VYTLONE

VytlOne Pipeline Q4 2026

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

October 2026

VYTLONE

Spotlight | Pipeline News

Broad generic Xarelto® launch expected in early 2027

- Rivaroxaban (Xarelto) remains a commonly prescribed direct oral anticoagulant for atrial fibrillation and venous thromboembolism indications.
- Generic versions of the lower volume 2.5mg and oral suspension formulations are already available, while the more commonly prescribed 10mg,15mg, and 20mg strengths are expected to enter the market in March 2027.
- Multiple FDA-approved manufacturers are positioned to launch generic rivaroxaban, increasing market competition and potential cost savings opportunities.

Influenza vaccine options expand for 2026-2027 season

The CDC's Advisory Committee on Immunization Practices (ACIP) did not issue updated influenza vaccination recommendations in 2026. As a result, guidance from the 2025-2026 season remains in effect. Influenza vaccines for the 2026-2027 season continue to target three influenza virus strains. Although vaccination is ideally completed in September or October, people can benefit from receiving the influenza vaccine later in the season while influenza viruses continue to circulate.

- The trivalent vaccines have been updated for the 2026-2027 season to include two subtypes of influenza A virus and one subtype of influenza B virus.
- On August 5, 2026, the FDA approved Moderna's mFlusiva®, the first mRNA-based influenza vaccine. Approved for people 50 years of age and older, this product shows good or better efficacy* than currently marketed vaccines. However, it does show higher adverse event rates and has a higher cost.

Indication expansion activity remains robust through 2026

Several marketed therapies are seeking FDA approval for additional indications with regulatory decisions expected through year-end 2026. If approved, these label expansions could extend use into new patient populations and impact clinical decisions.

Marketed Therapies Awaiting Indication Expansion Decision			
Drug	**Approved Indication**	**Pending Indication**	**Potential Approval**
Myqorzo®	Second-line oHCM	First-line oHCM	Q4 2026
Ozempic® tab (high dose)	Low dose - T2D; MACE risk reduction in T2D	25mg dose for use in adults with T2D	Q4 2026
Rinvoq®	RA, PsA, AD, UC, CD, AS, pJIA, GCA	Nonsegmental vitiligo, alopecia areata	Q4 2026, Q1 2027

Abbreviations: oHCM, obstructive hypertrophic cardiomyopathy; T2D, type 2 diabetes mellitus; MACE, major adverse cardiovascular event; RA, rheumatoid arthritis; PsA, psoriatic arthritis; AD atopic dermatitis; UC, ulcerative colitis; CD, Crohn's disease; AS, ankylosing spondylitis; pJIA, polyarticular juvenile idiopathic arthritis; GCA, giant cell arteritis

*FLUENT Phase 3 Trial (NCT06602024); New England Journal of Medicine, 2026.

Now Approved | New Brand Drugs to Market

Brand Name	Generic Name	Indication	ROA	Approval Month
CAVHANZA™	Nilotinib	Philadelphia chromosome positive chronic myeloid leukemia	PO	Jul-26
LUMVOA™	Veligrotug	Thyroid eye disease	IV	Jul-26
LYNAVOY™	Linerixibat	Primary biliary cholangitis	PO	Jul-26
TRUTAKNA™	Atacicept	IgA nephropathy	SC	Jul-26
VEPPANU™	Vepdegestrant	Breast cancer	PO	Jul-26
AWIQLI® FLEXTOUCH	Insulin Icodec	Diabetes Type 2	SC	Aug-26
JIDEYTRO™	Zidesamtinib	Non-small cell lung cancer	PO	Aug-26
LIPFENDRA®	Enlicitide	Hypercholesterolemia	PO	Aug-26
REVTORPYK®	Gedatolisib	Breast cancer	IV	Aug-26
OMLYCLO®	Omalizumab	Asthma	SC	Aug-26
ADQUEY™	Difamilast	Atopic dermatitis	EX	Sep-26
BIXLENVO™	Bictegravir-Lenacapavir	HIV-1	PO	Sep-26
CLOTIC®	Clotrimazole	Fungal otitis externa	OT	Jun-26
LISRAYA™	Brepocitinib	Dermatomyositis	PO	Sep-26
NUZOLVENCE®	Zoliflodacin	Uncomplicated urogenital gonorrhea	PO	Sep-26
PASATRU™	Garetosmab	Fibrodysplasia ossificans progressiva	IV	Sep-26
RASONQUE™	Daraxonrasib	Metastatic pancreatic adenocarcinoma	PO	Sep-26
ZENBEXUS™	Iberdomide	Multiple myeloma	PO	Sep-26
GENGLYCOS™	Pariglasgene Brecaparvovec	Glycogen storage disease type Ia	IV	Sep-26

