VYTLONE

VytlOne Pipeline Q3 2026

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

July 2026

Spotlight | Pipeline News

COVID-19 Emergency Use Authorizations being phased out

- The declaration for COVID-19 drugs and biologics is scheduled to terminate on June 29,2027, while medical device declarations will terminate on December 26, 2026.
- The FDA will work with manufacturers on transitioning products to traditional approval pathways where appropriate.

Near term GLP-1 pipeline introduces novel products

- On June 7, 2026, Novo Nordisk released Phase 3 results on its combination product, CagriSema. While weight-loss results fell short of market expectations, the study met its primary endpoints in HBA1c reduction and body weight loss.
- On April 28, 2026, Boehringer Ingelheim announced positive results for survodutide, demonstrating meaningful improvements in both weight loss and metabolic dysfunction-associated steatohepatitis (MASH).
- On May 21, 2026, Eli Lilly announced results for retatrutide, its investigational triple-receptor agonist. Among therapies approved to date, retatrutide demonstrated the greatest weight-loss efficacy, though it is also associated with a higher frequency of adverse events.

Novel GLP-1 Therapies in Near Term Obesity Pipeline

Drug	Manufacturer	Mechanism of Action	Potential Approval
CagriSema	Novo Nordisk	Amylin analog/GLP-1 RA	4Q2026
Survodutide	Boehringer Ingelheim	Glucagon/GLP-1 RA	Early 2027
Retatrutide	Eli Lilly	Glucagon/GLP-1/GIP RA	Mid/Late 2027

Abbreviations: RA, receptor agonist; GLP, Glucagon-like peptide-1; GIP, Glucose-dependent insulinotropic polypeptide

Accelerating Innovation: FDA's new process

- The FDA Commissioner's National Priority Voucher Pilot Program (CNPV) is a review pathway designed to accelerate approvals for specific therapies.
- The program aims to reduce review timelines from the traditional 6 to 12 months to as little as 1 to 2 months for selected drugs and biologics.
- The process uses enhanced FDA manufacturer collaboration and multidisciplinary review teams to streamline regulatory review.
- Safety, efficacy, and scientific standards remain unchanged when following this process, focusing on efficient reviews and not lowering approval standards.
- To qualify for CNPV approval, the product must align with one or more national health priorities, including: addressing a large unmet medical need, helping with a public health crisis, providing a transformative therapy option, or providing one of many affordability initiatives.

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Now Approved | New Brand Drugs to Market

Brand Name	Generic Name	Indication	ROA	Approval Month
AVLAYAH™	Tividenofusp alfa	Mucopolysaccharidosis II	PO	Apr-26
CONTEPO™	Fosfomycin	Complicated urinary tract infection	IV	Apr-26
FOUNDAYO™	Orforglipron	Obesity	PO	Apr-26
ICOTYDE™	Icotrokinra	Moderate-to-severe plaque psoriasis	PO	Apr-26
KYGEVVI®	Doxecitine-Doxribtimine	Thymidine kinase 2 deficiency	PO	Apr-26
LEROCHOL®	Lerodalcibep	Hypercholesterolemia	SC	Apr-26
LIFYORLI™	Relacorilant	Fallopian tube cancer	PO	Apr-26
NEREUS™	Tradipitant	Nausea or vomiting	PO	Apr-26
BYSANTI™	Milsaperidone	Schizophrenia	PO	May-26
IDVYNSO™	Doravirine-Islatravir	HIV	PO	May-26
XTORO™	Finafloxacin	Acute otitis externa	OT	May-26
BAXFENDY™	Baxdrostat	Hypertension	PO	Jun-26
DECNUPAZ™	Pivekimab Sunirine	Blastic plasmacytoid dendritic cell neoplasm	IV	Jun-26
EVDI®	Trabectedin	Liposarcoma	IV	Jun-26
FILKRI™	Filgrastim	Neutropenia	IJ	Jun-26
HEPCLUDEX®	Bulevirtide	HDV infection	SC	Jun-26
JUBEREQ®	Denosumab	Prevention of skeletal-related events	SC	Jun-26
OSVYRTI®	Denosumab	Osteoporosis	SC	Jun-26
XOCOVA®	Ensitrelvir	COVID-19	PO	Jun-26

