310	tividenofusp alfa	Denali	enzyme replacement therapy	Mucopolysaccharidosis II (Hunter Syndrome)	IV	InTrial	Late 2025	Yes	Yes
Zolgensma IT	onasemnogene abeparvovec-xioi	Novartis	gene therapy	Spinal muscular atrophy	Intrathecal	InTrial	Late 2025	Yes	Yes
BT-524	fibrinogen	Biotest	plasma fibrinogen concentrate	Fibrinogen deficiency	IV	Filed BLA	Late 2025	Yes	No
2026 Possible launch date									
mRNA-1083	influenza and COVID-19 vaccine	Moderna	mRNA	Prevention of influenza and COVID-19	IM	Filed BLA	01/13/2026	No	No
obicetrapib	obicetrapib	NewAmsterdam Pharma	selective cholesteryl ester transfer protein inhibitor	Hypercholesterolemia	PO	InTrial	1Q2026	No	No
INO-3107	INO-3107	Inovio Pharmaceuticals	immunotherapy	Recurrent respiratory papillomatosis	IM	InTrial	1Q2026	Yes	Yes

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
TransCon CNP	navepegritide	Ascendis Pharma	C-type natriuretic peptide	Achondroplasia	SC	InTrial	1Q2026	Yes	Yes
cytisine	cytisine	Achieve Life Sciences	nicotinic acetylcholine receptor antagonist	Smoking cessation	PO	InTrial	2Q2026	No	No
A-004 (AAV-RPGR)	botaretigene sparoparvovec	Janssen/ MeiraGTx	gene therapy	Retinitis pigmentosa	Undisclosed	InTrial	1H2026	Yes	Yes
DISC-1459	bitopertin	Disc Medicine	glycine transporter 1 inhibitor	Erythropoietic protoporphyria	PO	InTrial	1H2026	No	Yes
CNM-Au8	CNM-Au8	Clene	gold nanocrystal	Amyotrophic lateral sclerosis	PO	InTrial	1H2026	Yes	Yes
LY-3209590	insulin efsitora alfa	Eli Lilly	insulin	Diabetes mellitus	SC	InTrial	1H2026	No	No
LOU-064	remibrutinib	Novartis	Bruton's tyrosine kinase inhibitor	Chronic spontaneous urticaria	PO	InTrial	1H2026	Yes	No
Mim8	Mim8	Novo Nordisk	Factor VIII mimetic bispecific antibody	Hemophilia A	SC	InTrial	1H2026	Yes	Yes
CagriSema	cagrilintide/ semaglutide	Novo Nordisk	amylin and GLP-1 analog	Obesity/ type 2 diabetes	SC	InTrial	1H2026	No	No
VTI-001 (Brimochol PF)	brimonidine/ carbachol	Tenpoint Therapeutics	cholinergic muscarinic receptor agonist/ parasympathomimetic	Presbyopia	OPH	InTrial	1H2026	No	No

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
DTX-401	pariglasgene brecaparvovec	Ultragenyx Pharmaceutical	gene therapy	Glycogen storage disease type Ia	IV	InTrial	1H2026	Yes	Yes
XS-003	nilotinib	Xspray Pharma	kinase inhibitor	Chronic myeloid leukemia	PO	InTrial	1H2026	Yes	No
Sarclisa SC	isatuximab-irfc	Sanofi	CD38-directed cytolytic antibody	Multiple myeloma	SC	InTrial	1H2026	Yes	No
FE-203799	apraglutide	Ironwood	glucagon-like peptide-2 analog	Short bowel syndrome	SC	InTrial	1H2026	Yes	Yes
HLX-10	serplulimab	Henlius	anti-PD-1	Small cell lung cancer	IV	InTrial	1H2026	Yes	Yes
Aversa Fentanyl	fentanyl	Nutriband	opioid agonist	Pain	TOP	InTrial	1H2026	No	No
nemvaleukin alfa	nemvaleukin alfa	Mural Oncology	interleukin-2 receptor activator	Ovarian cancer	IV	InTrial	1H2026	Yes	No
VIS-649	sibeprenlimab	Otsuka	cytokine APRIL inhibitor	IgA nephropathy	SC	InTrial	1H2026	Yes	No
KO-539	ziftomenib	Kura	menin inhibitor	Acute myeloid leukemia	PO	InTrial	1H2026	Yes	No
VHX-896	iloperidone	Vanda Pharmaceuticals	atypical antipsychotic	Schizophrenia/ bipolar disorder	PO	InTrial	1H2026	No	No
SPR-994	tebipenem	Spero Therapeutics/ GSK	carbapenem	Complicated urinary tract infections	PO	CRL	Mid-2026	No	No

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
IdeS (immunoglobulin G-degrading enzyme of Streptococcus pyogenes)	imlifidase	Hansa Medical	bacterial enzyme	Kidney transplant	IV	InTrial	Mid-2026	Yes	Yes
CTX-1301	dexmethylphenidate	Cingulate	CNS stimulant	Attention deficit hyperactivity disorder	PO	InTrial	Mid-2026	TBD	No
GSK-4527223	latozinemab	GSK	anti-sortilin monoclonal antibody	Frontotemporal dementia	IV	InTrial	Mid-2026	Yes	Yes
SRP-9003	bidridistrogene xeboparvovec	Sarepta Therapeutics	gene therapy	Limb-girdle muscular dystrophy	IV	InTrial	Mid-2026	Yes	Yes
CTI-1601	nomlabofusp	Larimar Therapeutics	recombinant fusion protein	Friedreich's ataxia	SC	InTrial	Mid-2026	Yes	Yes
Trappsol Cyclo	beta-cyclodextrin	Cyclo Therapeutics	cyclodextrin	Niemann-Pick disease Type C	IV	InTrial	Mid-2026	Yes	Yes
ST-920	isaralgagene civaparvovec	Sangamo Therapeutics	gene therapy	Fabry disease	IV	InTrial	Mid-2026	Yes	Yes
zidesamtinib	zidesamtinib	Nuvalent	ROS1 inhibitor	Non-small cell lung cancer	PO	InTrial	Mid-2026	Yes	No
TQJ-230 (ISIS-681257)	pelacarsen	Novartis	antisense oligonucleotide targeting LP(a)	Cardiovascular disease	SC	InTrial	2H2026	TBD	No

