# VytlOne Pipeline Q3 2025

**MaxorPlus will be VytlOne on January 1, 2026**

Pipeline News | New to Market Brands and Generics | Drug Pipeline Spotlight

July 2025

# SPOTLIGHT | PIPELINE NEWS

## FDA Approves Twice-Yearly Injection for HIV Prevention

- On June 18, 2025, the FDA approved Yeztugo® (lenacapavir), an HIV-1 capsid inhibitor that is **injected twice yearly, as pre-exposure prophylaxis (PrEP)** therapy to reduce the risk of sexually acquired HIV in adults and adolescents (weighing >35kg). A negative HIV test is required before therapy is started.
- Results from the PURPOSE 2 trial demonstrated that lenacapavir was highly effective at reducing HIV infections among trial participants: 99.9% of participants did not acquire HIV in the lenacapavir twice-yearly group.
- Other PrEP therapies include generic Truvada®, Descovy®, and Apretude®, a bi-monthly injection.
- The drug is priced at $14,109 per injection or $29,218 annually.

| Pre-exposure Prophylaxis Approved Therapies | | |
|---|---|---|
| **Drug Name** | **Annual Cost** | **Administration** |
| **Emtricitabine/ tenofovir** | $250 | Once daily oral therapy |
| **Descovy** | $26,795 | Once daily oral therapy |
| **Apretude** | $24,151 | Intramuscular injection every 2 months |
| **Yeztugo** | $29,218 | Initial dose includes oral tablets on days 1 and 2 followed by subcutaneous injection every 6 months |

Source: IPD Analytics

## First Interchangeable Biosimilars to Prolia/Xgeva Launch

- On June 2, 2025, Sandoz **announced the U.S. launch** of Wyost® (denosumab-bbdz) and Jubbonti® (denusomab-bbdz), the first interchangeable biosimilars to Xgeva® and Prolia®, respectively.
- Both products are approved for the same indications and have the same dosage form, route, and dosing regimen as their respective reference products.
- Eight additional denosumab biosimilars (both branded and unbranded) have been approved by the FDA with at least three products expecting U.S. availability in late June 2025.
- Wyost launched at a 7% discount to brand Xgeva while Jubbonti launched at a 14.5% discount to brand Prolia.

## Nucala to Compete with Dupixent after COPD Indication Approval

- On May 22, 2025, Nucala® was granted FDA approval as an add-on maintenance treatment for adult patients with inadequately controlled eosinophilic chronic obstructive pulmonary disease (COPD).
- COPD is a chronic lung disease that affects over 16 million people in the United States. Eosinophilic phenotype is often linked to more exacerbations and poorer outcomes. **It is estimated that over 1 million people may fit the criteria for treatment for this indication.**
- Nucala was studied in a wider population of people (blood eosinophil count (BEC) >150 cells/uL) than Dupixent® ([BEC] >300 cells/uL). No formal guideline recommendations have been made regarding Nucala's place in therapy at the time of this publication.

# NOW APPROVED | NEW BRAND DRUGS TO MARKET

| Brand Name | Generic Name | Indication | ROA | Approval Month |
|---|---|---|---|---|
| CTEXLI™ | Chenodiol | Cerebrotendinous xanthomatosis | OR | Apr-25 |
| ENCELTO™ | Revakinagene taroretcel | Idiopathic macular 13 telangiectasia type 2 | IZ | Apr-25 |
| EPYSQLI® | Eculizumab | Eculizumab | IV | Apr-25 |
| QFITLIA® | Fitusiran | Hemophilia A or B | SC | Apr-25 |
| RYONCIL™ | Remestemcel | Graft versus host disease | IV | Apr-25 |
| SELARSDI™ | Ustekinumab | Inflammatory conditions | IV | Apr-25 |
| VYKAT™ XR | Diazoxide | Prader-Willi syndrome | OR | Apr-25 |
| AVMAPKI™ FAKZYNJA™ CO-PACK | Avutometinib & defactinib | Low-grade serous ovarian cancer | OR | May-25 |
| IMAAVY™ | Nipocalimab | Generalized myasthenia gravis | IV | May-25 |
| JUBBONTI® | Denosumab | Postmenopausal osteoporosis | SC | May-25 |
| MIUDELLA® | Copper IUD | Contraception | IU | May-25 |
| RYZNEUTA® | Efbemalenograstim alfa | Non-myeloid malignancies | SC | May-25 |
| VANRAFIA® | Atrasentan | IgA nephropathy | OR | May-25 |
| WYOST® | Denusomab | Hypercalcemia of malignancy | SC | May-25 |
| EMRELIS™ | Telisotuzumab | Non-small cell lung cancer | IV | Jun-25 |
| IBTROZI™ | Taletrectinib | Non-small cell lung cancer | OR | Jun-25 |
| LEQSELVI™ | Deuruxolitinib | Severe alopecia areata | OR | Jun-25 |
| OSENVELT® | Denosumab | Hypercalcemia of malignancy refractory to bisphosphonate therapy | SC | Jun-25 |
| STOBOCLO® | Denosumab | Bone mass in men with osteoporosis | SC | Jun-25 |
| ZELSUVMI™ | Berdazimer | Molluscum contagiosum | EX | Jun-25 |

