RxOutlook®

4th Quarter 2024

Optum Rx®

Welcome to the fourth quarter RxOutlook Report of 2024. 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 - Where Are We Today?

As of November 21, the FDA's Center for Drug Evaluation and Research (CDER) has approved 40 new molecular entities in 2024. Since the previous quarter's report, notable drug approvals have included: **Cobenfy™ (xanomeline/trospium chloride)**, the first antipsychotic drug approved to treat schizophrenia that targets cholinergic receptors; **Itovebi™ (inavolisib)**, a phosphatidylinositol 3-kinase (PI3K) inhibitor that is added to the current standard of care (Ibrance® [palbociclib] and fulvestrant) for select patients with breast cancer; and **Ebglyss™ (lebrikizumab-lbkz)**, the second interleukin-13 (IL-13) antagonist approved for atopic dermatitis and a competitor to LEO Pharma's Adbry® (tralokinumab-ldrm) and Sanofi/Regeneron's Dupixent® (dupilumab).

Looking Ahead to 1Q 2025

In this edition of RxOutlook, we will be discussing seven drug therapies with an approval decision by the end of the 1st quarter 2025. This includes two new potential indications for glucagon-like peptide-1 (GLP-1) receptor agonists – Zepbound® (tirzepatide) and Ozempic® (semaglutide). Zepbound is under FDA review for a new indication for treatment of obstructive sleep apnea (OSA) in obese patients; if approved, Zepbound would be the first pharmacotherapy approved for OSA. Ozempic is under FDA review for the treatment of chronic kidney disease in patients with type 2 diabetes; if approved, Ozempic would be the first GLP-1 receptor agonist approved for this indication.

Vertex Pharmaceuticals has two of the more high-profile FDA approval decisions in the first quarter 2025. **Vanzacaftor/tezacaftor/deutivacaftor** is a "next generation" treatment for cystic fibrosis (CF) and a potential successor to Vertex's own Trikafta® (elexacaftor/tezacaftor/ivacaftor; ivacaftor). **Suzetrigine** is a first-in-class, non-opioid treatment for acute pain. Suzetrigine would be the first novel therapy for pain in decades, and because of its unique mechanism of action, it is not associated with a risk of abuse or dependence.

Additionally, the report includes **rivoceranib plus camrelizumab**, two novel drugs used in combination with one another for the treatment of unresectable hepatocellular carcinoma; **gepotidacin**, a first-in-class antibiotic for the treatment of uncomplicated urinary tract infections; and **fitusiran**, a first-in-class small interference RNA therapeutic for hemophilia A and B.

Several other novel therapies that were discussed in prior editions of RxOutlook are also expecting approval decisions by the end of the first quarter 2025, including: datopotamab deruxtecan for non-small cell lung cancer and breast cancer and concizumab for hemophilia A and B.

Key FDA approval decisions expected by the end of the 1st quarter 2025

Drug Name	Manufacturer	Indication/Use	Expected FDA Decision Date
Zepbound (tirzepatide)	Eli Lilly	Obstructive sleep apnea	12/2024
Ozempic (semaglutide)	Novo Nordisk	Chronic kidney disease	1/2025
Vanzacaftor/tezacaftor/ deutivacaftor	Vertex Pharmaceuticals	Cystic fibrosis*	1/2/2025
Suzetrigine	Vertex Pharmaceuticals	Acute pain	1/30/2025
Rivoceranib plus camrelizumab	Elevar Therapeutics/ Hengrui Pharma	Hepatocellular carcinoma*	3/23/2025
Gepotidacin	GSK	Urinary tract infection	3/26/2025
Fitusiran	Sanofi	Hemophilia A and B*	3/28/2025

* 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 1st 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 1st 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

Tirzepatide (Brand Name: Zepbound®)

Manufacturer: Eli Lilly
Regulatory designation: Fast Track
Expected FDA decision: December 2024

Therapeutic use

Zepbound is under review for the treatment of moderate-to-severe obstructive sleep apnea (OSA) in adult patients with obesity.

Zepbound is currently approved as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults. Tirzepatide is also approved under the brand name Mounjaro® as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).

Patients suffering from sleep apnea experience multiple episodes of momentary apneas (breathing stops) and hypopneas (shallow breathing) while they sleep. OSA, the most common type of sleep apnea, is caused by the upper airway becoming blocked during sleep, reducing or completely stopping airflow. Risk factors for OSA include, but are not limited to age, endocrine disorders, large tonsils, gender (more common in men), and most notably, obesity. A common symptom associated with OSA is daytime sleepiness and OSA is a risk factor for cardiovascular disease.

The exact prevalence of OSA is unknown since it is significantly underdiagnosed, but it is believed to affect 13% of adult men and 6% of adult women in the U.S.

What you need to know:

Proposed Indication: Treatment of moderate-to-severe OSA in adults with obesity

Mechanism: GIP/GLP-1 receptor agonist

Efficacy: Mean change in AHI at Week 52:

- Study 1: –25.3 events/hour vs. –5.3 events/hour with placebo Reduced by 35.2% vs. routine prophylaxis
- Study 2: –29.3 events/hour vs. –5.5 events/hour with placebo

Common AEs: Nausea, diarrhea, vomiting, constipation

Dosing: SC once weekly

Why it Matters: Potentially the first drug approved for OSA, promising efficacy results in patients with or without concomitant PAP use

Important to Note: Trial was limited to patients with obesity, design and duration of studies did not support the assessment of long-term outcomes

Estimated Cost: ~$13,800 per year (based on current cost of Zepbound)

Clinical profile

Zepbound is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist. Zepbound can provide significant reductions in excess body weight and reduces markers of inflammation and vascular endothelial dysfunction, which are believed to have downstream positive effects on OSA.

Pivotal trial data:
The efficacy of Zepbound was evaluated in two Phase 3, randomized, double-blind, placebo-controlled studies (SURMOUNT-OSA) in adults with moderate-to-severe OSA and obesity. Study 1 included patients who were not receiving treatment with positive airway pressure (PAP) at baseline, and Study 2 included patients who were receiving PAP therapy at baseline. Patients were randomized to receive either the maximum tolerated dose of tirzepatide (10 mg or 15 mg) or placebo for 52 weeks. The primary endpoint was the change in the apnea-hypopnea index (AHI, the number of apneas and hypopneas during an hour of sleep) from baseline.

Tirzepatide *(continued...)*

At baseline, the mean AHI was 51.5 events/hour in Study 1 and 49.5 events/hour in Study 2, and the mean body mass index (BMI) was 39.1 kg/m² and 38.7 kg/m², respectively.

In Study 1, the mean change in AHI at Week 52 was a reduction of 25.3 events/hour with Zepbound vs. a reduction of 5.3 events/hour with placebo (estimated treatment difference of −20.0, 95% CI: −25.8, −14.2; $p < 0.001$). In Study 2, the mean change in AHI at week 52 was a reduction of 29.3 events/hour with Zepbound vs. a reduction of 5.5 events/hour with placebo (estimated treatment difference of −23.8, 95% CI: −29.6, −17.9; $p < 0.001$).

Safety:
The safety profile of Zepbound was consistent with that observed in previous studies, with the most common adverse events being nausea, diarrhea, vomiting, and constipation.

Dosing:
In the pivotal trials, Zepbound was administered subcutaneously (SC) once weekly.

Competitive environment

Zepbound would potentially be the first FDA approved therapy for OSA. Currently, commonly used treatments for OSA are breathing devices such as continuous positive airway pressure (CPAP) machines. CPAP machines are effective in reducing the symptoms of OSA but are often associated with poor adherence. Other treatment options include oral devices (mandibular repositioning mouthpieces) and surgical procedures.

The results from the two pivotal studies were promising, with Zepbound demonstrating a clinically meaningful reduction in AHI (≥ 15 events/hour) compared to placebo, regardless of baseline use of a PAP device. Additionally, approximately 50% of patients across the trials reached a threshold of disease severity at which PAP therapy may no longer be recommended.

However, the pivotal studies did have two key notable limitations. First, the studies were limited to patients with obesity (BMI ≥ 30 kg/m²) and therefore the results may not be generalizable to overweight patients or those with normal BMI. Second, the design and duration of the studies did not allow for assessing longer-term outcomes such as cardiovascular risk.

The Wholesale Acquisition Cost (WAC) for Zepbound is approximately $13,800 per year.

Semaglutide (Brand Name: Ozempic®)

Manufacturer: Novo Nordisk
Expected FDA decision: January 2025

Therapeutic use

Ozempic is under review for the prevention of progression of kidney impairment and risk of kidney and cardiovascular mortality in patients with type 2 diabetes (T2DM) and chronic kidney disease (CKD).

