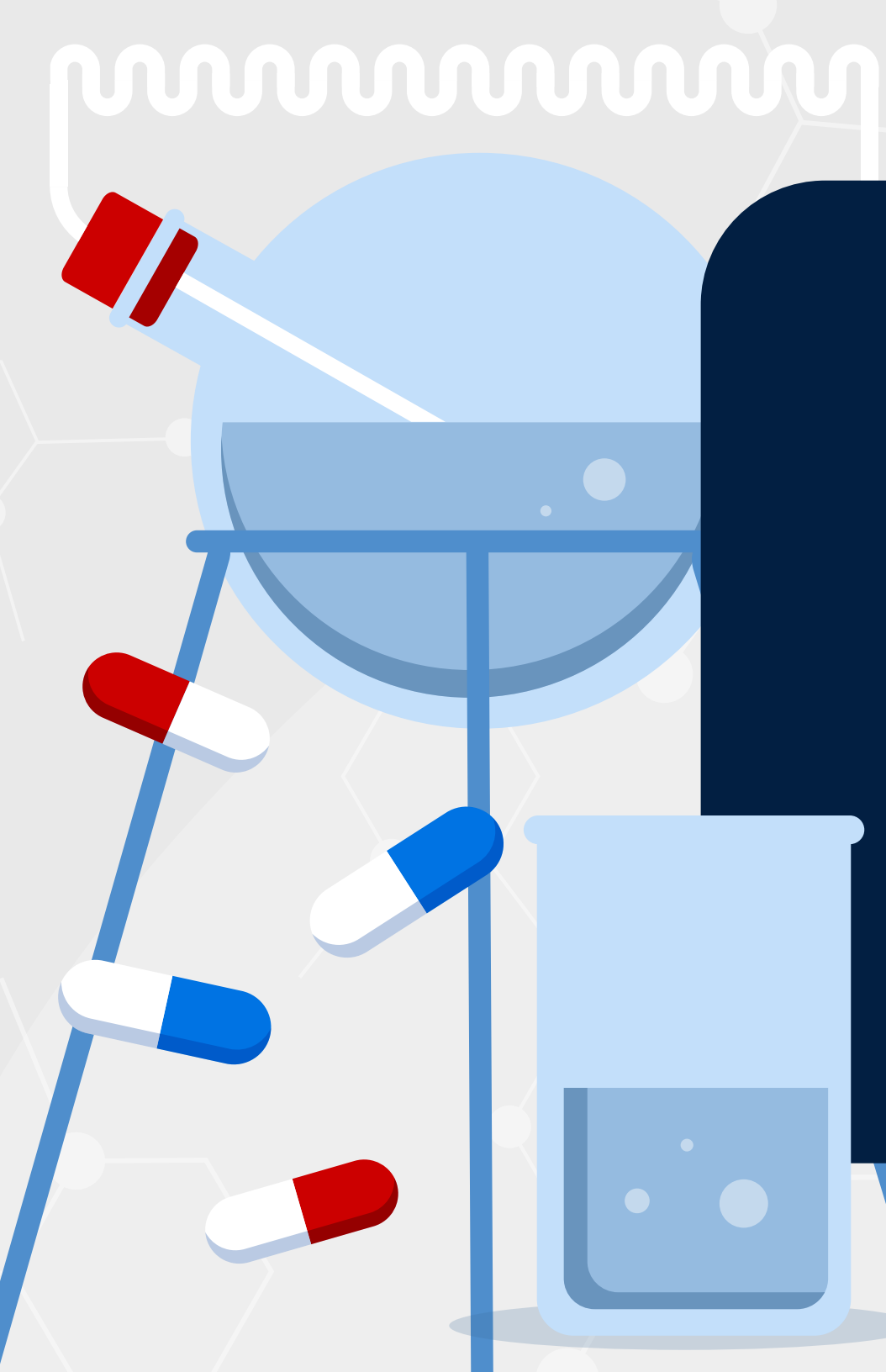

Pipeline Drugs to Watch Report

Q4 2024

Notable Upcoming Launches

CVS Health®

Specialty

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION AND MANUFACTURER[1]	PROPOSED INDICATION[1]	PHASE OF STUDY[1]	SELECT AVAILABLE FDA-APPROVED THERAPIES	COMMENTS
Amyloidosis	**acoramidis** Oral BridgeBio/Eidos Therapeutics	The treatment of transthyretin amyloidosis with cardiomyopathy	Pending FDA approval 11/29/2024	Vyndamax/Vyndaqel (tafamidis) oral **Pipeline agent:** Amvuttra (vutrisiran) SC (supplemental indication), Phase III, 2Q 2025	Acoramidis would provide an additional oral therapy option. **Anticipated impact:** Replacement spend, pharmacy benefit
Atopic Dermatitis	**Nemluvio** (nemolizumab-ilto) SC Galderma Laboratories	The treatment of moderate-to-severe atopic dermatitis in patients ages 12 years and older (supplemental indication)	Pending FDA approval 12/14/2024	**SC:** Adbry (tralokinumab-ldrm), Dupixent (dupilumab) **Pipeline agent:** lebrikizumab (pending FDA approval 09/15/2024) **Oral:** Cibinqo (abrocitinib), Rinvoq (upadacitinib) Numerous topical therapies may be used	Nemluvio would provide an additional SC therapy option with the potential for less frequent maintenance dosing as compared to Dupixent. **Anticipated impact:** Replacement spend, pharmacy benefit
Endocrine Disorders - Other	**crinecerfont** Oral Neurocrine Biosciences	The treatment of classic 21-hydroxylase deficiency congenital adrenal hyperplasia	Pending FDA approval 12/29/2024 (capsule) 12/30/2024 (oral solution)	Glucocorticoids, mineralocorticoids	Crinecerfont was granted Breakthrough Therapy designation. It would be added to existing glucocorticoid therapy as a steroid-sparing option and may reduce some of the complications associated with long-term glucocorticoid use. **Anticipated impact:** Incremental spend, pharmacy benefit

Specialty (continued)

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION AND MANUFACTURER[1]	PROPOSED INDICATION[1]	PHASE OF STUDY[1]	SELECT AVAILABLE FDA-APPROVED THERAPIES	COMMENTS