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
PH-94B	fasedienol	VistaGen Therapeutics	vomerophine	Social anxiety disorder	Intranasal	InTrial	2H2026	No	No
TRN-228	cebranopadol	Tris Pharma	opioid-receptor-like-1 agonist	Pain	PO	InTrial	2H2026	No	No
BLU-5937	camlipixant	GSK	P2X3 receptor antagonist	Refractory chronic cough	PO	InTrial	2H2026	No	No
atacicept	atacicept	Vera	transmembrane activator and CAML interactor receptor-immunoglobulin	IgA nephropathy	SC	InTrial	2H2026	Yes	No
OPT-302	sozinibercept	Opthea	dual VEGF-C and VEGF-D inhibitor	Wet age-related macular degeneration	Intravitreal	InTrial	2H2026	Yes	No
SAR-440340	itepekimab	Sanofi/ Regeneron	anti-interleukin-33 monoclonal antibody	Chronic obstructive pulmonary disease	SC	InTrial	2H2026	Yes	No
RGX-314	RGX-314	Abbvie/ REGENXBIO	gene therapy	Wet age-related macular degeneration	Subretinally	InTrial	2H2026	Yes	No
AMG-451	rocatinlimab	Amgen/ Kyowa Kirin	anti-OX40 monoclonal antibody	Atopic dermatitis	SC	InTrial	2H2026	Yes	No
OCU-400	OCU-400	Ocugen	gene therapy	Retinitis pigmentosa/ Leber congenital amaurosis	Intravitreal	InTrial	2H2026	Yes	Yes
VRDN-001	VRDN-001	Viridian Therapeutics	insulin-like growth factor-1 receptor inhibitor	Thyroid eye disease	IV	InTrial	2H2026	Yes	No

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
PTG-300	rusfertide	Protagonist Therapeutics	hepcidin mimetic peptide	Polycythemia vera	SC	InTrial	2H2026	Yes	Yes
MTX-005	MTX-005	Memo Therapeutics	monoclonal antibody	BKV infection	IV	InTrial	2H2026	TBD	No
LYN-005	risperidone	Lyndra Therapeutics	atypical antipsychotic	Schizophrenia	PO	InTrial	2H2026	No	No
NMRA-140	navacaprant	Neumora Therapeutics	kappa opioid receptor antagonist	Major depressive disorder	PO	InTrial	2H2026	No	No
TSR-022	cobolimab	GSK	anti-TIM-3 antibody	Non-small cell lung cancer	IV	InTrial	2H2026	Yes	No
cilostazol extended-release	cilostazol	Genovate Biotechnology	phosphodiesterase III inhibitor	Peripheral arterial disease	PO	InTrial	2H2026	No	No
tavapadon	tavapadon	AbbVie	dopamine partial agonist	Parkinson's disease	PO	InTrial	2H2026	No	No
RP-A501	RP-A501	Rocket Pharmaceuticals	gene therapy	Danon disease	IV	InTrial	2H2026	Yes	Yes
OST-HER2	OST-HER2	OS Therapies	immunotherapy	Osteosarcoma	IV	InTrial	2H2026	Yes	Yes
CGT-9486	bezuclastinib	Cogent Biosciences	KIT inhibitor	Mastocytosis	PO	InTrial	2H2026	Yes	No
AGEN-2034	balstilimab	Agenus	PD-1 antagonist	Colorectal cancer	IV	InTrial	2026	Yes	No

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
EBV-CTL (ATA-129)	tabelecleucel	Atara Biotherapeutics	cell therapy	Lymphoproliferative disorder	IV	CRL	2026	Yes	Yes
MOR-202	felzartamab	I-Mab	anti-CD38 monoclonal antibody	Multiple myeloma	IV	InTrial	2026	Yes	No
RP-5063	brilaroxazine	Reviva Pharmaceuticals	dopamine/serotonin parital agonist	Schizophrenia/ schizoaffective disorder	PO	InTrial	2026	No	No
ASP-1929 (RM-1929)	ASP-1929	Rakuten	EGFR inhibitor	Head and neck squamous cell carcinoma	IV	InTrial	2026	Yes	No
LNA-043	LNA-043	Novartis	chondrogenesis inducer	Osteoarthritis	Intraarticular	InTrial	2026	Yes	No
REGN-2477	garetosmab	Regeneron	Activin A antibody	Fibrodysplasia ossificans progressiva	IV/SC	InTrial	2026	Yes	Yes
SB-525	giroctocogene fitelparvovec	Sangamo Therapeutics	gene therapy	Hemophilia A	IV	InTrial	2026	Yes	Yes
PF-07940370	inclacumab	Pfizer	P-selectin inhibitor	Sickle cell disease	IV	InTrial	2026	Yes	Yes
REGN-4461	mibavademab	Regeneron	leptin receptor agonist	Generalized lipodystrophy	IV	InTrial	2026	Yes	No
EB-613	teriparatide	Entera Bio	parathyroid hormone	Osteoporosis	PO	InTrial	2026	No	No
CT-053	zevorcabtagene autoleucel	CARsgen Therapeutics	B-cell maturation antigen-directed genetically	Multiple myeloma	IV	InTrial	2026	Yes	Yes

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
			modified autologous T cell immunotherapy						
BBP-305	encaleret	BridgeBio	Ca sensing receptor antagonist	Autosomal dominant hypocalcemia type 1	PO	InTrial	2026	Yes	Yes
REGN-3767	fianlimab	Regeneron	anti lymphocyte-activation gene 3 monoclonal antibody	Melanoma	IV	InTrial	2026	Yes	No
CART-ddBCMA	anitocabtagene autoleucel	Arcellx	CAR T cell therapy	Multiple myeloma	IV	InTrial	2026	Yes	No
JNJ-2113	icotrokinra	Janssen/ Protagonist Therapeutics	interleukin-23 receptor antagonist	Plaque psoriasis	PO	InTrial	2026	Yes	No
FP-1304	bexmarilimab	Faron	anti-Clever-1 antibody	Myelodysplastic syndrome	IV	InTrial	2026	Yes	No
INCB-54707	povorcitinib	Incyte	Janus kinase inhibitor	Hidradenitis suppurativa	PO	InTrial	2026	Yes	No
BPN14770	zatolmilast	Shionogi	phosphodiesterase 4 inhibitor	Fragile X syndrome	PO	InTrial	2026	Yes	Yes
RG-6149	astegolimab	Roche	interleukin-33 antagonist	Chronic obstructive pulmonary disease	SC	InTrial	2026	Yes	No
QRX-003	QRX-003	Quoin Pharmaceuticals	serine protease inhibitor	Netherton syndromes	TOP	InTrial	2026	TBD	No

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
CG-0070	cretostimogene grenadenorepvec	CG Oncology	oncolytic immunotherapy	Bladder cancer	Intravesical	InTrial	2026	Yes	No
AMT-130	AMT-130	UniQure	gene therapy	Huntington's disease	Intracerebral	InTrial	2026	Yes	Yes
ONO-4059	tirabrutinib	Ono	Bruton's tyrosine kinase inhibitor	Primary central nervous system lymphoma	PO	InTrial	2026	Yes	Yes
LY-3502970	orforglipron	Eli Lilly	glucagon-like peptide-1 agonist	Diabetes/ obesity	PO	InTrial	Late 2026	No	No
TAK-861	oveporexton	Takeda	selective orexin receptor agonist	Narcolepsy	PO	InTrial	Late 2026	No	No
CHR-3996	nanatinostat	Viracta Therapeutics	histone deacetylase inhibitor	Peripheral T-cell lymphoma	PO	InTrial	Late 2026	Yes	No