Now Approved | New Generic Drugs to Market

Brand Name	Generic Name	Indication	Launch Month
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
COTEMPLA XR-ODT®	Methylphenidate	Attention Deficit Hyperactivity Disorder	July-26
EDARBI®	Azilsartan	Hypertension	July-26
INJECTAFER®	Ferric carboxymaltose	Iron supplement	Aug-26
JANUMET® XR	Sitagliptin/Metformin	Diabetes Type 2	Aug-26
PRIFTIN®	Rifapentine	Pulmonary tuberculosis	June-26
NUEDEXTA®	Dextromethorphan HBr-Quinidine	Pseudobulbar affect	Aug-26
RHOFADE®	Oxymetazoline	Rosacea	Aug-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

Obesity

CagriSema [Novo]

- Once-weekly subcutaneous combination of cagrilintide, an amylin analog, and semaglutide, a GLP-1 receptor agonist
- If approved, CagriSema would introduce a novel combination of two distinct mechanisms of action, differentiating it from currently available obesity therapies
- In late-stage development for additional indications, such as type 2 diabetes management, alcohol dependency, and reduction of cardiovascular events in patients with cardiovascular disease
- Annual treatment cost is expected be similar to other products in the obesity space
- Regulatory decision anticipated in late Q4 2026

Hypertension

Lorundrostat [Mineralys Therapeutics]

- Oral, once-daily selective aldosterone synthase inhibitor in development for treatment of uncontrolled/resistant hypertension
- Reduces aldosterone production upstream, representing a novel approach compared with mineralocorticoid antagonists
- Currently in Phase II development for additional indications, including chronic kidney disease and sleep apnea
- If approved, would become the second drug in this class in the U.S, following Baxfendy™ from AstraZeneca
- Annual WAC is estimated to be $10,000-$20,000
- FDA regulatory decision anticipated on December 22, 2026

Limb-Girdle Muscular Dystrophy

Ribitol [BridgeBio/ML Bio Solutions]