Ozempic is currently approved as an adjunct to diet and exercise to improve glycemic control in adults with T2DM and to reduce the risk of major adverse cardiovascular events in adults with T2DM and established cardiovascular disease. Semaglutide is also approved under the brand name Wegovy® in combination with a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight, and to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients.

An estimated 36 million people have T2DM in the U.S. Of patients with T2DM, about 40% are suffering from CKD and 16% have moderate-to-severe disease.

Clinical profile

Ozempic is a glucagon-like peptide 1 (GLP-1) receptor agonist. The renal protective effects of Ozempic are likely due to multiple mechanisms, including decreases in inflammation, oxidative stress, and fibrosis. Intrinsic kidney and immune cells contain the GLP-1 receptor, and GLP-1 receptor agonists reduce cellular expression of proinflammatory and profibrotic mediators.

What you need to know:

Proposed Indication: Prevention of progression of kidney impairment and risk of kidney and cardiovascular mortality in patients with T2DM a nd CKD

Mechanism: GLP-1 receptor agonist

Efficacy: Major kidney disease events: 5.8 per 100 patient-years vs. 7.5 per 100 patient-years with placebo (24% risk reduction in favor of Ozempic)

Safety: Serious AEs were reported in a lower percentage of patients with Ozempic vs. placebo

Dosing: SC once weekly

Why it Matters: Potentially the first GLP-1 receptor agonist approved for T2DM and CKD, promising data for both kidney protection and cardiovascular outcomes, large target population

Important to Note: Alternative treatment options available (eg, SGLT2 inhibitors, Kerendia), limited data for combination therapy with SGLT2 inhibitors

Estimated Cost: ~$12,600 per year (based on current cost of Ozempic)

Pivotal trial data:
The efficacy of Ozempic was evaluated in the FLOW trial, a Phase 3, randomized, double-blind, placebo-controlled, event-driven study in 3,533 adult patients with T2DM and CKD. Patients were randomized to Ozempic or placebo. The primary endpoint was major kidney disease events, a composite of the onset of kidney failure (dialysis, transplantation, or an estimated glomerular filtration rate [eGFR] of < 15 ml per minute per 1.73 m2), at least a 50% reduction in the eGFR from baseline, or death from kidney-related or cardiovascular causes. The median follow-up was 3.4 years, after early trial cessation was recommended at a prespecified interim analysis.

Primary-outcome events occurred less frequently in the Ozempic group than in the placebo group (5.8 per 100 patient-years of follow-up vs. 7.5 per 100 patient-years), which resulted in a 24% lower relative risk of the primary outcome in the Ozempic group (hazard ratio [HR] 0.76, 95% CI: 0.66, 0.88; p = 0.0003). Results were similar for a composite of the kidney-specific components of the primary outcome (HR 0.79, 95% CI: 0.66, 0.94) and death from cardiovascular causes (HR 0.71, 95% CI: 0.56, 0.89).

Semaglutide *(continued...)*

Safety:
Serious adverse events were reported in a lower percentage of patients in the Ozempic group than in the placebo group.

Dosing:
In the pivotal trial, Ozempic was administered SC once weekly.

Competitive environment

Ozempic would be the first GLP-1 receptor agonist approved for CKD and would offer an additional treatment option for patients with both T2DM and CKD. Currently, the standard of care for these patients are renin-angiotensin system (RAS) inhibitors (angiotensin converting enzyme [ACE] inhibitors or angiotensin II receptor blockers [ARB]), sodium-glucose cotransporter 2 (SGLT2) inhibitors, and Kerendia® (finerenone) (a mineralocorticoid-receptor antagonist). These other therapies have also demonstrated kidney protection and a reduction in the risk of adverse cardiovascular outcomes.

In the FLOW trial, over 95% of patients were being treated with a RAS inhibitor at baseline; however, because the study was initiated before SGLT2 inhibitors and mineralocorticoid-receptor antagonists were approved for CKD and T2DM, only a small percentage of patients were on baseline therapy with those drugs (15.6% on an SGLT2 inhibitor). Due to the small percentage of patients on baseline SGLT2 inhibitors, additional studies are needed to assess the benefits of combination therapy.

The WAC for Ozempic is approximately $12,600 per year.

Vanzacaftor/tezacaftor/deutivacaftor (Brand Name: To be determined)

Manufacturer: Vertex
Regulatory designation: Orphan Drug
Expected FDA decision: January 2, 2025

Therapeutic use

Vanzacaftor/tezacaftor/deutivacaftor (VNZ triple therapy) is under review for treatment of patients with cystic fibrosis (CF) ages 6 years and older who have at least one *F508del* mutation or another responsive mutation in the cystic fibrosis transmembrane conductance regulator *(CFTR)* gene to VNZ triple therapy.

CF is a genetic disease that can affect multiple organs in the body, including the lungs, liver, pancreas, gastrointestinal tract, sweat glands, and reproductive tract. CF is caused by a defective and/or missing CFTR protein resulting from different mutations in the *CFTR* gene, with most patients having at least one *F508del* mutation. Defective or absent CFTR protein leads to mucus that is abnormally thick and sticky which in the lungs, causes chronic lung infections and progressive lung damage.

CF affects about 35,000 people in the U.S. CF can be apparent soon after birth and most affected individuals are diagnosed by age 3.

What you need to know:

Proposed Indication: Treatment of patients with CF ages 6 years and older who have at least one *F508del* mutation or another responsive mutation in the CFTR gene to VNZ triple therapy

Mechanism: CFTR modulators

Efficacy: Change in ppFEV1 at Week 24: Non-inferior to Trikafta

Safety: Adverse events were consistent with that observed with Trikafta

Dosing: Oral once daily

Why it Matters: "Next-generation" CF treatment and potential successor to Trikafta, once daily administration (Trikafta is twice daily)

Important to Note: Not expected to significantly expand eligible target population, Trikafta is approved in younger patients (2 years and older) and is available in an oral granule formulation

Estimated Cost: ~$326,000 per year (based on pricing for Trikafta)

Clinical profile

Vanzacaftor and tezacaftor are designed to increase the amount of CFTR protein at the cell surface by facilitating the processing and trafficking of the CFTR protein. Deutivacaftor is a potentiator designed to improve the flow of salt and water across the cell membrane.

Pivotal trial data:
The efficacy of VNZ triple therapy was evaluated in SKYLINE 102 and SKYLINE 103, two Phase 3, randomized, double-blind, controlled studies in 971 patients aged 12 years and older who have at least one *F508del* mutation or a mutation responsive to triple combination CFTR modulators. All patients received a 4-week run-in on Trikafta® (elexacaftor/tezacaftor/ivacaftor) and then were randomized to either the VNZ triple therapy or Trikafta. The primary endpoint was the absolute change from baseline in percent predicted forced expiratory volume in 1 second (ppFEV1) through Week 24. A key secondary endpoint was the absolute change from baseline in sweat chloride (SwCl). SwCl measures CFTR protein dysfunction and higher levels of SwCl are associated with more severe disease.

Vanzacaftor/tezacaftor/deutivacaftor *(continued...)*

VNZ triple was noninferior to Trikafta on the primary endpoint of change from baseline in ppFEV1, with least squares mean differences of 0.2 in both SKYLINE 102 (95% CI: −0.7, 1.1; p < 0.0001) and SKYLINE 103 (95% CI: −0.5, 0.9; p < 0.0001). VNZ triple therapy demonstrated superiority for change from baseline in SwCl, with differences of −8.4 mmol/L (95% CI: −10.5, −6.3; p < 0.0001; SKYLINE 102) and −2.8 mmol/L (95% CI: −4.7, −0.9; p = 0.0034; SKYLINE 103).

In addition to the SKYLINE studies, VNZ triple therapy was evaluated in RIDGELINE 105, a Phase 3, open-label study in 78 pediatric CF patients aged 6 to 11 years. Before receiving VNZ triple therapy, all participants were on Trikafta for at least 4 weeks. The primary endpoint of this study was safety, but key secondary endpoints included absolute changes from baseline in SwCl concentration and ppFEV1.

Patients maintained their baseline level of lung function, with a ppFEV1 absolute mean change from baseline through Week 24 of 0.0 (95% CI: −2.0, 1.9), and had an absolute mean change from baseline through Week 24 in SwCl concentration of −8.6 mmol/L (95% CI: −11.0, −6.3).

Safety:
The safety profile of VNZ triple therapy was consistent with that observed with Trikafta.

Dosing:
In the pivotal trials, VNZ triple therapy was administered orally once daily.