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

Key pending indication forecast

Optum Rx key pending indication forecast

Brand Name	Generic Name	Company	Mechanism of Action	Indication Type	Proposed New/Revised/Removed Indication	Route	FDA Status	Projected Approval Date
2025 Possible launch date								
Furoscix	furosemide	scPharmaceuticals	diuretic	Revised	Treatment of edema due to fluid overload in patients with chronic kidney disease	SC	Filed sNDA	03/06/2025
Amvuttra	vutrisiran	Alnylam Pharmaceuticals	transthyretin-directed small interfering RNA	New	Treatment of transthyretin amyloid cardiomyopathy	SC	Filed sBLA	03/23/2025
Darzalex Faspro	daratumumab/ hyaluronidase-fihj	J&J	humanized anti-CD38 monoclonal antibody	New	In combination with bortezomib, lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma for whom autologous stem cell transplant (ASCT) is deferred or who are ineligible for ASCT	SC	Filed sBLA	03/30/2025
Pemgarda	pemivibart	Invivyd	Monoclonal Antibodies	New	Treatment of mild-to-moderate symptomatic COVID-19 in certain immunocompromised patients for whom alternative COVID-19 treatment options are not accessible or clinically appropriate	IV	Filed sBLA	1Q2025

Brand Name	Generic Name	Company	Mechanism of Action	Indication Type	Proposed New/Revised/Removed Indication	Route	FDA Status	Projected Approval Date
Cabometyx	cabozantinib	Exelixis	kinase inhibitor	New	Treatment of adults with previously treated, locally advanced/unresectable or metastatic, well- or moderately differentiated pancreatic neuroendocrine tumors (pNET), and the treatment of adults with previously treated, locally advanced/unresectable or metastatic, well- or moderately differentiated extra-pancreatic NET (epNET)	PO	Filed sNDA	04/03/2025
Uplizna	inebilizumab-cdon	Amgen	CD19-directed cytolytic antibody	New	Treatment of immunoglobulin G4-related disease	IV	Filed sBLA	04/03/2025
Prezcobix	darunavir/ cobicistat	Johnson & Johnson	HIV protease inhibitor/ CYP3A inhibitor	Revised	Treatment of HIV-1 infection in treatment-naïve and treatment-experienced adults and pediatric patients weighing at least 25 kg with no darunavir resistance-associated substitutions	PO	Filed sNDA	04/04/2025
Imfinzi	durvalumab	AstraZeneca	programmed death-ligand 1 blocking antibody	New	Treatment of patients with muscle-invasive bladder cancer	IV	Filed sBLA	04/06/2025
Dupixent	dupilumab	Sanofi/ Regeneron	interleukin-4/13 inhibitor	New	Treatment of adults and adolescents aged 12 years and older with chronic spontaneous urticaria that is not adequately controlled with the current standard of care, H1 antihistamine treatment	SC	Filed sBLA	04/18/2025

Brand Name	Generic Name	Company	Mechanism of Action	Indication Type	Proposed New/Revised/Removed Indication	Route	FDA Status	Projected Approval Date
Tremfya	guselkumab	Janssen	interleukin-23 inhibitor	New	Treatment of adults with moderately to severely active Crohn's disease	IV/SC	Filed sBLA	04/20/2025
Opdivo	nivolumab	Bristol Myers Squibb	programmed death receptor-1-blocking antibody	New	In combination with Yervoy (ipilimumab), for first-line treatment for adult patients with unresectable hepatocellular carcinoma	IV	Filed sBLA	04/21/2025
Yervoy	ipilimumab	Bristol Myers Squibb	programmed death receptor-1-blocking antibody	New	In combination with Opdivo (nivolumab), for first-line treatment for adult patients with unresectable hepatocellular carcinoma	IV	Filed sBLA	04/21/2025
Nucala	mepolizumab	GSK	interleukin-5 antagonist monoclonal antibody	New	Add-on treatment to inhaled corticosteroid-based maintenance treatment for the reduction of exacerbations in patients with chronic obstructive pulmonary disease and elevated blood eosinophil counts	SC	Filed sBLA	05/07/2025
Darzalex Faspro	daratumumab/ hyaluronidase-fihj	J&J	humanized anti-CD38 monoclonal antibody	New	Treatment of adult patients with high-risk smouldering multiple myeloma	SC	Filed sBLA	05/08/2025
Rinvoq	upadacitinib	AbbVie	janus kinase inhibitor	New	Treatment of adult patients with giant cell arteritis	PO	Filed sNDA	05/12/2025
Zoryve	roflumilast	Arcutis Biotherapeutics	phosphodiesterase 4 inhibitor	New	Treatment of adults and adolescents ages 12 and over with scalp and body psoriasis	TOP	Filed sNDA	05/22/2025

Brand Name	Generic Name	Company	Mechanism of Action	Indication Type	Proposed New/Revised/Removed Indication	Route	FDA Status	Projected Approval Date
MenQuadfi	meningococcal groups A, C, Y, W	Sanofi	vaccine	Revised	Active immunization for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W, and Y in children aged 6 weeks to 23 months	IM	Filed sBLA	05/23/2025
Ixchiq	chikungunya vaccine	Valneva	vaccine	Revised	Prevention of disease caused by chikungunya virus (CHIKV) in adolescents aged 12 to 17 years who are at increased risk of exposure to CHIKV	IM	Filed sBLA	05/26/2025
Welireg	belzutifan	Merck	hypoxia-inducible factor inhibitor	New	Treatment of adult and pediatric patients (12 years and older) with advanced, unresectable, or metastatic pheochromocytoma and paraganglioma	PO	Filed sNDA	05/26/2025
Rexulti	brexpiprazole	Otsuka/ Lundbeck	atypical antipsychotic	New	In combination with sertraline for the treatment of post-traumatic stress disorder in adults	PO	Filed sNDA	1H2025
Neffy	epinephrine	ARS Pharmaceuticals	alpha and beta-adrenergic receptor agonist	Revised	Emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 15 kg or greater	Intranasal	Filed sNDA	07/09/2025
mRESVIA	respiratory syncytial virus vaccine	Moderna	vaccine	Revised	Prevention of RSV infection in high-risk adults aged 18 to 59	IM	Filed sBLA	07/13/2025