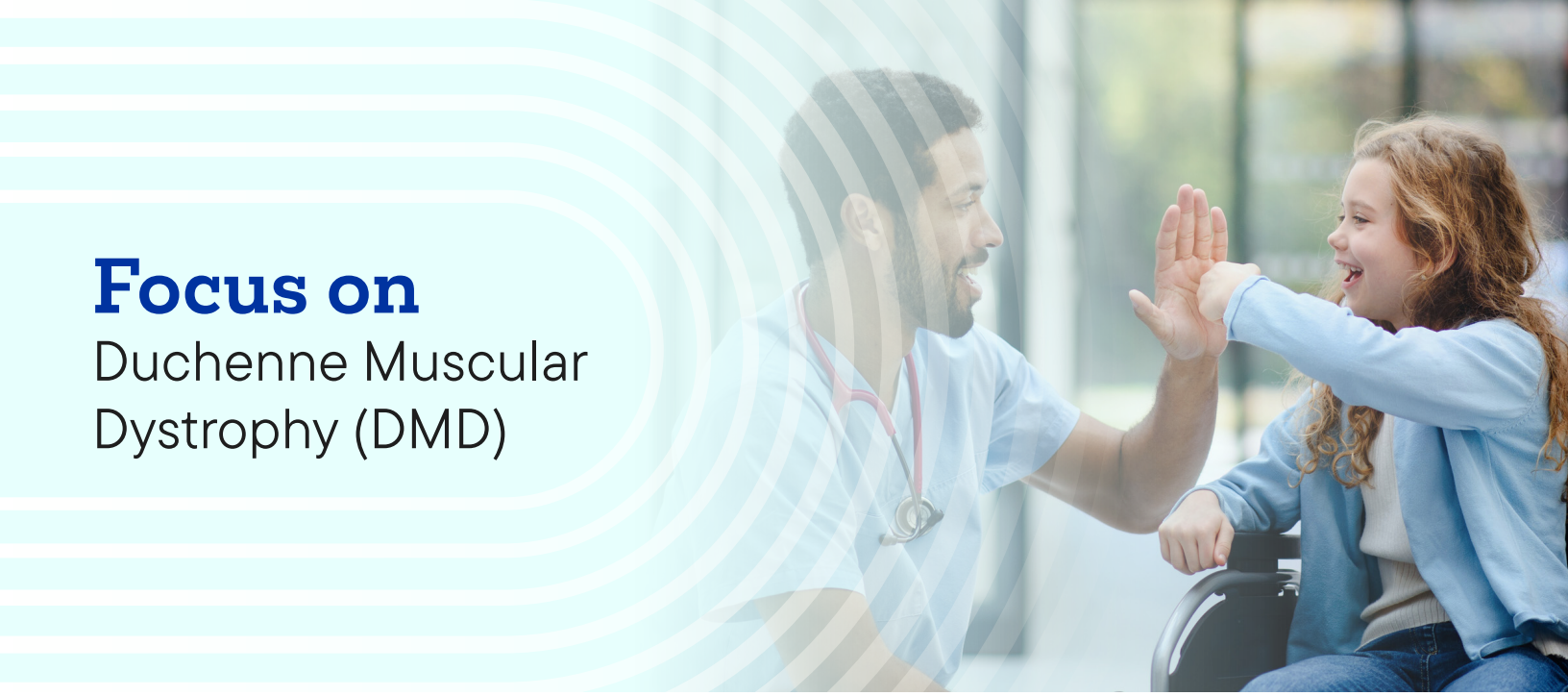
- Oral therapy that provides endogenous substrate upstream of the mutant FKRP enzyme to boost glycosylation pathways. This boost aims to restore or improve muscle strength and motor function.
- If approved, would become the first oral disease-modifying therapy for Limb-Girdle Muscular Dystrophy Type 2I/R9 (LGMD2I/R9)
- It is estimated that ~7,000 people in the United States live with this rare diagnosis
- Granted Fast Track and Orphan Drug designation by FDA
- Annual therapy cost expected to be $500,000-$750,000
- Regulatory decision anticipated on November 27, 2026

Oncology

Ivonescimab [Summit Therapeutics]

- First-in-class bispecific antibody targeting both the PD-1 and VEGF pathways, designed to enhance antitumor activity through dual immune checkpoint inhibition and antiangiogenic effects
- Under FDA review for treatment of non-small cell lung cancer (NSCLC) in combination with chemotherapy
- Potential to reshape treatment algorithms in metastatic NSCLC and may expand into additional tumor indications with ongoing development
- Coverage would fall under the medical benefit with treatment cost expected to be comparable or at a premium to other branded PD-1/PD-L1 inhibitors
- Regulatory decision is anticipated on November 14, 2026

Focus on
Duchenne Muscular Dystrophy (DMD)



Updates in currently approved therapies

- DMD is a progressive X-linked degenerative neuromuscular disease that impacts 400 to 600 male births annually. This disease is caused by mutations in the dystrophin gene, resulting in a near absence of dystrophin, a protein that helps keep muscle cells intact. DMD leads to premature death and has no cure.
- When focusing on updates in current therapies, the focus is on one-time gene therapies and exon-skipping therapies. Both treatment pathways aim at restoring dystrophin function.