Competitive environment

VNZ triple therapy would represent a “next generation” CF treatment and a potential advancement from the current standard of care, Trikafta. VNZ triple therapy can be administered once daily whereas Trikafta requires administration twice daily. The sweat test data indicated a potential incremental improvement over Trikafta with more patients reaching SwCl levels below the diagnostic threshold for CF (< 60 mmol/L) and to normal levels (< 30 mmol/L). Higher SwCl levels have been associated with poorer clinical outcomes in CF.

Currently, about 90% of patients have *CFTR* gene mutations that are amenable to treatment. VNZ triple therapy is expected to expand the number of mutations that would be responsive to treatment, but the overall increased number of patients that would be eligible for treatment is expected to be relatively small since these mutations are rarer.

Due to the data currently available, the initial indication for VNZ triple therapy is expected to be limited to patients 6 years of age and older. In contrast, Trikafta is approved in patients 2 years of age and older and is available in an oral granule formulation to support dosing in younger pediatric patients.

For reference, the WAC for Trikafta is approximately $326,000 per year.

Suzetrigine (Brand Name: To be determined)

Manufacturer: Vertex
Regulatory designation: Breakthrough Therapy, Fast Track
Expected FDA decision: January 30, 2025

Therapeutic use

Suzetrigine is under review for the treatment of adults with moderate-to-severe acute pain.

Acute pain is defined as pain lasting up to 3 months. It is estimated that about 80 million people are prescribed medication for acute pain every year in the U.S.

Clinical profile

Suzetrigine is a non-opioid, selective sodium channel $Na_V1.8$ inhibitor. $Na_V1.8$ is a voltage-gated sodium channel that is selectively expressed in peripheral pain-sensing neurons, where its role is to transmit pain signals. The presence of sodium channel $Na^V1.8$ is minimal to undetectable in the brain, and therefore $Na_VV1.8$ inhibitors are unlikely to be associated with central nervous system effects (eg, potential for abuse and dependence).

Pivotal trial data:
The efficacy of suzetrigine was evaluated in two Phase 3, randomized, double-blind, placebo-controlled studies in 2,191 adult patients with moderate-to-severe pain. One study was in patients following abdominoplasty surgery and one following bunionectomy surgery. In both studies, patients were randomized to suzetrigine, placebo, or hydrocodone/acetaminophen (HB/APAP) 5 mg/325 mg for 48 hours of treatment. The primary endpoint was the time-weighted sum of the pain intensity difference from 0 to 48 hours (SPID48) compared to placebo. SPID48 was calculated using the 11-point Numeric Pain Rating Scale (0 to 10), at a series of time intervals over 48 hours. The difference from baseline was assessed at each point, weighted by the amount of time elapsed and then added together to yield the total SPID48 score. The key secondary endpoint compared suzetrigine vs. HB/APAP for SPID48.

In the abdominoplasty study, the least squares (LS) mean SPID48 was 118.4 in the suzetrigine arm vs. 70.1 in the placebo arm (difference vs. placebo of 48.4, 95% CI: 33.6, 63.1; $p < 0.0001$). The trial did not meet its key secondary endpoint for superiority vs. HB/APAP. The LS mean SPID48 for HB/APAP was 111.8 (SPID48 difference of 6.6, 95% CI: −5.4, 18.7).

In the bunionectomy study , the LS mean SPID48 was 99.9 in the suzetrigine arm vs. 70.6 in the placebo arm (difference vs. placebo of 29.3, 95% CI: 14.0, 44.6; $p = 0.0002$). Like the abdominoplasty study, suzetrigine was not found to be superior to HB/APAP. The LS mean SPID48 for HB/APAP was 120.1 (SPID48 difference of −20.2, 95% CI: −32.7, −7.7).

What you need to know:

Proposed Indication: Treatment of adults with moderate-to-severe acute pain

Mechanism: $Na_V1.8$ pain signal inhibitor

Efficacy: Change in SPID48:

- Study 1: 118.4 with suzetrigine vs. 70.1 with placebo vs. 111.8 with HB/APAP
- Study 2: 99.1 with suzetrigine vs. 70.6 with placebo vs. 120.1 with HB/APAP

Common AEs: Nausea, constipation, headache, dizziness, hypotension

Dosing: Oral once daily

Why it Matters: First-in-class non-opioid analgesic, favorable safety profile vs. opioids, not associated with abuse/dependence (expected to be non-controlled substance), potential future use in diabetic peripheral neuropathy (trials begin in 2H 2024)

Important to Note: Alternative pain medications available generically (eg, NSAIDs, opioids), efficacy and safety limited to short-term acute pain management

Suzetrigine *(continued…)*

Safety:
The most common adverse events observed with suzetrigine use were nausea, constipation, headache, dizziness, and hypotension; the incidence of adverse events were lower than with placebo and generally consistent with a post-surgical setting.

Dosing:
In the pivotal trials, suzetrigine was administered orally twice daily.

Competitive environment

The current standard of care for acute pain management includes acetaminophen, nonsteroidal antiinflammatory drugs (NSAIDs), and opioid drugs. Almost all NSAIDs and opioids are available generically. Suzetrigine would represent the first novel mechanism of action for the treatment of pain in decades. The primary differentiator for suzetrigine relative to opioids is that it does not appear to be associated with a risk of abuse or dependence, and it is not expected to be a controlled substance. Opioid overdose deaths have finally started to decline in the U.S. but an estimated 81,038 still died in 2023 due to opioid overdose. In 2022, it was estimated that about 3.7% of adults had an opioid use disorder that needed treatment.

In the pivotal studies, suzetrigine had a favorable adverse event profile (eg, low rates of nausea, dizziness) and demonstrated a statistically superior reduction in pain scores relative to placebo. However, suzetrigine was not shown to be statistically superior to opioids for pain relief.

The current data for suzetrigine is primarily limited to post-surgical acute pain management. Vertex has announced plans to initiate Phase 3 studies for treatment of diabetic peripheral neuropathy in the second half of 2024. These studies will provide additional data on the role of suzetrigine for chronic pain and its longer-term safety.

Rivoceranib plus camrelizumab (Brand Name: To be determined)

Manufacturer: Elevar Therapeutics/Hengrui Pharma
Regulatory designation: Orphan Drug
Expected FDA decision: March 23, 2025

Therapeutic use

Rivoceranib, in combination with camrelizumab, is under review for first-line treatment of unresectable hepatocellular carcinoma (uHCC).

An estimated 42,000 new cases of liver cancer will be diagnosed and about 30,000 people will die of liver cancer in the U.S. in 2024. HCC is the most common form of liver cancer in adults. Surgery or transplant can be an option in some patients, but many patients have unresectable disease. Elevar Therapeutics estimates that nearly 16,000 patients in the U.S. receive first-line treatment for uHCC annually.

Clinical profile

Rivoceranib is a tyrosine kinase inhibitor (TKI) that works to inhibit the vascular endothelial growth factor receptor-2 (VEGFR-2). By inhibiting VEGFR-2, rivoceranib leads to the death of tumor cells and slows further cancer growth.

Camrelizumab is a monoclonal antibody that targets the programmed cell death protein 1 (PD-1) receptor. In cancer cells, the programmed cell death ligand 1 (PD-L1) protein binds to the PD-1 receptor, effectively allowing tumor cells to escape immunosurveillance. By targeting the PD-1 receptor, camrelizumab blocks this binding and allows T cells to start attacking tumor cells.

What you need to know:

Proposed Indication: First-line treatment of uHCC

Mechanism: VEGF inhibitor plus PD-1 inhibitor

Efficacy:

- Median OS: 23.8 months vs. 15.2 months with sorafenib
- Median PFS: 5.6 months vs. 3.7 months with sorafenib

Common AEs: Hypertension, palmar-plantar erythrodysesthesia syndrome, increased aspartate aminotransferase, increased alanine aminotransferase

Dosing: Oral once daily (rivoceranib) and IV once every 2 weeks (camrelizumab)

Why it Matters: Additional first-line treatment option for HCC, promising OS and PFS data, regimen includes an oral VEGF inhibitor

Important to Note: Alternative treatments available (including PD-1 inhibitor-based regimens), lack of head-to-head data vs. combination regimens (eg, Tecentriq + Avastin)

Pivotal trial data:
The efficacy of rivoceranib plus camrelizumab was evaluated in CARES-310, a randomized, open-label, controlled study in 543 patients with uHCC who had not previously received any systemic treatment. Patients were randomized to either (1) camrelizumab plus rivoceranib; or (2) sorafenib. The primary endpoints were overall survival (OS) and progression-free survival (PFS).

