VytlOne Pipeline Q4 2025

MaxorPlus will become VytlOne on January 1, 2026

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

October 2025

SPOTLIGHT | PIPELINE NEWS

Lilly and Novo release new data on oral weight loss products

- In September 2025, both Eli Lilly and Novo Nordisk released study data to support their respective products. The studies included adults with obesity or who were overweight and did not have diabetes. Oral semaglutide, the Novo product, showed an average weight loss of 16.6% body weight at the 64-week mark. Lilly's product, orforglipron, showed a 12.4% body weight loss at 72 weeks. This data is compelling for both products and does not account for differences in trial populations and other factors.
- Orforglipron has also **shown strong results for patients with type 2 diabetes** who are not able to control their disease with metformin. The head-to-head Achieve-3 study shows orforglipron outperformed oral semaglutide (Rybelsus®) in ability to lower A1C and help patients with diabetes lose weight.
- Oral semaglutide could be approved for obesity as early as December 2025. Both the Eli Lilly and Viking products are in Phase III development for obesity.

Oral Weight Loss Products in Late-Stage Development

Drug Name	Manufacturer	Expected Approval	Administration
Semaglutide	Novo Nordisk	Late 2025	Once daily oral GLP-1 RA therapy
Orforglipron	Eli Lilly	Late 2026	Once daily oral GLP-1 RA therapy
VK2735	Viking	2029+	Dual-acting GLP-1 RA and GIP; oral and injectable being studied

Source: IPD Analytics Abbreviations: GLP-1 RA – Glucagon-like peptide-1 receptor agonist; GIP – glucose-dependent insulinotropic polypeptide.

FDA approves subcutaneous formulation of Keytruda

- On September 19, 2025, Keytruda® Qlex, a subcutaneous (SC) formulation combining pemprolizumab with berahyaluronidase alfa was granted FDA approval.
- This formulation is approved for most solid tumor indications for which intravenous (IV) Keytruda is approved (not for hematological malignancies or primary mediastinal large B-cell lymphoma).
- Keytruda Qlex can be administered via the SC route by healthcare professionals in an outpatient setting. The convenience of a 1-or 2-minute injection every 3 or 6 weeks may provide a benefit to patients over the 30-minute IV infusion formulation.
- Pricing is expected to be at parity to Keytruda IV at approximately $200,000 annually.

Approval for small cell lung cancer sets new benchmark

- On October 3, 2025, the FDA announced that Zepzelca™, used in combination with Tecentriq®, was approved as first-line maintenance treatment in extensive-stage small cell lung cancer (ES-SCLC).
- First-line maintenance treatment is for patients who have not progressed after initial induction therapy. Given the high risk of relapse, this approval provides a new tool to help delay disease progression and extend survival.
- This regimen was recently **added to the National Comprehensive Cancer Network (NCCN) guidelines** as a preferred regimen in first-line ES-SCLC.
- SCLC accounts for 10% to 15% of all lung cancers and is characterized by aggressive disease progression. Approximately 70%to 80% of patients with SCLC have ES-SCLC at initial diagnosis.

VYTLONE

NOW APPROVED | NEW BRAND DRUGS TO MARKET

Brand Name	Generic Name	Indication	ROA	Approval Month
ANDEMBRY®	Garadacimab-gxii	Hereditary angioedema	SC	Jul-25
EKTERLY®	Sebetralstat	Hereditary angioedema	OR	Jul-25
HARLIKU™	Nitisinone	Reduction of urine homogentisic acid	OR	Jul-25
IMULDOSA®	Ustekinumab-srlf	Inflammatory conditions	SC	Jul-25
LYNOZYFIC™	Linvoseltamab-gcpt	Multiple myeloma	IV	Jul-25
TRYPTYR®	Acoltremon	Dry eye disease	OP	Jul-25
YEZTUGO®	Lenacapavir	HIV prevention	SC	Jul-25
ZUSDURI™	Mitomycin	Invasive bladder cancer	IS	Jul-25
ANZUPGO®	Delgocitinib	Chronic hand eczema	EX	Aug-25
BRINSUPRI™	Brensocatib	Non-cystic fibrosis bronchiectasis	OR	Aug-25
ORLYNVAH™	Sulopenem etzadroxil-probenecid	Uncomplicated urinary tract infections	OR	Aug-25
VIZZ™	Aceclidine	Presbyopia	OR	Sep-25
BRUKINSA®	Zanubrutinib	Mantle cell lymphoma	OR	Sep-25
DAWNZERA™	Donidalorsen	Hereditary angioedema	SC	Sep-25
HERNEXEOS®	Zongertinib	Non-small cell lung cancer	OR	Sep-25
KIRSTY™	Insulin aspart	Diabetes mellitus	SC	Sep-25
LEQEMBI® IQLIK™	Lecanemab-irmb	Alzheimer's disease	SC	Sep-25
MODEYSO™	Dordaviprone	Glioma	OR	Sep-25
PAPZIMEOS™	Zopapogene imadenovec-drba	Recurrent respiratory papillomatosis	SC	Sep-25
WAYRILZ™	Rilzabrutinib	Immune thrombocytopenia	OR	Sep-25