Brand Name	Generic Name	Company	Mechanism of Action	Indication Type	Proposed New/Revised/Removed Indication	Route	FDA Status	Projected Approval Date
Columvi	glofitamab-gxbm	Genentech	bispecific CD20-directed CD3 T-cell engager	New	In combination with gemcitabine and oxaliplatin for the treatment of people with relapsed or refractory diffuse large B-cell lymphoma who have received at least one prior line of therapy and are not candidates for autologous stem cell transplant	IV	Filed sBLA	07/20/2025
Nubeqa	darolutamide	Bayer	androgen receptor inhibitor	Revised	In combination with androgen deprivation therapy in patients with metastatic hormone-sensitive prostate cancer	PO	Filed sNDA	07/21/2025
Blenrep	belantamab mafodotin-blmf	GSK	BCMA-directed antibody and microtubule inhibitor conjugate	New	In combinations with bortezomib plus dexamethasone or pomalidomide plus dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior line of therapy	IV	Filed sBLA	07/23/2025
Doptelet	avatrombopag	Sobi	thrombopoietin receptor agonist	Revised	Treatment of thrombocytopenia in pediatric patients one year and older with persistent or chronic immune thrombocytopenia who have had an insufficient response to a prior therapy	PO	Filed sBLA	07/24/2025
Skytrofa	lonapegsomatropin-tcgd	Ascendis Pharma	growth hormone	Revised	Treatment of adults with growth hormone deficiency	SC	Filed sBLA	07/27/2025
Sunlenca	lenacapavir	Gilead	HIV-1 capsid inhibitor	New	In at-risk patients for pre-exposure prophylaxis (PrEP) to reduce the	SC	Filed sNDA	08/19/2025

Brand Name	Generic Name	Company	Mechanism of Action	Indication Type	Proposed New/Revised/Removed Indication	Route	FDA Status	Projected Approval Date
					risk of sexually acquired HIV-1 infection			
Dupixent	dupilumab	Sanofi/ Regeneron	interleukin-4/13 inhibitor	New	Treatment of bullous pemphigoid	SC	Filed sBLA	09/01/2025
Pyrukynd	mitapivat	Agios Pharmaceuticals	pyruvate kinase activator	New	Treatment of adult patients with non-transfusion-dependent and transfusion-dependent alpha- or beta-thalassemia	PO	Filed sNDA	09/07/2025
Elyxyb	celecoxib	Scilex	NSAID	New	Treatment of acute pain in adult patients	PO	Filed sNDA	09/21/2025
Opzelura	ruxolitinib	Incyte	Janus kinase inhibitor	Revised	Treatment of pediatric atopic dermatitis	TOP	Filed sNDA	3Q2025
Tremfya	guselkumab	Janssen	interleukin-23 inhibitor	New	Treatment of pediatric juvenile psoriatic arthritis	SC	Filed sBLA	10/02/2025
Tremfya	guselkumab	Janssen	interleukin-23 inhibitor	Revised	Treatment of patients ages 6 years and older with moderate-to-severe plaque psoriasis	SC	Filed sBLA	10/02/2025
Caplyta	lumateperone	Intra-Cellular Therapies	atypical antipsychotic	New	Adjunctive therapy to antidepressants for the treatment of major depressive disorder	PO	Filed sNDA	10/03/2025
Zoryve	roflumilast	Arcutis Biotherapeutics	phosphodiesterase-4 inhibitor	Revised	Treatment of mild-to-moderate atopic dermatitis in patients 2 years and older	TOP	Filed sNDA	10/16/2025

Brand Name	Generic Name	Company	Mechanism of Action	Indication Type	Proposed New/Revised/Removed Indication	Route	FDA Status	Projected Approval Date
Simponi	golimumab	Janssen	tumor necrosis factor blocker	Revised	Treatment of children two years and older with moderately to severely active ulcerative colitis	IV	Filed sBLA	10/16/2025
Kerendia	finerenone	Bayer	non-steroidal mineralocorticoid receptor antagonist	New	Treatment of chronic heart failure with preserved ejection fraction	PO	Filed sNDA	11/13/2025

Extended generic and biosimilar pipline forecast

Optum Rx generic and biosimilar pipeline forecast

(Bolded fields are Biosimilar products)

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
2025 Possible launch date					
JYNARQUE	tolvaptan	Otsuka	Polycystic Kidney Disease	Oral	2025
BOSULIF	bosutinib	Pfizer	Chronic Myelogenous Leukemia	Oral	2025
TYSABRI	natalizumab	Biogen	Multiple Sclerosis; Crohn's Disease	Intravenous	2025
ISENTRESS	raltegravir	Merck	Human Immunodeficiency Virus-1 Infection	Oral	2025
COMPLERA	emtricitabine/rilpivirine/tenofovir disoproxil fumarate	Gilead/Janssen	Human Immunodeficiency Virus-1 Infection	Oral	2025
NATAZIA	estradiol valerate/dienogest	Bayer	Prevention of Pregnancy; Menorrhagia	Oral	2025
PHOSLYRA	calcium acetate	Fresenius	Phosphate Binder	Oral	2025
FINACEA	azelaic acid	LEO Pharma	Rosacea	External	2025
HUMALOG	insulin lispro	Eli Lilly	Type 1 and 2 Diabetes Mellitus	Subcutaneous	1Q-2025
QSYMIA	phentermine/topiramate	Vivus	Chronic Weight Management	Oral	1Q-2025
BYETTA	exenatide	AstraZeneca	Type 2 Diabetes Mellitus	Subcutaneous	1Q-2025
NOVOLOG	insulin aspart	Novo Nordisk	Type 1 and 2 Diabetes Mellitus	Subcutaneous	1Q-2025
XARELTO	rivaroxaban	Bayer/Janssen	Reduce the Risk of Stroke, Myocardial Infarction, Cardiovascular Events and Blood Clots; Prevention and Treatment of Deep Vein Thrombosis and Pulmonary Embolism	Oral	03-2025
SOLIRIS	eculizumab	AstraZeneca	Paroxysmal Nocturnal Hemoglobinuria; Hemolytic Uremic Syndrome; Myasthenia Gravis; Neuromyelitis Optica	Intravenous	03-2025
AURYXIA	ferric citrate	Keryx/Akebia Therapeutics	Control of Serum Phosphorus Levels in Chronic Kidney Disease (CKD) on Dialysis; Iron Deficiency Anemia in Adult Patients with CKD Not on Dialysis	Oral	03-2025