Hemophilia, Von Willebrand Disease & Related Bleeding Disorders	**Alhemo** (concizumab) SC Novo Nordisk Pharmaceuticals	The prevention of bleeding episodes in patients with hemophilia A and B with inhibitors	Pending FDA approval 12/03/2024	**Hemophilia A:** Various factor VIII products IV, FEIBA (anti-inhibitor coagulant complex) IV, Hemlibra (emicizumab) SC, Roctavian (valoctocogene roxaparvovec-rvox) IV - without inhibitors **Hemophilia B:** Various factor IX products IV, Hemgenix (etranacogene dezaparvovec-drlb) IV – without inhibitors, Beqvez (fidanacogene elaparvovec-dzkt) IV – without inhibitors	Alhemo was granted Breakthrough Therapy designation. It would provide the first agent for the prevention of bleeding episodes both in patients with hemophilia A or B with inhibitors and will be administered once daily. Alhemo is also pending FDA approval for the prevention of bleeding episodes in patients with hemophilia A and B without inhibitors and may be approved for this indication in 3Q 2025. **Anticipated impact:** Replacement spend, pharmacy benefit
	marstacimab SC Pfizer	The prevention of bleeding episodes in patients ages 12 years and older with severe hemophilia A or B without inhibitors	Pending FDA approval 10/11/2024		Marstacimab would provide the first agent for the prevention of bleeding episodes both in patients with hemophilia A or B without inhibitors. It would also be the first monoclonal antibody product for patients with hemophilia B without inhibitors and will be administered once weekly. Marstacimab is also in late-stage development for the prevention of bleeding episodes in patients with hemophilia A and B with inhibitors and may be approved for this indication in 4Q 2025. **Anticipated impact:** Replacement spend, pharmacy benefit
Hormonal Therapies	**Yorvipath** (palopegteriparatide) SC Acendis Pharma	The treatment of hypoparathyroidism	FDA approved 08/12/2024, Pending launch 4Q 2024	Oral calcium + vitamin D Natpara SC (parathyroid hormone): only available through a special use program that will be permanently discontinued by end 2024 due to ongoing manufacturing issues.	Formerly referred to as TransCon PTH. Anticipated availability in 4Q 2024 or 1Q 2025. Yorvipath is the only FDA-approved exogenous parathyroid hormone product and provides a treatment option for patients who fail to achieve an adequate response to calcium and vitamin D supplementation. **Anticipated impact:** Incremental spend, pharmacy benefit

