



VytlOne Pipeline

Q1 2026

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

January 2026

SPOTLIGHT | PIPELINE NEWS



Study results announced for semaglutide in Alzheimer’s disease

- Results of the Phase III EVOKE and EVOKE+ clinical trial results indicate that oral semaglutide did not demonstrate a statistically significant reduction in the progression of Alzheimer’s disease (AD).
- The randomized, double-blind trials enrolled more than 3,800 participants diagnosed with mild cognitive impairment or mild dementia due to AD. While treatment did show improvement of AD-related biomarkers in both trials, these changes did not translate into a measurable delay in disease progression.
- The drug development pipeline remains active and robust in the search for additional therapies that can slow disease progression. As of late 2025, there were over 180 active clinical trials evaluating 138 novel drugs for AD.



Several blockbuster drugs facing generic competition in 2026

- With several high-revenue traditional and specialty drugs losing exclusivity in 2026, the market is expected to see impactful generic and biosimilar entrants over the next few years.

Key Upcoming Generics		
Drug Name	Therapy Class	Estimated Launch
Tradjenta®	Diabetes	1Q2026
Januvia®	Diabetes	May 2026
Xeljanz®	Chronic Inflammatory	2Q2026
Trintellix®	Behavioral Health	December 2026



Maximum Fair Pricing Takes Effect

- Starting on January 1, 2026, maximum fair prices (MFPs) were implemented on the first 10 drugs selected for the Medicare Drug Price Negotiation Program for IPAY 2026.
- The implementation of MFPs may cause Medicare Part D plans, along with commercial payers, to adjust their formulary strategies if rebates are affected when manufacturers reduce wholesale acquisitions costs (WACs) for these products.
- The U.S. government may see more savings on those drugs that do not already have generic or biosimilar competition such as Imbruvica® and Enbrel®.

Drugs Selected for IPAY 2026				
Januvia®	Novolog®/Fiasp®	Enbrel®	Xarelto®	Imbruvica®
Jardiance®	Farxiga®	Eliquis®	Entresto®	Stelara®

Abbreviation: IPAY, initial price applicability year

NOW APPROVED | NEW BRAND DRUGS TO MARKET

Brand Name	Generic Name	Indication	ROA	Approval Month
BILDYOS[®]	Denosumab-nxxp	Osteoporosis	SC	Oct-25
BLUJEPATM	Gepotidacin Mesylate	Uncomplicated urinary tract infections	OR	Oct-25
EXXUATM	Gepirone	Major depressive disorder	OR	Oct-25
FORZINITYTM	Elamipretide	Barth syndrome	SC	Oct-25
INLURIYOTM	lmlunestrant	Breast cancer	OR	Oct-25
JASCAYD[®]	Nerandomilast	Idiopathic pulmonary fibrosis	OR	Oct-25
KEYTRUDA[®] QLEX	Pembrolizumab-berahyaluron-pmph	Multiple malignancies	SC	Oct-25
KOSELUGO[®]	Selumetinib	Neurofibromatosis type 1	OR	Oct-25
PALSONIFYTM	Paltusotine	Acromegaly	OR	Oct-25
RHAPSIDO[®]	Remibrutinib	Chronic spontaneous urticaria	OR	Oct-25
ZURNAITM	Nalmefene	Opioid overdose	IJ	Oct-25
BLENREP[™]	Belantamab mafodotin-blmf	Multiple myeloma	IV	Nov-25
LYNKUET[®]	Elinzanetant	Vasomotor symptoms due to menopause	PO	Nov-25
OSPOMYV[®]	Denosumab-dssb	Osteoporosis	SC	Nov-25
HYRNUO[®]	Sevabertinib	Non-small cell lung cancer	PO	Dec-25
ITVISMA[®]	Onasemnogene Apeparvovec-brve	Spinal muscular atrophy	IT	Dec-25
KOMZIFTITM	Ziftomenib	Acute myeloid leukemia	OR	Dec-25
OMLONTI[®]	Omidenepag	Reduction of elevated intraocular pressure	OP	Dec-25
REDEMPLO[®]	Plozasiran	Familial chylomicronemia syndrome	SC	Dec-25
VOYXACT[®]	Sibeprenlimab-szsi	Immunoglobulin A nephropathy	SC	Dec-25

NOW APPROVED | NEW GENERIC DRUGS TO MARKET

Brand Name	Generic Name	Indication	Launch Month
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
ECOZA[®]	Econazole nitrate	Interdigital tinea pedis	Oct-25
ENDOMETRIN[®]	Progesterone	Infertility	Oct-25
GRALISE[®]	Gabapentin	Pain associated with postherpetic neuralgia	Oct-25
RAVICTI[®]	Glycerol phenylbutyrate	Urea cycle disorders	Oct-25
VABRINTY[®]	Leuprolide acetate	Advanced prostate cancer	Oct-25
GLEOSTINE[®]	Lomustine	Hodgkin's lymphoma	Dec-25
MAVENCLAD[®]	Cladribine	Multiple sclerosis	Dec-25
PREMARIN[®]	Estrogens, conjugated	Hormone therapy	Dec-25
RYTARY[®]	Carbidopa and levodopa	Parkinson's disease	Dec-25

CLINICAL PIPELINE

Breast Cancer

Camizestrant [AstraZeneca]

- This drug is an oral selective estrogen receptor degrader (SERD) in development for ER+/HER2- advanced breast cancer.
- Demonstrated progression-free survival benefit that may redefine first-line therapy for ESR-1 mutant ER+/HER2- metastatic breast cancer.
- Utilizes earlier intervention, guided by ctDNA rather than imaging, which may delay symptomatic disease progression and prolong effectiveness of ongoing CDK4/6 blockade.
- If approved, camizestrant would be the first SERD for first-line, ESR1 mutation-guided use, differentiating it from other SERDs as a precision-based treatment.
- Annual WAC is estimated to be \$200,000 to \$300,000.
- Regulatory decision expected in 1H2026.