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
HORIZANT	gabapentin enacarbil	Arbor	Restless Legs Syndrome; Postherpetic Neuralgia	Oral	04-2025
BRILINTA	ticagrelor	AstraZeneca	To Reduce the Risk of Cardiovascular Death, Myocardial Infarction (MI), and Stroke in Patients with Acute Coronary Syndrome, History of MI, Coronary Artery Disease, or Acute Ischemic Stroke or Transient Ischemic Attack	Oral	05-2025
APTIOM	eslicarbazepine	Sunovion/Bial	Partial-Onset Seizures	Oral	05-2025
TIROSINT-SOL	levothyroxine	IBSA Institut Biochemique	Hypothyroidism; Thyrotropin-Dependent Thyroid Cancer	Oral	05-2025
FYCOMPA	perampanel	Catalyst	Partial-Onset Seizures; Primary Generalized Tonic-Clonic Seizures	Oral	05-2025
PROLIA	denosumab	Amgen	Postmenopausal Osteoporosis; Bone Loss in Men and Women at Risk of Fracture	Subcutaneous	05-2025
XGEVA	denosumab	Amgen	Prevention of Fractures in Bone Malignancies and Multiple Myeloma; Giant Cell Tumor in Bone; Hypercalcemia	Subcutaneous	05-2025
TASIGNA	nilotinib	Novartis	Philadelphia Chromosome-Positive Chronic Myeloid Leukemia	Oral	06-2025
INVEGA TRINZA	paliperidone palmitate	Janssen	Schizophrenia	Intramuscular	06-2025
ZTLIDO	lidocaine	Sorrento	Pain Associated with Post-Herpetic Neuralgia	External	2H-2025
VUITY	pilocarpine	AbbVie	Presbyopia	Ophthalmic	2H-2025
ENTRESTO	sacubitril/valsartan	Novartis	Heart Failure	Oral	3Q-2025
PROMACTA	eltrombopag	Novartis	Thrombocytopenia; Aplastic Anemia	Oral	3Q-2025
GIAZO	balsalazide disodium	Bausch Health	Ulcerative Colitis in Male Patients	Oral	07-2025
RAVICTI	glycerol phenylbutyrate	Amgen	Urea Cycle Disorders	Oral	07-2025
RYANODEX	dantrolene	Eagle Pharmaceuticals	Malignant Hyperthermia	Intravenous	07-2025
RYTARY	carbidopa/levodopa	Amneal	Parkinson's Disease	Oral	07-2025
DIACOMIT	stiripentol	Biocodex	Dravet Syndrome	Oral	08-2025
ADZENYS XR-ODT	amphetamine polistirex	Neos Therapeutics	Attention Deficit Hyperactivity Disorder	Oral	09-2025
SIMPONI	golimumab	Janssen	Ankylosing Spondylitis; Psoriatic Arthritis; Rheumatoid Arthritis; Ulcerative Colitis	Subcutaneous	4Q-2025

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
SIMPONI ARIA	golimumab	Janssen	Rheumatoid Arthritis; Psoriatic Arthritis; Ankylosing Spondylitis; Juvenile Idiopathic Arthritis	Intravenous	4Q-2025
EDURANT	rilpivirine	Janssen	Human Immunodeficiency Virus-1 Infection	Oral	10-2025
TRADJENTA	linagliptin	Eli Lilly/Boehringer Ingelheim	Type 2 Diabetes Mellitus	Oral	11-2025
JENTADUETO XR	linagliptin/metformin	Boehringer Ingelheim/Eli Lilly	Type 2 Diabetes Mellitus	Oral	11-2025
JENTADUETO	linagliptin/metformin	Boehringer Ingelheim/Eli Lilly	Type 2 Diabetes Mellitus	Oral	11-2025
NUCYNTA	tapentadol	Collegium	Moderate to Severe Acute Pain	Oral	11-2025
OPSUMIT	macitentan	Janssen	Pulmonary Arterial Hypertension	Oral	12-2025
2026 Possible launch date					
SIMBRINZA	brimonidine/brinzolamide	Alcon	Reduction of Elevated Intraocular Pressure in Patients with Open-Angle Glaucoma or Ocular Hypertension	Ophthalmic	2026
BRYHALI	halobetasol	Bausch Health	Plaque Psoriasis	External	2026
MAVENCLAD	cladribine	Serono	Multiple Sclerosis	Oral	2026
XOLAIR	omalizumab	Roche/Genentech	Asthma; Idiopathic Urticaria; Nasal Polyps; IgE-Mediated Food Allergy	Subcutaneous	2026
POMALYST	pomalidomide	Celgene	Multiple Myeloma; Kaposi Sarcoma	Oral	1Q-2026
YONSA	abiraterone	Sun	Prostate Cancer	Oral	01-2026
VELPHORO	sucroferric oxyhydroxide	Vifor Fresenius Medical Care Renal Pharma (VFMCRP)	Hyperphosphatemia In Patients with Chronic Kidney Disease on Dialysis	Oral	01-2026
BYVALSON	nebivolol/valsartan	AbbVie	Hypertension	Oral	01-2026
JEVTANA	cabazitaxel	Sanofi	Hormone-Refractory Metastatic Prostate Cancer	Intravenous	01-2026
EDARBI	azilsartan kamedoxomil	Arbor	Hypertension	Oral	01-2026
SERNIVO	betamethasone dipropionate	Encore Dermatology	Plaque Psoriasis	External	01-2026
ELLA	ulipristal	Afaxys/Perrigo	Emergency Contraception	Oral	01-2026
TYVASO	treprostinil	United Therapeutics	Pulmonary Arterial Hypertension; Pulmonary Hypertension with Interstitial Lung Disease	Inhalation	01-2026
GELNIQUE	oxybutynin	Allergan	Overactive Bladder	External	01-2026

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
QBRELIS	lisinopril	Silvergate	Hypertension; Heart Failure; Acute Myocardial Infarction	Oral	01-2026
IZBA	travoprost	Alcon	Open-Angle Glaucoma; Ocular Hypertension	Ophthalmic	01-2026
BRIVIACT	brivaracetam	UCB	Epilepsy	Oral; intravenous	02-2026
SAVELLA	milnacipran	AbbVie	Fibromyalgia	Oral	03-2026
XELJANZ XR	tofacitinib	Pfizer	Rheumatoid Arthritis; Psoriatic Arthritis; Ulcerative Colitis; Ankylosing Spondylitis	Oral	2Q-2026
XELJANZ	tofacitinib	Pfizer	Rheumatoid Arthritis; Ulcerative Colitis; Psoriatic Arthritis; Juvenile Idiopathic Arthritis; Ankylosing Spondylitis	Oral	2Q-2026
OFEV	nintedanib	Boehringer Ingelheim	Idiopathic Pulmonary Fibrosis; Systemic Sclerosis-Associated Interstitial Lung Disease (ILD); Chronic Fibrosing ILD	Oral	04-2026
QTERN	dapagliflozin/saxagliptin	AstraZeneca	Type 2 Diabetes Mellitus	Oral	04-2026
NULOJIX	belatacept	Bristol-Myers Squibb	Prophylaxis of Organ Rejection in Kidney Transplant	Intravenous	04-2026
JANUVIA	sitagliptan	Merck	Type 2 Diabetes Mellitus	Oral	05-2026
JANUMET	sitagliptan/metformin	Merck	Type 2 Diabetes Mellitus	Oral	05-2026
EVOMELA	melphalan	Acrotech/Aurobindo	Multiple Myeloma; Conditioning for Stem Cell Transplant	Intravenous	06-2026
CERDELGA	eliglustat	Sanofi/Genzyme	Gaucher Disease Type 1	Oral	06-2026
SUPPRELIN LA	histrelin	Endo	Central Precocious Puberty	Subcutaneous	06-2026
COTEMPLA XR-ODT	methylphenidate	Neos Therapeutics	Attention Deficit Hyperactivity Disorder	Oral	07-2026
INJECTAFER	ferric carboxymaltose	American Regent/CSL Limited	Iron Deficiency Anemia	Intravenous	07-2026
JANUMET XR	sitagliptin/metformin	Merck	Type 2 Diabetes Mellitus	Oral	07-2026
NUEDEXTA	dextromethorphan/quinidine sulfate	Avanir	Pseudobulbar Affect	Oral	07-2026
COMETRIQ	cabozantinib (S)-malate	Exelixis	Medullary Thyroid Cancer	Oral	08-2026
ILARIS	canakinumab	Novartis	Cryopyrin-Associated Periodic Syndromes; Familial Cold Autoinflammatory Syndrome; Muckle-Wells Syndrome; Tumor Necrosis Factor Receptor Associated Periodic Syndrome; Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency;	Subcutaneous	4Q-2026