NOW APPROVED | NEW GENERIC DRUGS TO MARKET

Brand Name	Generic Name	Indication	Launch Month
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-rilpivirine-tenofovir	HIV-1	May-25
FYCOMPA®	Perampanel	Seizures	May-25
TASIGNA®	Nilotinib	Chronic myeloid leukemia	Jul-25
EPRONTIA®	Topiramate	Seizures	Jul-25
XARELTO® SUSP	Rivaroxaban	Thromboprophylaxis	Jul-25
ARNUITY ELLIPTA®	Fluticasone	Asthma	Aug-25
DIFICID®	Fidaxomicin	Clostridioides difficile-associated diarrhea	Aug-25
VUITY®	Pilocarpine	Presbyopia	Aug-25
ADZENYS® XR-ODT	Amphetamine	ADHD	Sep-25
JAYTHARI®	Deflazacort	Duchenne muscular dystrophy	Sep-25
SAXENDA®	Liraglutide	Obesity	Sep-25
TRACLEER®	Bosentan	Pulmonary arterial hypertension	Sep-25
VENOFER®	Iron sucrose	Anemia	Sep-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.maxorplus.com
Abbreviation: ROA- Route of Administration; EX-External; IJ-Injection; IM-Intramuscular;IS-Intravesical; IV-Intravenous; OR-Oral; SC-Subcutaneous; IZ-Intravitreal; IO- Intraocular; IN-Intranasal

CLINICAL PIPELINE

Spinocerebellar Ataxia (SCA)

Troriluzole *[Biohaven]*

- SCA is a rare genetic neurodegenerative disease characterized by the progressive loss of voluntary motor control and brainstem atrophy. An estimated 15,000 to 20,000 people in the U.S. have SCA.
- Troriluzole is a prodrug conjugate of riluzole that reduces levels of synaptic glutamate, the most abundant excitatory neurotransmitter in the brain.
- If approved, troriluzole would be the first FDA-approved treatment for SCA. Currently, symptoms are managed by assistive devices, therapy, and medications to manage muscle spasms.
- Annual price is estimated to be around $400,000 for SCA treatment.
- Regulatory decision expected in 4Q2025.

Wiskott-Aldrich Syndrome (WAS)

Etuvetidigene Autotemcel *[GSK/Fondazione Telethon]*

- WAS is a rare genetic disorder that is characterized by eczema, immune deficiency, and low platelet count, which leads to abnormal bleeding episodes. The only available treatment currently is stem cell transplantation.
- Estimated incidence in the United States is 1 in 250,000 live male births.
- If approved, this one-time gene therapy would be an option for patients who are eligible for transplant but cannot find a matched donor.
- One-time treatment is expected to be priced at $3,000,000.
- Regulatory decision expected in 4Q2025.

Familial Chylomicronemia Syndrome (FCS)

Plozasiran *[Arrowhead Pharmaceuticals]*

- FCS is a rare genetic disorder that prevents the body from breaking down fats (triglycerides) in the blood. People with FCS are either unable to make lipoprotein lipase, an enzyme that helps break down fats, or have a broken form of it in their body.
- Plozasiran is a small interfering RNA that works to reduce apolipoprotein C-III which reduces triglycerides and restores lipids to normal levels.
- The drug is also under development for severe hypertriglyceridemia and mixed dyslipidemia, which are more common indications than FCS.
- Annual treatment cost for FCS is estimated to be around $600,000.
- Regulatory decision is expected by November 18, 2025.

Cushing Syndrome

Relacorilant *[Corcept Therapeutics]*

- Cushing syndrome is a condition that is caused by high levels of cortisol, a naturally occurring hormone, in the body.
- Relacorilant is an oral selective cortisol modulator with no affinity for the progesterone receptor, eliminating antiprogesterone side effects. This distinction may make it preferable, particularly for women, compared to other therapies that affect the progesterone receptor.
- This drug is also being studied in ovarian cancer with a regulatory decision date in July 2026.
- Annual treatment cost for Cushing is expected to be $550,000 to $650,000.
- Regulatory decision for relacorilant is expected by December 30, 2025.