Now Approved | New Generic Drugs to Market

Brand Name	Generic Name	Indication	Launch Month
NUCYNTA®	Tapentadol	Acute pain	Mar-26
POMALYST®	Pomalidomide	Multiple myeloma	Mar-26
ATROVENT HFA®	Ipratropium	Chronic obstructive pulmonary disease	April-26
NUCYNTA ER®	Tapentadol	Acute pain	April-26
SAVELLA®	Milnacipran	Fibromyalgia	April-26
OFEV®	Nintedanib	Idiopathic pulmonary fibrosis	April-26
FARXIGA®	Dapagliflozin	Diabetes Type 2	April-26
INCRUSE ELLIPTA®	Umeclidinium	Chronic obstructive pulmonary disease	April-26
XIGDUO XR®	Dapagliflozin/Metformin	Diabetes Type 2	April-26
BOSULIF®	Bosutinib	Chronic myeloid leukemia	June-26
` JANUMET®	Sitagliptin/Metformin	Diabetes Type 2	June-26
JANUVIA®	Sitagliptin	Diabetes Type 2	June-26
OPSUMIT®	Macitentan	Pulmonary arterial hypertension	June-26
RELGAABI®	Gabapentin	Postherpetic neuralgia	June-26
XELJANZ®	Tofacitinib	Chronic inflammatory conditions	June-26
XELJANZ XR®	Tofacitinib	Chronic inflammatory conditions	June-26

For informational purposes only. Pipeline timelines, cost estimates, and market projections are subject to change and do not constitute clinical, legal, or formulary recommendations. This information should not be solely relied upon for formulary decision-making purposes and is subject to change. Sources include publicly available data current as of the date of the publication. Visit www.vytlone.com
Abbreviation: ROA- Route of Administration; EX-External; IJ-Injection; IM-Intramuscular; IV-Intravenous; OP-Ophthalmic; OT-Otic; PO-by mouth; SC-Subcutaneous; IN-Intranasal; IT-Intrathecal

Clinical Pipeline

Hemophilia A

Denecimig (Mim8) [Novo Nordisk/Genmab]

- Subcutaneous bispecific antibody that mimics Factor VIIIa to restore blood coagulation in patients with hemophilia A with and without inhibitors
- Designed to provide prophylactic bleed protection while reducing treatment burden associated with conventional factor replacement therapies
- Being studied as a subcutaneous prefilled self-injector pen device, which may be preferred by some patients over Hemlibra© vials
- Annual treatment cost is expected to be $500,000 to $700,000, consistent with Hemlibra, its main competitor
- Regulatory decision anticipated in 3Q2026

Dermatomyositis

Brepocitinib [Pfizer/Roivant/Priovant]

- Oral dual JAK1/TYK2 inhibitor being studied for many immune-mediated diseases along with dermatomyositis (DM), which affects ~50,000 patients in the United States
- Granted Fast Track designation by FDA
- If approved, would become the first-in-class oral therapy for patients following first-line treatments such as glucocorticoids or IVIG
- Uptake would likely be higher in patients who do not respond to or decline IVIG therapy, typically about 50% of those diagnosed with DM
- Annual therapy cost expected to be $300,000 to $500,000
- Regulatory decision anticipated in 3Q2026

Narcolepsy

Oveporexton [Takeda]

- Oral orexin-2 receptor agonist that is taken twice daily
- Granted Breakthrough Therapy and Orphan Drug designations by FDA
- If approved, would be the first orexin agonist approved for narcolepsy.
- Oveporexton is among the first therapies designed to restore orexin signaling directly, potentially addressing the root cause of narcolepsy rather than only treating symptoms
- Annual WAC is estimated to be $200,000 to $300,000
- Regulatory decision anticipated in 3Q2026

Parkinson's Disease

Tavapadon [Cerevel/Pfizer/AbbVie]