Study Updates for Currently Approved Products

Drug (Manufacturer)	MOA	Approval	Pipeline Update
Elevidys™ (Sarepta)	Gene therapy	2023	Results expected in early 2027 for ongoing study to address safety concerns in non-ambulatory patients. Could result in expanded approval
Amondys 45 (Sarepta)	Exon-skipping therapy	2021	Currently approved under accelerated approval. Secured FDA review for potential full or traditional approval. FDA decision expected in February 2027.
Vyondys 53 (Sarepta)	Exon-skipping therapy	2019	

Near-term approvals bring novel treatment options

- The DMD treatment landscape continues to evolve with emerging therapies designed to provide longer lasting benefits, better support muscle and heart health, and reduce treatment burden through less frequent dosing.
- Multiple products are expected to reach regulatory milestones through 2026 and into 2027. Ongoing studies will be important to understand their long-term effectiveness and safety.

Near-Term DMD Pipeline

Drug (Manufacturer)	Development Notes
Deramiocel (Capricor)	• Off-the-shelf cell therapy that uses cardio-sphere-derived cells (CDCs) harvested from donor heart tissue • If approved, would be the first cell therapy for treatment of DMD cardiomyopathy, mutation agnostic • Pending regulatory decision on November 22, 2026
Zeleciment rostudirsen (Dyne Therapeutics)	• Exon-skipping therapy targeting exon 51 • Offers less frequent once-monthly dosing and higher dystrophin expression levels than Exondys 51 • Pending regulatory decision on January 21, 2027
Delpacibart zotadirsen (Avidity Biosciences)	• Exon-skipping therapy targeting exon 44 • Offers 6-week dosing interval • If approved, would be first therapy specifically for exon 44 skipping • Pending regulatory approval in February 2027

Focus on
Cell and Gene Therapy Pipeline

A growing pipeline with expanding approval potential

Cell and gene therapies are redefining treatment expectations across multiple disease states with many candidates designed to deliver potentially one-time therapeutic benefit. Currently, all late-stage pipeline products are anticipated to fall under the medical benefit given their administration requirements.

Although several pipeline products have faced regulatory delays and Complete Response Letters, evolving FDA review pathways and opportunities for submission may enable additional therapies to reach the market over the next several years. This reinforces the need for proactive readiness and planning as these costly therapies come to market.

Near-term Cell and Gene Pipeline Products

Drug (Brand Company)	Indication	Route of Admin	Development Notes	Potential approval
Doruxapapogene ralaplasmid (Inovio)	Doruxapapogene ralaplasmid (Inovio)	Intramuscular (followed by electroporation)	• Current studies look at every 6-month dosing • If approved, would compete with Precigen's Papzimeos® • Estimated cost is $360,000 per year	Oct. 30, 2026
Sonpiretigene isteparvovec (Catalent/Nanoscope Therapeutics)	Retinitis pigmentosa (RP)	Intravitreal	• One-time intravitreal injection • Competing with Ocugen's OCU400 to be first gene therapy for RP regardless of cause • Estimated cost $1M-$2M for both eyes	Q2 2027
Ifezuntirgene inilparvovec (uniQure)	Huntington's disease (HD)	Intracranial	• One-time intracranial therapy • Potential first disease-modifying therapy for HD • Estimated cost $2.5M-$3.5M	Q2 2027
Rexlemestrocel-L (Mesoblast)	Ischemic heart failure with reduced ejection fraction (HFrEF)	Intracardiac	• One-time intracardiac injection • If approved, would be first MPC therapy approved for heart failure • Estimated cost $150,000	2028

Abbreviations: MPC, mesenchymal precursor cells