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
			Familial Mediterranean Fever; Still's Disease; Gout Flares		
ADEMPAS	riociguat	Bayer	Pulmonary Arterial Hypertension; Chronic Thromboembolic Pulmonary Hypertension	Oral	4Q-2026
UPTRAVI	selexipag	Janssen	Pulmonary Arterial Hypertension	Oral	10-2026
VEREGEN	sinecatechins	Sandoz	External Genital and Perianal Warts	External	10-2026
HEMADY	dexamethasone	Acrotech Biopharma	Multiple Myeloma	Oral	10-2026
CYRAMZA	ramucirumab	Eli Lilly	Gastric Cancer; Gastroesophageal Cancer; Metastatic Gastric Cancer; Non-Small Cell Lung Cancer	Intravenous	10-2026
ADASUVE	loxapine	Alexza	Agitation Associated with Schizophrenia or Bipolar Disorder	Inhalation	10-2026
AVYCAZ	ceftazidime/avibactam	AbbVie	Intra-Abdominal Infections; Urinary Tract Infections, including Pyelonephritis; Pneumonia; Bacterial Pneumonia	Intravenous	11-2026
TRINTELLIX	vortioxetine	Takeda/Lundbeck	Major Depressive Disorder	Oral	12-2026
2027 Possible launch date					
FIRMAGON	degarelix	Ferring	Prostate Cancer	Subcutaneous	2027
KYPROLIS	carfilzomib	Amgen	Multiple Myeloma	Intravenous	2027
SAXENDA	liraglutide	Novo Nordisk	Chronic Weight Management	Subcutaneous	2027
ENTYVIO	vedolizumab	Takeda	Ulcerative Colitis; Crohn's Disease	Intravenous; subcutaneous	2027
IBRANCE	palbociclib	Pfizer	Breast Cancer	Oral	1Q-2027
BONJESTA	doxylamine/pyridoxine	Duchesnay	Nausea and Vomiting Associated with Pregnancy	Oral	01-2027
DIFICID	fidaxomicin	Merck	Treatment of Clostridium difficile-Associated Diarrhea	Oral	01-2027
OSPHENA	ospemifene	Duchesnay	Menopause Symptoms; Dyspareunia	Oral	01-2027
BELEODAQ	belinostat	Acrotech/Aurobindo	Relapsed or Refractory Peripheral T-cell Lymphoma	Intravenous	01-2027
VIBATIV	telavancin	Cumberland	Infections	Intravenous	01-2027
CUBICIN RF	daptomycin	Merck	Complicated Skin and Skin Structure Infections; Staphylococcus aureus Bloodstream Infections	Intravenous	01-2027

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
PERJETA	pertuzumab	Genentech	HER-2 Positive Breast Cancer	Intravenous	01-2027
ENVARSUS XR	tacrolimus	Veloxis	Prophylaxis of Organ Rejection in Kidney Transplant Patients	Oral	01-2027
RYDAPT	midostaurin	Novartis	Acute Myeloid Leukemia; Systemic Mastocytosis; Mast Cell Leukemia	Oral	01-2027
JUBLIA	efinaconazole	Bausch Health	Onychomycosis of the Toenail	External	01-2027
NUCYNTA ER	tapentadol	Collegium	Moderate to Severe Chronic Pain	Oral	01-2027
VALTOCO	diazepam	Neurelis	Epilepsy	Intranasal	01-2027
VIVITROL	naltrexone	Alkermes	Alcohol and/or Opioid Dependence	Intramuscular	01-2027
BELBUCA	buprenorphine	BioDelivery Sciences International	Severe Pain	Oral	01-2027
NATPARA	parathyroid hormone 1-84	Takeda	Hypoparathyroidism	Subcutaneous	01-2027
SUBSYS	fentanyl	BTcP Pharma	Breakthrough Pain in Cancer Patients	Oral	01-2027
NEVANAC	nepafenac	Harrow Health	Pain and Inflammation Associated with Cataract Surgery	Ophthalmic	01-2027
ALTABAX	retapamulin	Aqua Pharmaceuticals/Almirall	Impetigo	External	02-2027
BYDUREON	exenatide	AstraZeneca	Type 2 Diabetes Mellitus	Subcutaneous	02-2027
VITEKTA	elvitegravir	Gilead	Human Immunodeficiency Virus-1 Infection	Oral	02-2027
DUAVEE	conjugated estrogens/bazedoxifene acetate	Pfizer/Ligand Pharmaceuticals	Treatment of Moderate to Severe Vasomotor Symptoms Associated with Menopause; Prevention of Postmenopausal Osteoporosis	Oral	03-2027
TUDORZA PRESSAIR	aclidinium	AstraZeneca	Chronic Obstructive Pulmonary Disease	Inhalation	04-2027
DUAKLIR PRESSAIR	aclidinium/formoterol fumarate	AstraZeneca	Chronic Obstructive Pulmonary Disease	Inhalation	04-2027
MOXATAG	amoxicillin	Vernalis	Tonsillitis/Pharyngitis	Oral	05-2027
RAPIVAB	peramivir	BioCryst	Treatment of Acute Uncomplicated Influenza	Intravenous	05-2027
AVEED	testosterone undecanoate	Endo	Testosterone Replacement	Intramuscular	05-2027
LUMIGAN	bimatoprost	Allergan/AbbVie	Glaucoma; Ocular Hypertension	Ophthalmic	06-2027
AVEED	testosterone undecanoate	Endo	Testosterone Replacement	Intramuscular	05-2027
LUMIGAN	bimatoprost	Allergan/AbbVie	Glaucoma; Ocular Hypertension	Ophthalmic	06-2027