At the time of final analysis, median OS was 23.8 months in the camrelizumab plus rivoceranib arm vs. 15.2 months in the sorafenib arm (HR 0.64, 95% CI: 0.52, 0.79; $p < 0.0001$). Median PFS was 5.6 months vs. 3.7 months, respectively (HR 0.54, 95% CI: 0.44, 0.67; $p < 0.0001$).

Safety:
The most common adverse events with rivoceranib plus camrelizumab use were hypertension, palmar-plantar erythrodysesthesia syndrome, increased aspartate aminotransferase, and increased alanine aminotransferase.

Dosing:
In the pivotal trial, rivoceranib was administered orally once daily and camrelizumab was administered intravenously (IV) every 2 weeks.

Rivoceranib plus camrelizumab *(continued...)*

Competitive environment

If approved, rivoceranib plus camrelizumab would offer an additional first-line treatment option for uHCC with promising OS and PFS data. Compared indirectly, the survival data suggests that this regimen could be a preferred first-line option for uHCC. From a dosing perspective, the regimen includes an oral component whereas most of the current combination regimens require two separate IV administered products.

Alternative drugs and regimens are available, including PD-1 inhibitor-based regimens. These alternatives, such as Tecentriq® (atezolizumab) plus Avastin® (bevacizumab), are well-established and include drugs approved across multiple cancers. While rivoceranib plus camrelizumab did demonstrate superiority vs. a first-line option (sorafenib), there is a lack of data comparing the regimen vs. other combination therapies.

Gepotidacin (Brand Name: To be determined)

Manufacturer: GSK
Expected FDA decision: March 26, 2025

Therapeutic use

Gepotidacin is under review for the treatment of female adults and adolescents with uncomplicated urinary tract infections (UTIs).

Uncomplicated UTIs are bacterial infections of the bladder in females with no structural abnormalities of their urinary tract. Approximately half of all women experience at least one UTI in their lifetime, and more than a quarter suffer from recurrent infections.

Clinical profile

Gepotidacin is a triazaacenaphthylene antibiotic that selectively interacts with two key bacterial enzymes that are responsible for bacterial replication, DNA gyrase and topoisomerase IV (type II topoisomerases).

Pivotal trial data:
The efficacy of gepotidacin was evaluated in EAGLE-2 and EAGLE-3, two Phase 3, randomized, double-blind, active-controlled studies in 3,136 women aged 12 years or older with uncomplicated UTI. Patients were randomized to gepotidacin or nitrofurantoin. The primary endpoint was therapeutic response (success or failure) at test-of-cure (ie, Day 10 to 13) in patients with nitrofurantoin-susceptible qualifying pathogens. After an interim analysis, which was prospectively agreed as a protocol amendment, both studies were stopped for efficacy. The primary analysis population included only patients who, at the time of the interim analysis data cutoff, had the opportunity to reach the test-of-cure visit or were known to not have attained therapeutic success before the test-of-cure visit.

Gepotidacin was non-inferior to nitrofurantoin in both studies and superior to nitrofurantoin in EAGLE-3. In EAGLE-2, therapeutic success was achieved in 50.6% of patients with gepotidacin vs. 47.0% of patients with nitrofurantoin (difference 4.3, 95% CI: -3.6, 12.1). In EAGLE-3, therapeutic success was achieved in 58.5% of patients with gepotidacin vs. 43.6% of patients with nitrofurantoin (difference 14.6, 95% CI: 6.4, 22.8).

What you need to know:

Proposed Indication: Treatment of female adults and adolescents with uncomplicated UTIs

Mechanism: Triazaacenaphthylene antibiotic

Efficacy: Therapeutic response:

- EAGLE-2 trial: 50.6% vs. 47.0% with nitrofurantoin (non-inferiority met but not superiority)
- EAGLE-3 trial: 58.5% vs. 43.6% with nitrofurantoin (non-inferiority and superiority met)

Common AEs: Diarrhea, nausea

Dosing: Oral twice daily

Why it Matters: First-in-class antibiotic, demonstrated non-inferiority (including superiority in one study) vs. first-line therapy

Important to Note: First-line antibiotics for uncomplicated UTI are available generically, lack of head-to-head trial data vs. other first-line agents, use likely to be reserved for patients with known resistance or contraindications to existing antibiotics

Gepotidacin *(continued…)*

Safety:
The most common adverse events with gepotidacin use were diarrhea and nausea.

Dosing:
In the pivotal trials, gepotidacin was administered orally twice daily for 5 days.

Competitive environment

If approved, gepotidacin would provide a novel mechanism of action for the treatment of uncomplicated UTI. The current standard of care for treatment of uncomplicated UTIs includes different antibiotics across various mechanisms of action, including nitrofurantoin, trimethoprim–sulfamethoxazole, fosfomycin, β-lactams (eg, amoxicillin), and quinolones (eg, ciprofloxacin). Antibiotic resistance is increasing in the U.S. and the resistance rate is estimated to be over 20% for some drugs/classes.

In clinical trials, gepotidacin was well tolerated and demonstrated non-inferiority (including superiority in one study) when compared to nitrofurantoin. However, all the treatment options listed above for uncomplicated UTI are well established and have generic alternatives available. Gepotidacin was not compared against any other first line agent besides nitrofurantoin.

In addition to existing treatment options, gepotidacin will potentially be competing with Utility Therapeutics' Pivya™ (pivmecillinam), a β-lactam antibiotic that has been used outside of the U.S. for uncomplicated UTI. Pivya was approved in April 2024 and is expected to launch sometime in 2025. Additionally, the FDA approved Iterum Therapeutics' oral carbapenem, Orlynvah™ (sulopenem etzadroxil/probenecid), on October 25, 2024, for adult women with uncomplicated UTI who have limited or no alternative oral antibacterial treatment options.

Fitusiran (Brand Name: To be determined)

Manufacturer: Sanofi
Regulatory designations: Orphan Drug, Breakthrough Therapy, Fast Track
Expected FDA decision: March 28, 2025

Therapeutic use

Fitusiran is under review for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and adolescents with hemophilia A or hemophilia B with or without inhibitors.

Hemophilia is a genetic bleeding disorder in which the blood does not clot properly due to a clotting factor deficiency. People with hemophilia A or B have low levels of either factor VIII (FVIII) or factor IX (FIX), respectively. Hemophilia can lead to spontaneous bleeding as well as excessive bleeding following injuries or surgery. Additionally, bleeding within the joints can lead to chronic joint disease and pain.

As many as 33,000 males are estimated to be living with hemophilia in the U.S., with hemophilia A accounting for most cases.

A common treatment approach for hemophilia is factor replacement therapy, which replaces missing clotting factors. However, about 1 in 5 people with hemophilia A and about 3 in 100 people with hemophilia B will develop an inhibitor (or antibody) to factor replacement therapy. Patients with inhibitors typically require higher doses of factor for treatment, are twice as likely to be hospitalized for a bleeding complication, and they are at increased risk of death.

What you need to know:

Proposed Indication: Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and adolescents with hemophilia A or hemophilia B with or without inhibitors

Mechanism: siRNA therapeutic targeting antithrombin

Efficacy: Annualized bleeding rate:

- ATLAS-PPX trial: 0.0 vs. 4.4 to 6.5 with routine prophylaxis (during run-in period)
- ATLAS-A/B trial: 0.0 vs. 21.8 with on-demand standard of care
- ATLAS-INH trial: 1.7 vs. 18.1 with on-demand standard of care

Common AEs: Increased alanine aminotransferase

Dosing: SC once monthly

Why it Matters: Novel mechanism of action, promising data in patients with inhibitors, self-administered SC administration

Important to Note: Alternatives are available including SC administered Hemlibra and recently approved Hympavzi, potential future competition (eg, Novo Nordisk's concizumab), safety concern for increased risk of thromboembolic events

Estimated Cost: ~$795,000 per year (based on pricing for Hympavzi)

Clinical profile

Fitusiran is a small interference RNA (siRNA) therapeutic that is designed to lower antithrombin, a protein that inhibits blood clotting, with the goal of promoting thrombin generation to rebalance hemostasis and prevent bleeds.

Pivotal trial data:
The efficacy of fitusiran was evaluated across three Phase 3 trials (ATLAS-PPX, ATLAS-A/B, and ATLAS-INH) in patients 12 years and older with hemophilia A or B.