Specialty (continued)

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION AND MANUFACTURER[1]	PROPOSED INDICATION[1]	PHASE OF STUDY[1]	SELECT AVAILABLE FDA-APPROVED THERAPIES	COMMENTS
Oncology - Injectable	**datopotamab deruxtecan** IV AstraZeneca/ Daiichi Sankyo	The treatment of previously treated advanced or metastatic non-squamous non-small cell lung cancer with or without actionable genomic alterations	Pending FDA approval 12/20/2024	IV chemotherapy (e.g., docetaxel)	Datopotamab deruxtecan would provide a novel mechanism of action for non-small cell lung cancer and an alternative to conventional IV chemotherapy with a lower incidence of severe adverse events. **Anticipated impact:** Incremental spend, medical benefit
Oncology - Oral	**inavolisib** oral Genentech/Roche	The first-line treatment of PIK3CA-mutant, HR-positive, HER2-negative breast cancer, in combination with Ibrance (palbociclib) and fulvestrant	Pending FDA approval 11/27/2024	An oral CDK 4/6 inhibitor (Ibrance [palbociclib], Kisqali [ribociclib], or Verzenio [abemaciclib]) in combination with either an oral aromatase inhibitor (anastrozole [e.g., Arimidex], letrozole [e.g., Femara], exemestane [e.g., Aromasin]) or fulvestrant IM; Truqap (capivasertib) oral in combination with fulvestrant IM	Inavolisib was granted Breakthrough Therapy designation. Inavolisib would be used in combination with a standard first-line regimen. **Anticipated impact:** Incremental spend, pharmacy benefit
	Scemblix (asciminib) oral Novartis	The first-line treatment of adults with Ph-positive chronic myeloid leukemia in chronic phase (supplemental indication)	Pending FDA approval 11/29/2024	Oral tyrosine kinase inhibitors: Bosulif (bosutinib), dasatinib (e.g., Sprycel), imatinib (e.g., Gleevec), Tasigna (nilotinib)	Scemblix was granted Breakthrough Therapy designation. Scemblix has evidence of improved efficacy as compared with standard of care tyrosine kinase inhibitors. **Anticipated impact:** Replacement spend, pharmacy benefit
	Tagrisso (osimertinib) oral AstraZeneca	Maintenance therapy in adults with locally advanced, unresectable EGFR-mutated non-small cell lung cancer whose disease has not progressed following definitive platinum-based chemoradiation therapy (supplemental indication)	Pending FDA approval 10/10/2024	Imfinzi (durvalumab) IV	Tagrisso was granted Breakthrough Therapy designation. Tagrisso would provide a targeted treatment option in a setting with limited treatment options. **Anticipated impact:** Replacement spend, pharmacy benefit

Specialty (continued)