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
ORENITRAM	treprostinil diolamine	Supernus/United Therapeutics	Pulmonary Arterial Hypertension	Oral	06-2027
PLEGRIDY	peginterferon beta-1a	Biogen	Relapsing-Remitting Multiple Sclerosis	Subcutaneous	06-2027
XTANDI	enzalutamide	Astellas/Pfizer	Prostate Cancer	Oral	3Q-2027
RELISTOR	methylnaltrexone	Bausch Health	Opioid-Induced Constipation	Subcutaneous	07-2027
MYALEPT	metreleptin	Aegerion	Leptin Deficiency in Patients with Lipodystrophy	Subcutaneous	07-2027
DOPTELET	avatrombopag	AkaRx	Thrombocytopenia	Oral	07-2027
PIZENSY	lactitol	Braintree/Sebela	Chronic Idiopathic Constipation	Oral	08-2027
ILUVIEN	fluocinolone acetonide	Alimera Sciences	Diabetic Macular Edema	Intravitreal	08-2027
CRESEMBA	isavuconazonium	Astellas	Invasive Aspergillosis; Invasive Mucormycosis	Oral	09-2027
SOLOSEC	secnidazole	Lupin	Bacterial Vaginosis; Trichomoniasis	Oral	09-2027
GRASTEK	timothy grass pollen allergen extract	ALK-Abello/Catalent	Grass Pollen-Induced Allergic Rhinitis	Sublingual	4Q-2027
BRONCHITOL	mannitol	Arna Pharma	Cystic Fibrosis	Inhalation	10-2027
TALICIA	amoxicillin/rifabutin/omeprazole	Redhill Biopharma	Helicobacter pylori	Oral	11-2027
FANAPT	iloperidone	Vanda	Schizophrenia; Bipolar Disorder	Oral	11-2027
NUCALA	mepolizumab	GSK	Severe Asthma; Rhinosinusitis with Nasal Polyps; Eosinophilic Granulomatosis with Polyangitis; Hypereosinophilic Syndrome	Subcutaneous	11-2027
ZOKINVY	lonafarnib	Sentynl Therapeutics	Hutchinson-Gilford Progeria Syndrome	Oral	11-2027
TRULICITY	dulaglutide	Eli Lilly	Type 2 Diabetes Mellitus	Subcutaneous	12-2027
ZONTIVITY	vorapaxar sulfate	Key Pharma	Reduction of Thrombotic Cardiovascular Events in Patients with a History of Myocardial Infarction or with Peripheral Arterial Disease	Oral	12-2027
ADYNOVATE	antihemophilic factor recombinant pegylated	Takeda	Hemophilia A	Intravenous	12-2027
2028 Possible launch date (1st half)					
TRIUMEQ	abacavir/dolutegravir/lamivudine	ViiV Healthcare	Human Immunodeficiency Virus Infection	Oral	2028
TIVICAY	dolutegravir	ViiV Healthcare	Human Immunodeficiency Virus Infection	Oral	2028
KEYTRUDA	pembrolizumab	Merck	Cancer	Intravenous	2028

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
ORENCIA	abatacept	Bristol-Myers Squibb	Rheumatoid Arthritis; Juvenile Idiopathic Arthritis; Psoriatic Arthritis; Graft Vs. Host Disease	Intravenous; subcutaneous	2028
EDARBYCLOR	azilsartan kamedoxomil/chlorthalidone	Azurity Pharmaceuticals	Hypertension	Oral	01-2028
INLYTA	axitinib	Pfizer	Advanced Renal Cell Carcinoma	Oral	01-2028
GILOTRIF	afatinib	Boehringer Ingelheim	Non-Small Cell Lung Cancer	Oral	01-2028
ENSTILAR	betamethasone dipropionate/calcipotriol	LEO Pharma	Plaque Psoriasis	External	01-2028
INVOKANA	canagliflozin	Janssen/Vifor	Type 2 Diabetes Mellitus (T2DM); Reduce the Risk of Major Adverse Cardiovascular (CV) Events in Patients with CV Disease; Reduce the Risk of End-Stage Kidney Disease and CV events in Adults with T2DM and Chronic Kidney Disease	Oral	01-2028
GLOPERBA	colchicine	Scilex	Prophylaxis of Gout Flares	Oral	01-2028
ONUREG	azacitidine	Celgene/Bristol-Myers Squibb	Acute Myeloid Leukemia	Oral	01-2028
XIFAXAN	rifaximin	Bausch Health	Traveler's Diarrhea; Hepatic Encephalopathy	Oral	01-2028
KALYDECO	ivacaftor	Vertex	Cystic Fibrosis	Oral	01-2028
INVOKAMET XR	canagliflozin/metformin	Janssen	Type 2 Diabetes Mellitus; Reduce the Risk of Major Adverse Cardiovascular Events in Patients with Cardiovascular Disease	Oral	01-2028
IMPOYZ	clobetasol propionate	Encore Dermatology/Dr. Reddy's	Psoriasis	External	01-2028
MEKINIST	trametinib dimethyl sulfoxide	Novartis/GSK	Melanoma; Non-Small Cell Lung Cancer; Anaplastic Thyroid Cancer; Glioma; Solid Tumors	Oral	01-2028
INVOKAMET	canagliflozin/metformin	Janssen	Type 2 Diabetes Mellitus; Reduce the Risk of Major Adverse Cardiovascular Events in Patients with Cardiovascular Disease	Oral	01-2028
KYBELLA	deoxycholic acid	Allergan	Improvement in the Appearance of Moderate to Severe Convexity or Fullness Associated with Submental Fat in Adults	Subcutaneous	01-2028
THYQUIDITY	levothyroxine	Vistapharm	Hypothyroidism; Pituitary Thyrotropin Suppression	Oral	01-2028
EXPAREL	bupivacaine	Pacira	Postsurgical Analgesia	Injection	01-2028
WAKIX	pitolisant	Harmony Biosciences	Narcolepsy	Oral	01-2028

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
YUTIQ	fluocinolone	Alimera Sciences	Non-Infectious Uveitis	Intravitreal	01-2028
NEXTSTELLIS	drospirenone/estetrol	Mayne	Prevention of Pregnancy	Oral	01-2028
NAYZILAM	midazolam	UCB	Epilepsy	Intranasal	01-2028
NOURIANZ	istradefylline	Kyowa Kirin	Parkinson's Disease	Oral	01-2028
ZETONNA	ciclesonide	Covis Pharma	Seasonal and Perennial Allergic Rhinitis	Intranasal	02-2028
PERSERIS	risperidone	Indivior	Schizophrenia	Subcutaneous	02-2028
REYVOW	lasmiditan	Eli Lilly	Acute Treatment of Migraine	Oral	02-2028
WINLEVI	clascoterone	Cassiopea/Cosmo Technologies	Acne Vulgaris	External	02-2028
INGREZZA	valbenazine	Neurocrine	Tardive Dyskinesia; Chorea Associated with Huntington's Disease	Oral	03-2028
KOVALTRY	antihemophilic factor recombinant	Bayer	Hemophilia A	Intravenous	03-2028
ZOLINZA	vorinostat	Merck	Cutaneous T-Cell Lymphoma	Oral	03-2028
CINQAIR	reslizumab	Teva Respiratory	Severe Asthma	Intravenous	03-2028
ELIQUIS	apixaban	Pfizer/Bristol-Myers Squibb	Reduce the Risk of Stroke and Systemic Embolism in Patients with Nonvalvular Atrial Fibrillation; Prophylaxis of Deep Vein Thrombosis (DVT) in Patients Who Have Undergone Hip or Knee Replacement Surgery; Treatment of DVT and PE	Oral	04-2028
DALVANCE	dalbavancin	AbbVie	Acute Bacterial Skin and Skin Structure Infections	Intravenous	05-2028
VERKAZIA	cyclosporine	Santen	Vernal Keratoconjunctivitis	Ophthalmic	06-2028
VYONDYS 53	golodirsen	Sarepta Therapeutics	Duchenne Muscular Dystrophy	Intravenous	06-2028

References:

AbbVie Press Release. AbbVie Web site. AbbVie submits Biologics License Application to the FDA for telisotuzumab vedotin (Teliso-V) in previously treated non-small cell lung cancer. https://news.abbvie.com/2024-09-27-AbbVie-Submits-Biologics-License-Application-to-the-FDA-for-Telisotuzumab-Vedotin-Teliso-V-in-Previously-Treated-Non-Small-Cell-Lung-Cancer. September 27, 2024. Accessed February 10, 2025.