ATLAS-PPX was an open-label study in patients with or without inhibitors, who received prior bypassing agent (BPA)/clotting factor concentrate (CFC) prophylaxis. Patients continued their prior BPA/CFC prophylaxis for 6 months before switching to fitusiran prophylaxis for 7 months (onset and efficacy periods). The primary endpoint was the annualized bleeding rate (ABR) in the BPA/CFC prophylaxis and fitusiran efficacy period. In the 65 patients eligible for ABR analysis, the observed median ABRs were 6.5 and 4.4 with BPA and CFC prophylaxis, respectively vs. 0.0 in the corresponding fitusiran efficacy period. Estimated mean ABRs were reduced with fitusiran by 79.7% (p = 0.0021) and 46.4% (p = 0.0598) vs. BPA and CFC prophylaxis, respectively.

Fitusiran *(continued...)*

ATLAS-A/B was a randomized, open-label study in 120 patients without inhibitors who had previously been treated with on-demand clotting factor concentrates. Patients were randomized to fitusiran prophylaxis or on-demand clotting factor concentrates for a total of 9 months. The primary endpoint was the ABR. The median ABR was 0.0 in the fitusiran group vs. 21.8 in the on-demand clotting factor concentrates group. The estimated mean ABR reduction with fitusiran prophylaxis vs. on-demand clotting factor was 89.9% (95% CI: 84.1, 93.6; $p < 0.0001$).

ATLAS-INH was a randomized, open-label study in 54 patients with inhibitors previously treated with on-demand BPA. Patients were randomized to fitusiran prophylaxis or to continue with BPA on-demand therapy for 9 months. The primary endpoint was the ABR. The mean ABR was significantly lower in the fitusiran prophylaxis group (1.7) than in the BPA on-demand group (18.1), corresponding to a 90.8% (95% CI: 80.8, 95.6; $p < 0.0001$) reduction.

Safety:
The most common adverse event with fitusiran use was increased alanine aminotransferase.

Dosing:
In the pivotal trials, fitusiran was administered SC once monthly.

Competitive environment

If approved, fitusiran would offer a first-in-class, SC administered treatment option for the treatment of both hemophilia A and B. The current standard of care includes intravenously (IV) administered factor therapies, which can be used for both hemophilia A and B, and Genentech's Hemlibra® (emicizumab), a SC administered factor IXa- and factor X-directed antibody, which is used to treat hemophilia A. In October 2024, the FDA approved Hympavzi™ (marstacimab-hncq), for patients with hemophilia A or B without inhibitors. Like Hemlibra and fitusiran, Hympavzi is a non-factor-based therapy and a first-in-class tissue factor pathway inhibitor (TFPI) antagonist. Fitusiran will be competing with Hemlibra and Hympavzi as a self-administered SC injectable. Fitusiran is dosed once a month, Hemlibra can be dosed up to once a month, and Hympavzi is dosed once weekly.

The efficacy data for fitusiran are promising, particularly in hemophilia B patients with inhibitors – a subgroup of patients with limited options. The improvements in ABRs across both hemophilia A and B and in patients with or without inhibitors were substantial relative to factor replacement therapy.

The key limitation with fitusiran use is that the pivotal trials signaled an increased risk of thromboembolic events. The trials evaluated fitusiran 80 mg once monthly. Sanofi proposed a revised dosing regimen for all ongoing trials, starting at 50 mg once every 2 months to address the risk of thromboembolic events. However, the overwhelming efficacy and safety data available for fitusiran are based on the 80 mg dose once monthly dose.

Finally, another non-factor replacement therapy, Novo Nordisk's anti-TFPI, concizumab, is also under FDA review for both hemophilia A and B and could be approved by the end of the first quarter 2025.

For reference, the WAC for Hympavzi is approximately $795,000 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
2024 Possible launch date									
CSL-312	garadacimab	CSL Limited	anti-factor XIIa monoclonal antibody	Hereditary angioedema	SC	Filed BLA	12/14/2024	Yes	Yes
IONIS-APOCIII-LRx (ISIS-678354)	olezarsen	Ionis	antisense drug	Familial chylomicronemia syndrome	SC	Filed BLA	12/19/2024	Yes	Yes
DS-1062	datopotamab deruxtecan	Daiichi Sankyo/ AstraZeneca	trop-2 antibody-drug conjugate	Breast cancer/ non-small cell lung cancer	IV	Filed BLA	12/20/2024	Yes	No
Rybrevant SC	amivantamab-vmjw/ hyaluronidase	Johnson & Johnson	bispecific EGF receptor-directed and MET receptor-directed antibody	Non-small cell lung cancer	SC	Filed BLA	12/20/2024	Yes	No
ZP-1848	glepaglutide	Zealand Pharma	glucagon peptide-2 agonist	Short bowel syndrome	SC	Filed NDA	12/22/2024	Yes	Yes
DCCR	diazoxide choline controlled-release	Soleno Therapeutics	vasodilator	Prader-Willi syndrome	PO	Filed NDA	12/27/2024	Yes	Yes
X-396	ensartinib	Xcovery	anaplastic lymphoma kinase inhibitor	Non-small cell lung cancer	PO	Filed NDA	12/28/2024	Yes	No

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
CK-301	cosibelimab	Checkpoint Therapeutic	anti programmed cell death ligand 1	Cutaneous squamous cell carcinoma	IV	Filed NDA	12/28/2024	Yes	No
NBI-74788	crinecerfont	Neurocrine Biosciences	corticotropin-releasing factor type 1 receptor antagonist	Congenital adrenal hyperplasia	PO	Filed NDA	12/29/2024	Yes	Yes
Opdivo SC	nivolumab/ hyaluronidase	Bristol Myers Squibb	programmed death receptor-1-blocking antibody	Various cancers	SC	Filed BLA	12/29/2024	Yes	No
Humacyl	human acellular vessel	Humacyte	cellular therapy	End-stage renal disease	Implant	Filed BLA	Late 2024	Yes	No
2025 Possible launch date									
VX-121/ tezacaftor/ deutivacaftor	vanzacaftor/ tezacaftor/ deutivacaftor	Vertex	CF transmembrane conductance modulators	Cystic fibrosis	PO	Filed NDA	01/02/2025	Yes	Yes
Subvenite	lamotrigine	OWP Pharmaceuticals	anticonvulsant	Epilepsy/ bipolar disorder	PO	Filed NDA	01/03/2025	No	No
Prochymal	remestemcel-L	Mesoblast	mesenchymal stem cells	Graft vs. host disease	IV	Filed BLA	01/08/2025	Yes	Yes
EBV-CTL (ATA-129)	tabelecleucel	Atara Biotherapeutics	cell therapy	Lymphoproliferative disorder	IV	Filed BLA	01/15/2025	Yes	Yes
MTP-131 (SS-31)	elamipretide	Stealth Biotherapeutics	mitochondrial permeability transition pore inhibitor	Barth syndrome	SC	Filed NDA	01/29/2025	Yes	Yes

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
Ovastat	treosulfan	Medexus Pharmaceuticals	alkylating agent	Hematopoietic stem cell transplantation	IV	Filed NDA	01/30/2025	Yes	Yes
VX-548	suzetrigine	Vertex	selective NaV1.8 inhibitor	Acute pain	PO	Filed NDA	01/30/2025	No	No
AXS-07	meloxicam/rizatriptan	Axsome Therapeutics	non-steroidal anti-inflammatory drug/triptan	Migraine	PO	Filed NDA	01/31/2025	No	No
Translarna	ataluren	PTC Therapeutics	gene transcription modulator	Duchenne muscular dystrophy	PO	Filed NDA	01/2025	Yes	Yes
NN-7415	concizumab	Novo Nordisk	anti-tissue factor pathway inhibitor	Hemophilia A and B	SC	Filed BLA	01/2025	Yes	Yes
SPN-830	apomorphine	Supernus Pharmaceuticals	non-ergoline dopamine agonist	Parkinson's disease	SC infusion	Filed NDA	02/01/2025	Yes	No
PB-2452	bentracimab	SFJ Pharmaceuticals	antiplatelet monoclonal antibody	Antiplatelet drug toxicity	IV	Filed BLA	02/02/2025	No	No
MCLA-128	zenocutuzumab	Merus	neuregulin/HER3 inhibitor	Non-smell cell lung cancer/ pancreatic cancer	IV	Filed BLA	02/04/2025	Yes	Yes
MenABCWY	meningococcal vaccine	GSK	vaccine	Meningococcal disease	IM	Filed BLA	02/14/2025	No	No
DCC-3014	vimseltinib	Deciphera	CSF1R inhibitor	Tenosynovial giant cell tumor	PO	Filed NDA	02/17/2025	Yes	No