# NOW APPROVED | NEW GENERIC DRUGS TO MARKET

| Brand Name | Generic Name | Indication | Launch Month |
|---|---|---|---|
| STENDRA® | Avanafil | Erectile dysfunction | Nov-24 |
| BETIMOL® | Timolol | Elevated intraocular pressure | Nov-24 |
| MOTEGRITY® | Prucalopride | Chronic idiopathic constipation | Jan-25 |
| XARELTO® | Rivaroxaban | Thromboembolic disorders | Mar-25 |
| AURYXIA® | Ferric citrate | Hyperphosphatemia in chronic kidney disease | Mar-25 |
| ANORO ELLIPTA® | Umeclidinium-vilanterol | Chronic obstructive pulmonary disease | Apr-25 |
| APTIOM® | Eslicarbazepine | Partial-onset seizures | May-25 |
| BRILINTA® | Ticagrelor | Reduce the rate of cardiovascular death | May-25 |
| JYNARQUE® | Tolvaptan | Autosomal dominant polycystic kidney disease | May-25 |
| PROMACTA® | Eltrombopag | Thrombocytopenia | May-25 |
| QSYMIA® | Phentermine-topiramate | Obesity | May-25 |
| COMPLERA® | Emtricitabine-rilpivir-ine-tenofovir | HIV-1 | May-25 |
| FYCOMPA® | Perampanel | Seizures | May-25 |
| TASIGNA® | Nilotinib | Chronic myeloid leukemia | Jun-25 |

The report provided is for informational purposes only. This information should not be solely relied upon for formulary decision-making purposes and is subject to change. www.vytlone.com
Abbreviation: ROA- Route of Administration; EX-External; IJ-Injection; IM-Intramuscular; IV-Intravenous; OR-Oral; SC-Subcutaneous; IZ-Intravitreal; IO- Intraocular; IN-Intranasal

# CLINICAL PIPELINE

### Non-cystic Fibrosis Bronchiectasis

Brensocatib *[AstraZeneca/Insmed]*

- Non-cystic fibrosis bronchiectasis (NCFB) is a chronic lung condition where the airways become widened and damaged.
- NCFB, once considered an orphan disease, is more prevalent worldwide due to greater availability of diagnostic imaging. There are an estimated 500,000 people diagnosed with NCFB in the U.S.
- If approved, brensocatib would be the first FDA-approved therapy for NCFB. The drug would be limited distribution with VytlOne Specialty Pharmacy being one of three network pharmacies.
- Insmed has indicated pricing would be between $40,000 and $96,000 annually.
- Regulatory decision expected by August 12, 2025.

### Alzheimer's Disease

Leqembi SC *[Eisai/Biogen]*

- Leqembi® is currently approved for the treatment of adult patients with Alzheimer's disease and is available as an intravenous injection.
- A subcutaneous auto-injector (SC-AI) version for maintenance dosing has been granted Fast Track designation by the FDA.
- If approved, the Leqembi SC-AI would be the only treatment for Alzheimer's disease that can be administered subcutaneously at home, moving the drug from the medical benefit to the pharmacy benefit.
- Pricing expected to be similar to Leqembi IV at ~$27,000 annually.
- Regulatory decision expected by August 31, 2025.

### Non-small Cell Lung Cancer (NSCLC)

Sunvozertinib *[Dizal Pharmaceutical]*

- This agent is an oral epidermal growth factor receptor (EGFR) inhibitor for the treatment of adults with locally advanced NCSLC with EGFR exon 20 insertion mutations. These mutations are found in about 2% to 3% of people with NSCLC.
- Studies are evaluating this therapy in people who have disease progression after receiving a platinum-based chemotherapy.
- Sunvozertinib could provide an oral alternative for managing chronic and progressive disease.
- Annual treatment cost estimated to be $200,000 - $300,000.
- The FDA granted the drug accelerated approval on July 2, 2025.