Achondroplasia

Navepegritide [Ascendis]

- Achondroplasia is an autosomal dominant form of skeletal dysplasia and is the most common cause of short stature, affecting one in 20,000 births in North America.
- Navepegritide is a prodrug of C-type natriuretic peptide and is administered subcutaneously once weekly.
- If approved, it would compete with Voxzogo®, a once-daily therapy.
- Annual treatment cost is expected to be \$375,000 to \$450,000
- Regulatory decision is expected by February 28, 2026.

Obesity

Orforglipron [Eli Lilly]

- An oral, small molecule glucagon-like peptide-1 (GLP-1) agonist taken once daily.
- Does not require mealtime dose restrictions, differentiating this therapy from other available options.
- Phase III studies observed weight loss results of -11.2% at 72 weeks which is marginally less when compared to oral Wegovy® which showed -13.6% at 64 weeks.
- Therapy cost expected to be under \$1,000 per month with cash price expected to be \$149 to \$399 per month, and is included in federal pricing agreements pending FDA approval.
- Regulatory decision expected in 1H2026.

Cholestatic Pruritus

Linerixibat [GSK]

- Cholestatic pruritus is the relentless itching that is experienced by up to 80% of patients with primary biliary cholangitis (PBC), a rare autoimmune liver disease.
- Linerixibat is an ileal bile acid transporter inhibitor, a first-in-class therapy that works to reduce the levels of itch-driving bile acids in the bloodstream.
- If approved, it would compete as a second-line option with existing PBC therapies, Iqirvo® and Livdelzi®, that also improve pruritus symptoms.
- Annual treatment cost is estimated to be \$100,000 to \$300,000.
- Regulatory decision is expected by March 24, 2026.



SPOTLIGHT

Biosimilar Pipeline



Biosimilar void highlights opportunity for growth

- The biosimilar pipeline continues to expand rapidly driven by increasing approvals, competitive market dynamics, and growing demand for cost-effective biologic alternatives.
- It is estimated that of the approximately 118 biologics losing exclusivity in the next 10 years, only 10% have biosimilars in development.
- Of the biologics generating at least \$500 million in sales annually, only 23% have biosimilars in the pipeline. Cost of development, regulatory barriers, and market uncertainty may influence a manufacturer's interest in investing in biosimilar development for a product.

FDA introduces initiatives to accelerate biosimilar development

- In an effort to make it faster and less costly to produce biosimilar medications, the FDA has proposed updates that would simplify requirements and reduce clinical testing currently required for biosimilar product development.
- The proposed guidance reduces the requirement for developers to conduct comparative human clinical studies, allowing analytical testing to demonstrate any product differences.
- A separate guidance addresses the testing that products must take to gain interchangeability status. The goal is to make all biosimilar products interchangeable at approval, increasing access to these lower-cost therapies.

Upcoming Biosimilar Launches					
Launch Year	Chronic Inflammatory	Oncology	Pulmonology	Endocrinology	Neurology
2026	Simponi [®] /Simponi Aria [®]	Perjeta [®]	Xolair [®]	Humalog [®]	
2027	Orencia [®]				
2028	Cimzia [®]				
2029	Enbrel [®] Cosentyx [®]	Keytruda [®]			Ocrevus [®]

SPOTLIGHT

Sjögren's Syndrome



Multiple therapies vie to be first approved to treat Sjögren's

- Sjögren's syndrome is an autoimmune disease that causes the body's glands to produce less moisture than they should. The main symptom is chronic dryness throughout the body, especially in the eyes and mouth.
- This disease can lead to profound fatigue, chronic pain, major organ involvement, and neuropathies. It can occur alone or with another autoimmune disease such as rheumatoid arthritis or lupus.
- While Sjögren's is often misrepresented as a rare disease, it is estimated that **four million Americans** have it, making it one of the most prevalent autoimmune diseases.
- There are currently no FDA-approved therapies for Sjögren's although corticosteroids, eyedrops, and immune suppressants are used to help manage the disease.

Pipeline includes both novel and existing products

- While many novel products are in development, there are also existing products looking to gain approval for the Sjögren's indication. Examples of currently available products are:
 - Sotyktu[®] - an **oral tablet** in Phase III clinical trials with a potential approval in late 2027
 - Imaavy[®] - a subcutaneous option with potential for approval in 2028+
 - Vyvgart Hytrulo[®] - a subcutaneous injection with potential for approval in 2028+

Novel Sjögren's Therapies in Development Pipeline			
Drug	Route	Mechanism	Potential approval
VAY736 (ianalumab)	Intravenous Subcutaneous	Anti-B-cell activating factor antibody	2H26+
VIB4920 (dazodalibep)	Intravenous	CD40L inhibitor	2H27+
IMVT-1402	Subcutaneous	FcRn antagonist	2028+
AMG 329	Subcutaneous	FMS-like receptor tyrosine kinase 3 inhibitor	2028+

Abbreviations: FcRn, neonatal Fc receptor; CD40L, type II transmembrane protein primarily expressed on activated T cells