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
PD-0325901	mirdametinib	SpringWorks Therapeutics	MEK 1/2 inhibitor	Neurofibromatosis	PO	Filed NDA	02/28/2025	Yes	Yes
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	TBD	No
ALN-APC (ALN-AT3)	fitusiran	Sanofi	RNAi therapeutic	Hemophilia A and B	SC	Filed BLA	03/28/2025	Yes	Yes
PDP-716	brimonidine	Visiox Pharma	alpha-2 agonist	Glaucoma	OPH	Not Approved	1Q2025	No	No
NS-2 (ALDX-1E1, ADX-102)	reproxalap	Aldeyra Therapeutics	aldehyde antagonist	Dry eye disease	OPH	Filed NDA	04/02/2025	No	No

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
UGN-102	mitomycin	UroGen	alkylating drug	Bladder cancer	Intravesical	Filed NDA	04/15/2025	Yes	No
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
AEB-1102	pegzilarginase	Aeglea BioTherapeutics	enzyme replacement/ arginase-I stimulator	Arginase 1 deficiency	IV	Filed BLA	05/05/2025	Yes	Yes
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
AR-15512	AR-15512	Aerie Pharmaceuticals	TRPM8 agonist	Dry eye disease	OPH	Filed NDA	05/30/2025	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
KVD-900	sebetralstat	KalVista Pharmaceuticals	plasma kallikrein inhibitor	Hereditary angioedema	PO	Filed NDA	06/17/2025	Yes	Yes

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
Xinlay	atrasentan	Novartis	selective endothelin-A receptor antagonist	IgA nephropathy	PO	Filed NDA	06/2025	Yes	No
chenodeoxycholic acid	chenodeoxycholic acid	Mirum Pharmaceuticals	farnesoid X receptor agonist	Cerebrotendinous xanthomatosis	PO	Filed NDA	06/28/2025	Yes	Yes
Leqembi SC	lecanemab	Eisai/Biogen	beta-amyloid targeted therapy	Alzheimer's disease	SC	Filed BLA	2Q2025	Yes	No
VS-6766	avutometinib	Verastem	RAF/MEK clamp	Ovarian cancer	PO	Filed NDA	06/30/2025	Yes	No
S-217622	ensitrelvir fumaric acid	Shionogi	Protease inhibitor	COVID-19 treatment	PO	InTrial	1H2025	No	No
SDN-037	difluprednate	Visiox	corticosteroid	Ocular inflammation/pain	OPH	InTrial	Mid-2025	No	No
INS-1007	brensocatib	Insmed	dipeptidyl peptidase 1 inhibitor	Bronchiectasis	PO	InTrial	Mid-2025	No	No
GZ-402671 (SAR-402671)	venglustat (ibiglustat)	Sanofi	glucosylceramide synthase inhibitor	M2 Gangliosidosis	PO	InTrial	Mid-2025	Yes	Yes
RP-L102 (RPL-102)	RP-L102	Rocket Pharmaceuticals	gene therapy	Fanconi anemia	IV	InTrial	Mid-2025	Yes	Yes
K-127	pyridostigmine	Amneal	cholinesterase inhibitor	Myasthenia gravis	PO	InTrial	Mid-2025	No	No
ADI-PEG20	pegargiminase	Polaris	pegylated arginine deiminase	Mesothelioma	IM	InTrial	Mid-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
PRN-1008	rilzabrutinib	Sanofi	BTK inhibitor	Chronic immune thrombocytopenia	PO	InTrial	Mid-2025	No	Yes
SEL-212	SVP-rapamycin/ pegsiticase	Selecta Biosciences/ 3SBio	synthetic vaccine particle/ enzyme combination	Gout	IV	InTrial	Mid-2025	Yes	No
CK-274	aficamten	Cytokinetics	cardiac myosin inhibitor	Obstructive hypertrophic cardiomyopathy	PO	Filed NDA	Mid-2025	Yes	Yes
RP-L201	marnetegragene autotemcel	Rocket Pharmaceuticals	gene therapy	Leukocyte adhesion deficiency-I	IV	CRL	Mid-2025	Yes	Yes
RGX-121	RGX-121	Regenxbio	gene therapy	Mucopolysaccharidosis Type II	Intracisternal	InTrial	Mid-2025	Yes	Yes
CAM-2029	octreotide	Camurus	somatostatin analogue	Acromegaly	SC	CRL	Mid-2025	Yes	Yes
PRGN-2012	PRGN-2012	Precigen	immunotherapy	Respiratory papillomatosis	SC	InTrial	Mid-2025	Yes	Yes
Keytruda SC	pembrolizumab	Merck	programmed death receptor-1-blocking antibody	Various cancers	SC	InTrial	Mid-2025	Yes	No
DZD-9008	sunvozertinib	Dizal	EGFR inhibitor	Non-small cell lung cancer	PO	Filed NDA	07/08/2025	Yes	No
ARO-APOC3	plozasiran	Arrowhead Pharmaceuticals	RNAi targeting apolipoprotein C-III	Familial chylomicronemia syndrome	SC	Filed BLA	07/18/2025	Yes	Yes

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
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
mRNA-1283	COVID-19 vaccine, mRNA	Moderna	messanger RNA	COVID-19 prevention	IM	InTrial	2025	No	No
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
IONIS-PKK-LRx (ISIS-721744)	donidalorsen	Ionis	antisense drug	Hereditary angioedema	SC	Filed NDA	08/21/2025	Yes	Yes
SPI-014	lanthanum dioxycarbonate	Unicycive	phosphate binder	Hyperphosphatemia	PO	Filed NDA	09/03/2025	No	No
CRN-00808	paltusotine	Crinetics Pharmaceuticals	somatostatin receptor 2 agonist	Acromegaly	PO	Filed NDA	09/26/2025	Yes	Yes
PTC-743	vatiquinone	PTC Therapeutics	undisclosed	Friedreich's ataxia	PO	InTrial	3Q2025	Yes	Yes
ONS-5010	bevacizumab-vikg	Outlook Therapeutics	anti-VEGF antibody	Wet age-related macular degeneration	Intravitreal	CRL	3Q2025	Yes	No
BHV-4157	troriluzole	Biohaven	glutamate modulator	Spinocerebellar ataxia	PO	InTrial	3Q2025	Yes	Yes

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
CAP-1002	deramiocel	Capricor Therapeutics	cellular therapy	Duchenne muscular dystrophy	IV	InTrial	3Q2025	Yes	Yes
MT-1621	deoxythymidine/ deoxycytidine	UCB	deoxynucleoside	Thymidine kinase 2 deficiency	PO	InTrial	3Q2025	Yes	Yes
UX-111 (ABO-102)	UX-111	Ultragenyx Pharmaceutical	gene therapy	Sanfilippo syndrome type A	IV	InTrial	3Q2025	Yes	Yes
RP-1	vusolimogene oderparepvec	Replimune	oncolytic immunotherapy	Cutaneous skin cell cancer	Intratumoral	InTrial	3Q2025	Yes	No
VS-6063	defactinib	Verastem	focal adhesion kinase inhibitor	Ovarian cancer	PO	InTrial	3Q2025	Yes	Yes
NP-001	sodium chlorite	Neuvivo	neuroprotective agent	Amyotrophic lateral sclerosis	IV	Filed NDA	10/07/2025	Yes	Yes
Tonmya	cyclobenzaprine	Tonix	muscle relaxant	Fibromyalgia	PO	Filed NDA	10/16/2025	No	No
SRK-015	apitegromab	Scholar Rock	myostatin activation inhibitor	Spinal muscular atrophy	IV	InTrial	4Q2025	Yes	Yes
SAR-442168	tolebrutinib	Sanofi	Bruton's tyrosine kinase inhibitor	Multiple sclerosis	PO	InTrial	4Q2025	Yes	No
GSK-3511294	depemokimab	GlaxoSmithKline	interleukin-5 antagonist	Eosinophilic asthma	SC	InTrial	4Q2025	Yes	No

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
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
PAX-101	suramin	PaxMedica	unknown	trypanosomiasis	IV	InTrial	2H2025	No	No
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
CORT-125134	relacorilant	Corcept Therapeutics	glucocorticoid receptor II antagonist	Cushing's syndrome	PO	InTrial	2H2025	Yes	Yes
AXS-12	reboxetine	Axsome Therapeutics	norepinephrine reuptake inhibitor	Narcolepsy	PO	InTrial	2H2025	Yes	Yes
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