### Multiple Sclerosis (MS)

Tolebrutinib *[Sanofi]*

- A Bruton's tyrosine kinase inhibitor (BTKi) that is differentiated by its ability to penetrate the brain.
- If approved, would be the first BTKi approved for MS and the first therapy specifically for non-relapsing secondary progressive multiple sclerosis (SPMS).
- Relapsing and primary progressive MS indications are also being studied.
- Results from the HERCULES trial showed that the drug was able to delay the time to six-month disability progression by 31% compared to placebo.
- Expected annual price could range from $100,000 - $200,000.
- Regulatory decision expected by September 28, 2025.

# SPOTLIGHT
# GLP-1 UPDATE

## Phase III Study Results Released for Combination Therapy Product

- NovoNordisk recently released phase III results from the REDEFINE trials for CagriSema, a product in development that combines a GLP-1, semaglutide, and an amylin receptor agonist, cagrilintide.
- When compared to existing therapies, the results showed that CagriSema is considered within the highest range of efficacy observed with existing weight loss options. Higher weight loss percentages were expected by some based on earlier trials.
- The drug will be entered for regulatory approval in the first quarter of 2026 with potential for approval in early 2027. Further studies are ongoing to assess the drug's potential for sustained weight loss.

## Oral GLP-1 Shows Successful Results in Phase III Study

- Pfizer released results for orforglipron, the investigational once-daily oral pill, that show overall safety and efficacy consistent with injectable GLP-1 medications.
- The drug is under investigation for both obesity and for improvement of glycemic control in people with type 2 diabetes. It is also be evaluated for obstructive sleep apnea indication.
- Pfizer plans to file for approval in late 2025, making approval possible as soon as late 2026.

## Developments in Weight Management

- Global sales of GIP/GLP-1 therapies totaled $110 billion in 2024 and are expected to exceed $150 billion globally by 2029.
- This growth is being driven by the products that are available now along with those that are in development with approval and launch expected in the next one to three years.
- While drug manufacturers are developing different therapy combinations and routes of administration for these drugs, not all agents move on to the next phase.
- A few key agents have been withdrawn from the development pipeline for different reasons.

**GLP-1 Products Withdrawn from Development**

| Drug Name | Manufacturer | Route of Administration | Reason for Withdrawal |
|---|---|---|---|
| **Semaglutide (once weekly)** | Novo Nordisk | Oral | Focus resources on once-daily formulation |
| **Danuglipron** | Pfizer | Oral | Potential drug-induced liver injury |
| **Lotiglipron** | Pfizer<br>Osei Heptares | Oral | Elevated liver enzymes |

Source: IPD Analytics
Abbreviations: GIP: glucose-dependent insulinotropic polypeptide; GLP-1: glucagon-like peptide-1

# SPOTLIGHT
# ACUTE MYOCARDIAL INFARCTION PIPELINE

## Updated Guidelines for Management of Acute Coronary Syndromes

- On February 27, 2025, the American College of Cardiology published **updated guidelines** for syndromes including angina, coronary artery disease, and myocardial infarction (MI).
- An estimated 805,000 acute myocardial infarction (AMI) events occur in the United States annually, with 200,000 of those being considered recurrent.
- New guideline focuses mainly on the management of type 1 AMI or AMI due to coronary atherosclerosis.

## Both Medical and Pharmacy Benefits Affected by Pipeline

- Four pipeline agents are in late-stage development for AMI. If approved, all four products could be used in addition to current standard of care, increasing medication costs to payers.
- All of these agents can potentially decrease downstream costs by reducing recurrent AMI, cardiovascular-related hospitalization, and cardiovascular-related mortality. Additional studies and data will be needed to determine their impact on outcomes.

Potentially

**DECREASE**

Downstream Costs

**Acute MI Management Pipeline Agents**

| Drug Name | Administration | Place in Therapy | Benefit | Estimated WAC | Estimated Approval |
|---|---|---|---|---|---|
| **Selatrogrel [*Idorsia, Halozyme*]** | SC; single-dose | Sole pipeline agent for patients at risk of recurrent type 1 AMI | Pharmacy | <$5,000/dose | 2026 |
| **Sodium iodide [*Faraday Pharmaceuticals*]** | IV; single-dose | Patients with recurrent anterior STEMI; given pre-PCI | Medical | $10,000-$20,000/dose | 2026-2027 |
| **Dutogliptin [*Recardio*]** | SC; 14-day course | Patients with recurrent STEMI; given post-PCI | Pharmacy | $10,000-$20,000/course | 2027 |
| **Ziltivekimab [*Novo, Corvidia*]** | SC; once-monthly therapy | Patients with recurrent type 1 AMI; given post-PCI | Pharmacy | $50,000-$100,000/year | 2027 |

Source: IPD Analytics, June 2025
Abbreviations:AMI, acute myocardial infarction; STEMI, ST-elevated myocardial infarction; PCI, percutaneous coronary intervention;