SPOTLIGHT
Bronchiectasis

Bronchiectasis prevalence continues to rise in United States

- Bronchiectasis is a chronic progressive lung disease that affects about 350,000 to 500,000 adults in the United States, including those with cystic fibrosis (CF). Non-cystic fibrosis bronchiectasis (NCFB) is not associated with CF.
- The clinical features of the disease include permanent and abnormal dilation of the bronchi, airway inflammation, airway wall thickening, impaired mucociliary clearance, and frequent lung infections.
- Disease management has traditionally focused on symptom control and exacerbation prevention through interventions such as airway clearance techniques, pulmonary rehabilitation, antibiotic therapy, and mucolytic agents.
- The rising prevalence is associated with increased provider awareness, use of high-resolution diagnostic imaging, and an aging population.

First therapy for non-cystic fibrosis bronchiectasis approved

- On August 12, 2025, Insmed's Brinsupri™ was approved for the treatment of NCFB in people over 12 years of age.
- This first-in-class DPP1 inhibitor targets neutrophilic inflammation, a feature of bronchiectasis.
- Brinsupri is intended to be used in combination with existing drug and non-drug therapies rather than as a replacement therapy.
- This oral tablet is available in 10mg and 25mg strengths, both administered once daily and priced equivalently. The drug is available through a limited specialty pharmacy network, which includes Maxor Specialty Pharmacy.

Development continues for additional bronchiectasis therapies

- Multiple pharmaceutical companies are engaged in advancing product development in this therapeutic space.
- Brinsupri was the first therapy to gain FDA approval and is expected to maintain a position without direct competition for several years.
- While several investigational therapies are in the pipeline, the earliest Phase III trial is not anticipated to conclude until September 2028, indicating that any potential regulatory approvals remain several years away.

Clinical Products in Development for NCFB

Drug Name	Manufacturer	Development Phase	Mechanism of Action
Verducatib	Boehringer Ingelheim	Phase III	DPP1/cathepsin C inhibitor *NCFB and bronchiectasis in CF
Itepekimab	Sanofi/Regeneron	Phase II	Interleukin 33 (IL-33) antagonist
Ohtuvayre™ (ensifentrine)	Verona Pharma	Phase II	Phosphodiesterase 3 and 4 inhibitor

Source: IPD Analytics; American Lung Association ; Brinsupri prescribing information Abbreviations: DPP1:didpeptidyl peptidase 1 inhibitor;

SPOTLIGHT

Metabolic Dysfunction-Associated Steatohepatitis (MASH)

Wegovy becomes second drug approved for MASH

- On August 15, 2025, Wegovy® was granted FDA approval for treatment of adults with noncirrhotic MASH with moderate to advanced fibrosis.
- MASH is the most severe form of metabolic dysfunction-associated steatotic liver disease (MASLD). MASH and alcoholism are the top two indications for liver transplant in the U.S.
- It is estimated that about 15 million people in the U.S. have a form of MASH. That number is expected to expand as additional diagnostic tests become available

Comparison of FDA-approved MASH Products

	Wegovy	Rezdiffra™
Administration	Once weekly, SC self-injection	Once daily, oral tablet
Distribution	Open	LDD
Annual WAC	$17,537	$50,077
Advantages	• Cardiovascular risk reduction • Weight loss • Glycemic benefits	• Oral option • Well tolerated • First to market
Disadvantages	• Poor tolerability affects adherence • Requires self-injection	• No added metabolic benefits • Providers may not be familiar with drug's mechanism

Source: IPD Analytics Abbreviations: GLP-1 RA – Glucagon-like peptide-1 receptor agonist; GIP – glucose-dependent insulinotropic polypeptide

Pipeline development continues for additional MASH products

- Pharmaceutical groups and professional organizations specializing in liver disease have projected that the pharmaceutical market for MASH therapies would reach $35 billion by 2030.
- Currently, more than 30 therapies are in development to treat MASH. Many of these products are glucagon-like peptide 1 (GLP-1) receptor agonists, with Ozempic® and Zepbound® both in advanced stages of development. In addition, multiple other mechanisms of action are being explored within this therapeutic area.
- A sample of the products that are in Phase III development include:

Lanifibranor

- Oral peroxisome proliferator-activated receptor (PPAR) agonist
- Studies show improved cardiovascular biomarkers, including dyslipidemia and high blood pressure – highlighting possible benefits for patients with high cardiovascular risk
- Annual pricing expected to be in the $50,000 to $100,000 range
- Approval may occur in late 2027 to early 2028

Pegozafermin

- Subcutaneous fibroblast growth factor analog that mimics the beneficial effects on many metabolic processes in the body
- Offers positive impact on cardiovascular parameters along with weekly or every other week SC dosing
- Annual pricing expected to be in the $50,000 to $100,000 range
- Approval for MASH could occur in 2028