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
PF-06939926	fordadistrogene movaparvovec	Pfizer	gene therapy	Duchenne muscular dystrophy	IV	InTrial	2H2025	Yes	Yes
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
RPC-4046 (ABT-308)	cendakimab	Bristol Myers Squibb	interleukin-13 inhibitor	Eosinophilic esophagitis	SC	InTrial	2H2025	Yes	Yes
Revascor (NeoFuse, Replicart, MPC-150-IM, MPC-25, MPC-150, MPC-300, CEP-41750)	rexlemestrocel-L	Mesoblast	allogeneic autologous mesenchymal precursor cell	Heart failure	IV	InTrial	2H2025	Yes	Yes
LOU-064	remibrutinib	Novartis	Bruton's tyrosine kinase inhibitor	Chronic spontaneous urticaria	PO	InTrial	2H2025	Yes	No
GSK-2330672	linerixibat	GlaxoSmithKline	ileal bile acid transfer inhibitor	Primary biliary cholangitis	PO	InTrial	2H2025	Yes	Yes
TAK-935	soticlestat	Takeda	cholesterol 24-hydroxylase inhibitor	Lennox-Gastaut syndrome/ Dravet syndrome	PO	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
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
LIB-003	lerodalcibep	LIB Therapeutics	PCSK9 inhibitor	Hypocholesteremia	SC	InTrial	2H2025	No	No
ANB-019	imsidolimab	AnaptysBio	interleukin-36 receptor antagonist	Generalized pustular psoriasis	IV	InTrial	2H2025	Yes	Yes
CT-041	CT-041	CARsgen Therapeutics	chimeric antigen receptor T cell therapy	Gastric cancer	IV	InTrial	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
HLX-10	serplulimab	Henlius	anti-PD-1	Small cell lung cancer	IV	InTrial	2H2025	Yes	Yes
AB-106	taletrectinib	Nuvation Bio	ROS1/NTRK tyrosine kinase inhibitor	Non-small cell lung cancer	PO	InTrial	2H2025	Yes	Yes
BNT161+BNT162b2	influenza and COVID-19 vaccine	Pfizer/BioNTech	mRNA	Prevention of influenza and COVID-19 infection	IM	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
LAI-287	insulin icodec	Novo Nordisk	ultra-long-acting basal insulin	Diabetes mellitus	SC	CRL	2025	No	No
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
OMS-721	narsoplimab	Omeros	anti-MASP-2 monoclonal antibody	Hematopoietic stem cell transplant-associated thrombotic microangiopathy	IV	CRL	2025	Yes	Yes
MOR-202	felzartamab	I-Mab	anti-CD38 monoclonal antibody	Multiple myeloma	IV	InTrial	2025	Yes	No
REGN-5458	linvoseltamab	Regeneron	BCMA and CD3 bispecific antibody inhibitor	Multiple myeloma	IV	CRL	2025	Yes	No
Mino-Lok	minocycline-EDTA-ETOH	Citrus	tetracyclines	Bacterial infection	Intracatheter	InTrial	2025	No	No
Dasynoc	dasatinib	Xspray Pharma	kinase inhibitor	Chronic myeloid leukemia	PO	CRL	2025	Yes	Yes
CUTX-101	copper histidinate	Fortress Biotech	copper replacement	Menkes Disease	SC	InTrial	2025	Yes	Yes
F-901318	olorofim	F2G	orotomide antifungal	Aspergillosis	PO/IV	CRL	2025	No	Yes

Pipeline Drug Name(s)	Generic Name	Company	Mechanism of Action	Disease State	Route	FDA Status	Projected Launch Date	Specialty	Orphan Drug Status
Dihydroergotamine autoinjector	dihydroergotamine	Amneal Pharmaceuticals	ergot derivative	Migraine	SC	InTrial	2025	No	No
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-1083	influenza and COVID-19 vaccine	Moderna	mRNA	Prevention of influenza and COVID-19	IM	InTrial	2025	No	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
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
SB-525	giroctocogene fitelparvovec	Pfizer/ Sangamo Therapeutics	gene therapy	Hemophilia A	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
ANX-005	ANX-005	Annexon	C1q inhibitor	Guillain-Barré syndrome	IV	InTrial	Late 2025	Yes	Yes
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
DNL-310	tividenofusp alfa	Denali	enzyme replacement therapy	Mucopolysaccharidosis II (Hunter Syndrome)	IV	InTrial	Late 2025	Yes	Yes
FE-203799	apraglutide	Ironwood	glucagon-like peptide-2 analog	Short bowel syndrome	SC	InTrial	Late 2025	Yes	Yes
TAR-200	gemcitabine	J&J	nucleoside metabolic inhibitor	Bladder cancer	Intravesical	InTrial	Late 2025	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	Projected Approval Date
2024 Possible launch date							
Nemluvio	nemolizumab-ilto	Galderma	interleukin-31 receptor antagonist	New	Treatment of moderate-to-severe atopic dermatitis	SC	12/12/2024
Vtama	tapinarof	Dermavant Sciences	aryl hydrocarbon receptor agonist	New	Treatment of moderate-to-severe atopic dermatitis in patients 2 years of age and older	TOP	12/14/2024
Imfinzi	durvalumab	AstraZeneca	programmed death-ligand 1 blocking antibody	New	Treatment of patients with limited-stage small cell lung cancer whose disease has not progressed following platinum-based concurrent chemoradiotherapy	IV	12/15/2024
Inpefa	sotagliflozin	Lexicon Pharmaceuticals	sodium-glucose cotransporter 2 inhibitor	New	As an adjunct to insulin therapy for glycemic control in patients with type 1 diabetes and chronic kidney disease	PO	12/20/2024
Imcivree	setmelanotide	Rhythm Pharmaceuticals	melanocortin 4 receptor agonist	Revised	Chronic weight management in adult and pediatric patients 2 years of age and older with monogenic or syndromic obesity due to: (1) Pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are	SC	12/26/2024

Brand Name	Generic Name	Company	Mechanism of Action	Indication Type	Proposed New/Revised/Removed Indication	Route	Projected Approval Date
					interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS); or (2) Bardet-Biedl syndrome		
Tevimbra	tislelizumab	BeiGene	programmed death receptor-1–blocking antibody	New	In combination with fluoropyrimidine- and platinum-containing chemotherapy, for the treatment of patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma	IV	12/2024
Enhertu	fam-trastuzumab deruxtecan-nxki	AstraZeneca/ Daiichi Sankyo	HER2-directed antibody and topoisomerase inhibitor conjugate	Revised	Third-line treatment of advanced/refractory, metastatic HER2+ breast cancer	IV	2H2024
Zepbound	tirzepatide	Eli Lilly	glucose-dependent insulinotropic polypeptide receptor and glucagon-like peptide-1 receptor agonist	New	Treatment of moderate-to-severe obstructive sleep apnea in adult patients with obesity	SC	Late 2024
2025 Possible launch date							
Gemtesa	vibegron	Sumitomo Pharma America	beta-3 adrenergic receptor agonist	Revised	Treatment of men with overactive bladder symptoms receiving pharmacological therapy for benign prostatic hyperplasia	PO	01/13/2025
Ozempic	semaglutide	Novo Nordisk	glucagon-like peptide-1 receptor agonist	New	Prevention of progression of kidney impairment and risk of kidney and cardiovascular mortality in patients with type 2 diabetes and chronic kidney disease	SC	01/2025
Enhertu	fam-trastuzumab deruxtecan-nxki	AstraZeneca/ Daiichi Sankyo	HER2-directed antibody and topoisomerase inhibitor conjugate	Revised	Treatment of adult patients with unresectable or metastatic HER2 low (IHC 1+ or IHC 2+/ISH-) or HER2 ultralow (IHC 0 with membrane staining) breast cancer who have	IV	02/01/2025

Brand Name	Generic Name	Company	Mechanism of Action	Indication Type	Proposed New/Revised/Removed Indication	Route	Projected Approval Date
					received at least one endocrine therapy in the metastatic setting		
Calquence	acalabrutinib	AstraZeneca	Bruton's tyrosine kinase inhibitor	Revised	Treatment of adult patients with previously untreated mantle cell lymphoma	PO	02/03/2025
Rexulti	brexpiprazole	Otsuka/ Lundbeck	atypical antipsychotic	New	In combination with sertraline for the treatment of post-traumatic stress disorder in adults	PO	02/08/2025
Furoscix	furosemide	scPharmaceuticals	diuretic	Revised	Treatment of edema due to fluid overload in patients with chronic kidney disease	SC	03/06/2025
Adcetris	brentuximab vedotin	Pfizer	CD30-directed antibody-drug conjugate	Revised	In combination with lenalidomide and rituximab for patients with relapsed/refractory large B-cell lymphoma	IV	03/2025
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	03/30/2025
Omvoh	mirikizumab-mrkz	Eli Lilly	interleukin-23 antagonist	New	Treatment of adults with moderately to severely active Crohn's disease	IV/SC	1Q2025
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,	PO	04/03/2025