- Oral, once-daily, selective partial agonist of dopamine D1/D5 receptors designed to maximize motor benefit while reducing the receptor overexcitation that can lead to dyskinesias
- Being developed as both early-stage monotherapy and adjunctive therapy in advanced disease
- If approved, would be entering a highly generic landscape and compete primarily with levodopa products
- Annual WAC is expected to be close to $15,000
- Regulatory decision is anticipated in 3Q2026

Focus on
Ulcerative Colitis

Novel therapies needed to manage disease

- Ulcerative colitis (UC) is an inflammatory condition that affects the large intestine and is diagnosed in more than 1 million people in the United States.
- As of mid-2026, there are 14 biologics and small molecules approved to treat moderate to severe UC, not including biosimilars of the branded products.
- Even with multiple treatment options, clinical remission rates at 1 year have not exceeded ~50% and many patients lose response to therapy, requiring trials of multiple medications over time.

Additional therapy option for pediatric UC

- More than 25,000 children younger than 18 years of age are estimated to have a UC diagnosis in the United States.
- Currently, only tumor necrosis factor (TNF) inhibitors are approved for pediatric UC treatment.
- Stelara©, an interleukin 12/23 antagonist, has been given an August 2026 decision date for this diagnosis. If approved, it would offer an additional treatment option to children with moderate to severe disease.

Pipeline Products | Moderate to Severe UC

Drug (Manufacturer)	MOA	Estimated FDA Approval	ROA	Estimated Annual WAC
Obefazimod (Abivax)	Anti-inflammatory agent	2H 2027	Oral	~$100,000-$200,000
Tulisokibart (Merck)	TL1A inhibitor	2027+	IV, SC	~$200,000
Afimkibart (Roche)	TL1A inhibitor	2028+ (for adults) 2030+ (for pediatrics)	IV, SC	~$200,000
Duvakitug (Sanofi)	TL1A inhibitor	2029+	SC	~$200,000
Icotyde© (J&J)	IL-23 antagonist	2029+	Oral	$100,000-$200,000
Ivarmacitinib (Jiangsu Hengrui)	JAK inhibitor	Unknown status; active Phase 3 program in manufacturer's pipeline	Oral	$50,000-$100,000

Abbreviations: ROA- Route of Administration; MOA, mechanism of action; TL1A, tumor necrosis factor-like cytokine 1A; IL-23, interleukin-23; JAK inhibitor, janus kinase inhibito

Focus on
Chronic Obstructive Pulmonary Disease (COPD)

COPD treatment landscape shifting to biologic therapies

The COPD pipeline is moving from traditional inhalers towards the development of biologic therapies. As of July 2026, there are two biologics that are approved for COPD, Dupixent© and Nucala©. Eight drugs are currently in phase 3 trials for COPD. Seven of these therapies are biologics.

Biologics addressed in updated guidelines

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2026 Guidelines recommend a stepwise approach based on symptoms and exacerbation risk. Biologics and other add-on therapies (Ohtuvayre©) are reserved for patients with inadequately controlled disease despite optimized inhaled therapy.

Phase 3 COPD Products

Drug (Manufacturer)	Mechanism	Route	Potential approval
Tozorakimab (AstraZeneca)	IL-33 antagonist	SC	Late 2027
Trimbow© (Chiesi)	ICS,LABA,LAMA	IN	2027
Astegolimab (Roche/ Genentech)	IL-33 antagonist	SC	2030+
Itepekimab (Regeneron/ Sanofi)	IL-33 antagonist	SC	2030+
Tezspire© (Amgen/ AstraZeneca)	TSLP inhibitor	SC	2030+
Lunsekimig (Sanofi)	IL-13 antagonist/TSLP inhibitor	SC	2030+
Exdensur© (GSK)	IL-5 antagonist	SC	2030+
Tilrekimig (Pfizer)	IL-4R/IL-13 antagonist/TSLP inhibitor	SC	2031+

Abbreviations:IL, interleukin; SC, subcutaneous; ICS, inhaled corticosteroid; LABA, long-acting beta-2 adrenoreceptor agonist; LAMA ,long-acting muscarinic antagonist; IN, inhaled; TSLP, thymic stromal lymphopoietin