Alnylam Press Release. Alnylam Web site. Alnylam announces U.S. Food and Drug Administration acceptance of supplemental New Drug Application for vutrisiran for the treatment of ATTR amyloidosis with cardiomyopathy. https://investors.alnylam.com/press-release?id=28546. November 25, 2024. Accessed December 17, 2024.

American Cancer Society. Lung cancer. https://www.cancer.org/cancer/types/lung-cancer.html. Accessed February 10, 2025.

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

Camidge DR, Bar J, Horinouchi H, et al. Telisotuzumab vedotin monotherapy in patients With previously treated c-Met protein-overexpressing advanced nonsquamous EGFR-wildtype non-small cell lung cancer in the Phase II LUMINOSITY Trial. J Clin Oncol. 2024;42(25):3000-3011.

Centers for Disease Control and Prevention (CDC). CDC Web site. Inflammatory bowel disease (IBD) https://www.cdc.gov/inflammatory-bowel-disease/index.html. Accessed February 10, 2025.

Fontana M, Berk JL, Gillmore JD, et al; HELIOS-B Trial Investigators. Vutrisiran in patients with transthyretin amyloidosis with cardiomyopathy. N Engl J Med. 2024. Epub ahead of print.

Heerspink HJL, Jardine M, Kohan DE, et al; ALIGN Study Investigators. Atrasentan in patients with IgA nephropathy. N Engl J Med. 2024 Oct 25.

Johnson & Johnson Press Release. Johnson & Johnson Web site. Johnson & Johnson seeks first approval of nipocalimab to treat broadest population living with antibody positive generalized myasthenia gravis. https://www.jnj.com/media-center/press-releases/johnson-johnson-seeks-first-approval-of-nipocalimab-to-treat-broadest-population-living-with-antibody-positive-generalized-myasthenia-gravis. August 29, 2024. Accessed December 19, 2024.

Johnson & Johnson Press Release. Johnson & Johnson Web site. Johnson & Johnson submits application to U.S. FDA seeking approval of Tremfya® (guselkumab) for the treatment of moderately to severely active Crohn's disease. https://www.jnj.com/media-center/press-releases/johnson-johnson-submits-application-to-u-s-fda-seeking-approval-of-tremfya-guselkumab-for-the-treatment-of-moderately-to-severely-active-crohns-disease. June 20, 2024. Accessed February 10, 2025.

Johnson & Johnson Press Release. Johnson & Johnson Web site. Nipocalimab pivotal Phase 3 trial demonstrates longest sustained disease control in FcRn class. https://www.jnj.com/media-center/press-releases/nipocalimab-pivotal-phase-3-trial-demonstrates-longest-sustained-disease-control-in-fcrn-class. June 28, 2024. Accessed December 19, 2024.

Johnson & Johnson Press Release. Johnson & Johnson Web site. Tremfya® (guselkumab) is the first and only IL-23 inhibitor to demonstrate robust results with a fully subcutaneous regimen in both induction and maintenance in Crohn's disease. https://www.jnj.com/media-center/press-releases/tremfya-guselkumab-is-the-first-and-only-il-23-inhibitor-to-demonstrate-robust-results-with-a-fully-subcutaneous-regimen-in-both-induction-and-maintenance-in-crohns-disease. October 28, 2024. Accessed February 10, 2025.

KalVista Press Release. KalVista Web site. KalVista announces FDA acceptance of New Drug Application for sebetralstat for oral on-demand treatment of hereditary angioedema. https://ir.kalvista.com/news-releases/news-release-details/kalvista-announces-fda-acceptance-new-drug-application. September 3, 2024. Accessed December 17, 2024.

Milestone Pharmaceuticals Press Release. Milestone Web site. Milestone Pharmaceuticals announces FDA acceptance of New Drug Application for CARDAMYST™. https://investors.milestonepharma.com/news-releases/news-release-details/milestone-pharmaceuticals-announces-fda-acceptance-new-drug. May 29, 2024. Accessed January 21, 2025.

National Organization for Rare Disorders (NORD). Hereditary angioedema. https://rarediseases.org/rarediseases/hereditary-angioedema. Accessed December 17, 2024.

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) IgA Nephropathy. NIDDK Web site. https://www.niddk.nih.gov/health-information/kidney-disease/iga-nephropathy Accessed January 22, 2025.

National Organization for Rare Disorders (NORD). IgA nephropathy. NORD Web site. https://rarediseases.org/rare-diseases/iga-nephropathy. Accessed January 22, 2025.

National Organization for Rare Disorders (NORD). Myasthenia gravis. https://rarediseases.org/rare-diseases/myasthenia-gravis. Accessed December 19, 2024.

Panaccione R, Danese S, Feagan B, et al. Efficacy And safety of guselkumab therapy in patients with moderately to severely active Crohn's disease: results of the Galaxi 2 & 3 Phase 3 studies [abstract]. Arthritis Rheumatol. 2024; 76 (suppl 9). https://acrabstracts.org/abstract/efficacy-and-safety-of-guselkumab-therapy-in-patients-with-moderately-to-severely-active-crohns-disease-results-of-the-galaxi-2-3-phase-3-studies. Accessed February 10, 2025.

Riedl MA, Farkas H, Aygören-Pürsün E, et al; KONFIDENT Investigators. Oral sebetralstat for on-demand treatment of hereditary angioedema attacks. N Engl J Med. 2024;391(1):32-43.

Stambler BS, Camm AJ, Alings M, et al; RAPID Investigators. Self-administered intranasal etripamil using a symptom-prompted, repeat-dose regimen for atrioventricular-nodal-dependent supraventricular tachycardia (RAPID): a multicentre, randomised trial. Lancet. 2023;402(10396):118-128.

Stambler BS, Plat F, Sager PT, et al. First randomized, multicenter, placebo-controlled study of self-administered intranasal etripamil for acute conversion of spontaneous paroxysmal supraventricular tachycardia (NODE-301). Circ Arrhythm Electrophysiol. 2022;15(12):e010915.

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

Optum Rx®

optum.com/optumrx