Brand Name	Generic Name	Company	Mechanism of Action	Indication Type	Proposed New/Revised/Removed Indication	Route	Projected Approval Date
					well- or moderately differentiated extra-pancreatic NET (epNET)		
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	04/04/2025
Amvuttra	vutrisiran	Alnylam Pharmaceuticals	transthyretin-directed small interfering RNA	New	Treatment of transthyretin amyloid cardiomyopathy	SC	04/09/2025
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	04/18/2025
Tremfya	guselkumab	Janssen	interleukin-23 inhibitor	New	Treatment of adults with moderately to severely active Crohn's disease	IV/SC	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	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	04/21/2025
Darzalex Faspro	daratumumab/ hyaluronidase-fihj	J&J	humanized anti-CD38 monoclonal antibody	New	Treatment of adult patients with high-risk smouldering multiple myeloma	SC	05/08/2025

Brand Name	Generic Name	Company	Mechanism of Action	Indication Type	Proposed New/Revised/Removed Indication	Route	Projected Approval Date
Rinvoq	upadacitinib	AbbVie	janus kinase inhibitor	New	Treatment of adult patients with giant cell arteritis	PO	05/12/2025
Susvimo	ranibizumab	Roche	vascular endothelial growth factor inhibitor	New	Treatment of diabetic macular edema and diabetic retinopathy	Intravitreal	05/18/2025
Spravato	esketamine	J&J	NMDA receptor antagonist	Revised	Monotherapy for adults living with treatment-resistant depression	Intranasal	05/22/2025
Zoryve	roflumilast	Arcutis Biotherapeutics	phosphodiesterase 4 inhibitor	New	Treatment of adults and adolescents ages 12 and over with scalp and body psoriasis	TOP	05/22/2025
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	05/23/2025
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	07/09/2025
Nubeqa	darolutamide	Bayer	androgen receptor inhibitor	Revised	In combination with androgen deprivation therapy in patients with metastatic hormone-sensitive prostate cancer	PO	07/26/2025
Skytrofa	lonapegsomatropin-tcgd	Ascendis Pharma	growth hormone	Revised	Treatment of adults with growth hormone deficiency	SC	07/30/2025
Opzelura	ruxolitinib	Incyte	Janus kinase inhibitor	Revised	Treatment of pediatric atopic dermatitis	TOP	3Q2025

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
2024 Possible launch date					
NYMALIZE	nimodipine	Arbor	Subarachnoid Hemorrhage	Oral	2H-2024
HUMALOG	insulin lispro	Eli Lilly	Type 1 and 2 Diabetes Mellitus	Subcutaneous	4Q-2024
ISENTRESS	raltegravir	Merck	Human Immunodeficiency Virus-1 Infection	Oral	4Q-2024
NOVOLOG	insulin aspart	Novo Nordisk	Type 1 and 2 Diabetes Mellitus	Subcutaneous	4Q-2024
GIAZO	balsalazide disodium	Bausch Health	Ulcerative Colitis in Male Patients	Oral	4Q-2024
QSYMIA	phentermine/topiramate	Vivus	Chronic Weight Management	Oral	12-2024
2025 Possible launch date					
JYNARQUE	tolvaptan	Otsuka	Polycystic Kidney Disease	Oral	2025
SIMPONI	golimumab	Janssen	Ankylosing Spondylitis; Psoriatic Arthritis; Rheumatoid Arthritis; Ulcerative Colitis	Subcutaneous	2025
SIMPONI ARIA	golimumab	Janssen	Rheumatoid Arthritis; Psoriatic Arthritis; Ankylosing Spondylitis; Juvenile Idiopathic Arthritis	Intravenous	2025
BOSULIF	bosutinib	Pfizer	Chronic Myelogenous Leukemia	Oral	2025
PROMACTA	eltrombopag	Novartis	Thrombocytopenia	Oral	2025
COMPLERA	emtricitabine/rilpivirine/tenofovir disoproxil fumarate	Gilead/Janssen	Human Immunodeficiency Virus-1 Infection	Oral	2025
TYSABRI	natalizumab	Biogen	Multiple Sclerosis; Crohn's Disease	Intravenous	2025
OZOBAX	baclofen	Metacel	Spasticity from Multiple Sclerosis	Oral	1H-2025
NAMZARIC	memantine/donepezil	AbbVie	Moderate to Severe Dementia of the Alzheimer's Type	Oral	01-2025
TRACLEER	bosentan	Actelion/Janssen	Pulmonary Arterial Hypertension	Oral	01-2025

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
LEXETTE	halobetasol	Mayne	Plaque Psoriasis	External	01-2025
IZBA	travoprost	Alcon	Open-Angle Glaucoma; Ocular Hypertension	Ophthalmic	01-2025
STELARA	ustekinumab	Janssen	Plaque Psoriasis; Psoriatic Arthritis; Ulcerative Colitis; Crohn's Disease	Subcutaneous; intravenous	01-2025
NATAZIA	estradiol valerate/dienogest	Bayer	Prevention of Pregnancy; Menorrhagia	Oral	01-2025
PHOSLYRA	calcium acetate	Fresenius	Phosphate Binder	Oral	01-2025
FINACEA	azelaic acid	LEO Pharma	Rosacea	External	01-2025
SANCUSO	granisetron	Kyowa Hakko Kirin/ProStrakan	Prevention of Nausea and Vomiting in Patients Receiving Moderately and/or Highly Emetogenic Chemotherapy	External	01-2025
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	Paroxsymal 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
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

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
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
ZTLIDO	lidocaine	Sorrento	Pain Associated with Post-Herpetic Neuralgia	External	2H-2025
PERJETA	pertuzumab	Genentech	HER-2 Positive Breast Cancer	Intravenous	2H-2025
VUITY	pilocarpine	AbbVie	Presbyopia	Ophthalmic	2H-2025
ENTRESTO	sacubitril/valsartan	Novartis	Heart Failure	Oral	3Q-2025
CARDENE IV	nicardipine	Chiesi	Short-Term Treatment of Hypertension When Oral Therapy is Not Possible	Intravenous	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
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					
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

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
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
QBRELIS	lisinopril	Silvergate	Hypertension; Heart Failure; Acute Myocardial Infarction	Oral	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

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
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
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
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; Familial Mediterranean Fever; Still's Disease; Gout Flares	Subcutaneous	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					
KYPROLIS	carfilzomib	Amgen	Multiple Myeloma	Intravenous	2027
CIMZIA	certolizumab pegol	UCB/Royalty Pharma	Psoriatic Arthritis; Rheumatoid Arthritis; Ankylosing Spondylitis; Crohn's Disease; Plaque Psoriasis; Axial Spondyloarthritis	Subcutaneous	2027
SAXENDA	liraglutide	Novo Nordisk	Chronic Weight Management	Subcutaneous	2027

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
ENTYVIO	vedolizumab	Takeda	Ulcerative Colitis; Crohn's Disease	Intravenous; subcutaneous	2027
FIRMAGON	degarelix	Ferring	Prostate Cancer	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
EXPAREL	bupivacaine	Pacira	Postsurgical Analgesia	Injection	01-2027
VIBATIV	telavancin	Cumberland	Infections	Intravenous	01-2027
SIMBRINZA	brimonidine/brinzolamide	Alcon	Reduction of Elevated Intraocular Pressure in Patients with Open-Angle Glaucoma or Ocular Hypertension	Ophthalmic	01-2027
CUBICIN RF	daptomycin	Merck	Complicated Skin and Skin Structure Infections; Staphylococcus aureus Bloodstream Infections	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

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
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
ORENITRAM	treprostinil diethanolamine	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
CREXONT	carbidopa/levodopa	Amneal Specialty	Parkinson's Disease	Oral	08-2027
PIZENSY	lactitol	Braintree/Sebela	Chronic Idiopathic Constipation	Oral	08-2027
ILUVIEN	fluocinolone acetonide	Alimera Sciences	Diabetic Macular Edema	Intravitreal	08-2027
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

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
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
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

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
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
THYQUIDITY	levothyroxine	Vistapharm	Hypothyroidism; Pituitary Thyrotropin Suppression	Oral	01-2028
WAKIX	pitolisant	Harmony Biosciences	Narcolepsy	Oral	01-2028
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
CRESEMBA	isavuconazonium	Astellas	Invasive Aspergillosis; Invasive Mucormycosis	Oral; 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

Trade Name	Generic Name	Brand Company(ies)	Indications	Route of Administration	Anticipated Availability
VYONDYS 53	golodirsen	Sarepta Therapeutics	Duchenne Muscular Dystrophy	Intravenous	06-2028

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