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION AND MANUFACTURER[1]	PROPOSED INDICATION[1]	PHASE OF STUDY[1]	SELECT AVAILABLE FDA-APPROVED THERAPIES	COMMENTS
Psoriasis	**Bimzelx** (bimekizumab-bkzx) SC UCB	The treatment of non-radiographic axial spondyloarthritis (nrAS), active ankylosing spondylitis (AS), and psoriatic arthritis (PsA) (supplemental indications)	Pending FDA approval 10/15/2024	nrAS: Cimzia (certolizumab pegol) SC, Cosentyx (secukinumab) SC, Rinvoq (upadacitinib) oral, Taltz (ixekizumab) SC AS: adalimumab SC (e.g., Humira, biosimilars), Cimzia SC, Cosentyx SC, Enbrel (etanercept) SC, infliximab IV (e.g., Remicade, biosimilars), Rinvoq oral, Simponi SC/ Simponi Aria IV (golimumab), Taltz SC, Xeljanz/Xeljanz XR (tofacitinib) oral PsA: adalimumab SC, Cimzia SC, Cosentyx SC, Enbrel SC, infliximab IV, Orencia (abatacept) IV/SC, Otezla (apremilast) oral, Rinvoq oral, Simponi SC/Simponi Aria IV, Stelara (ustekinumab) SC, Skyrizi (risankizumab) SC, Taltz SC, Tremfya (guselkumab) SC, Xeljanz/ Xeljanz XR oral	Bimzelx would provide an additional therapy option for several autoimmune conditions. **Anticipated impact:** Replacement spend, pharmacy benefit
		The treatment of moderate-to-severe hidradenitis suppurativa (HS) (supplemental indication)	Pending FDA approval 12/04/2024	HS: adalimumab SC, Cosentyx SC	

Non-Specialty

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION AND MANUFACTURER[1]	PROPOSED INDICATION[1]	PHASE OF STUDY[1]	SELECT AVAILABLE FDA-APPROVED THERAPIES	COMMENTS
Antiobesity	**Zepbound** (tirzepatide) SC Eli Lilly	The treatment of moderate-to-severe obstructive sleep apnea in obese adults (supplemental indication)	Pending FDA approval 12/21/2024	None	Zepbound would be the first agent approved for the treatment of obstructive sleep apnea. It may be used in addition to positive airway pressure therapy. **Anticipated impact:** Incremental spend, pharmacy benefit
Antipsychotics	**KarXT** (xanomeline/ trospium) Oral Bristol-Myers Squibb/ Karuna Pharmaceuticals	The treatment of schizophrenia in adults	Pending FDA approval 09/26/2024 Anticipated launch 4Q 2024	Multiple first-generation ("typical") and second-generation ("atypical") antipsychotic agents are available in a variety of dosage formulations and routes of administration and with varying administration schedules.	KarXT would provide an alternative, twice-daily administered therapy option for schizophrenia. KarXT has a novel mechanism of action that may provide a differentiated safety profile from existing antipsychotics, many of which are available as generic products. **Anticipated impact:** Incremental spend, pharmacy benefit

Respiratory syncytial virus, or RSV, is a seasonal infectious disease that can pose serious health risks. There are new drugs in the pipeline to prevent RSV for a wide range of age groups. **Read our *Insights* post to learn more**.

First-time Biosimilars

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION AND MANUFACTURER(S)	REFERENCE PRODUCT AND MANUFACTURER	REFERENCE BRAND INDICATIONS	PROPOSED BIOSIMILAR INDICATION(S)	ANTICIPATED BIOSIMILAR LAUNCH	COMMENTS
Inflammatory Bowel Disease and Multiple Sclerosis	**Tyruko** (natalizumab-sztn) IV Sandoz	**Tysabri** (natalizumab) Biogen	• Relapsing forms of multiple sclerosis • Crohn's disease	• Relapsing forms of multiple sclerosis • Crohn's disease	4Q 2024	A biosimilar for Tysabri could launch as early as 4Q 2024. Timing of launch is dependent on FDA approval of a companion JC virus assay. Specialty product **Anticipated impact:** Replacement spend (potential for decreased spend), medical benefit

Abbreviations

FDA - U.S. Food and Drug Administration

SC - Subcutaneous

IM - Intramuscular

IV - Intravenous

1. RxPipeline, September 2024.