Pipeline Drugs to Watch Report

Q2 2025

Notable Upcoming Launches

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Specialty

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION AND MANUFACTURER	PROPOSED INDICATION	PHASE OF STUDY	SELECT AVAILABLE FDA-APPROVED THERAPIES	COMMENTS
Dermatological disorders – other	**Dupixent (dupilumab)** SC Regeneron Pharmaceuticals/ Sanofi	The treatment of chronic spontaneous urticaria in patients ages 12 years and older (supplemental indication)	Pending FDA approval 04/18/2025	Xolair (omalizumab) SC **Pipeline agent:** remibrutinib oral (Phase III; 4Q 2025)	Dupixent would provide an additional SC biologic treatment option for patients with an inadequate response to high-dose antihistamine-based therapy. **Anticipated impact:** Replacement spend, pharmacy benefit
Hereditary angioedema	**sebetralstat** Oral Kalvista Pharmaceuticals	The on-demand treatment of hereditary angioedema attacks in patients ages 12 years and older	Pending FDA approval 06/17/2025	**SC:** icatibant (e.g., Firazyr – adults), Kalbitor (ecallantide – ages 12+ years) **IV (no age limit):** Berinert (C1 esterase inhibitor [human]), Ruconest (C1 esterase inhibitor, recombinant)	Sebetralstat would be the first oral therapy option for the acute treatment of hereditary angioedema attacks **Anticipated impact:** Incremental spend, pharmacy benefit
Inflammatory bowel disease	**Tremfya (guselkumab)** IV & SC Janssen Pharmaceuticals/ Johnson & Johnson	The treatment of moderately-to-severely active Crohn's disease (supplemental indication)	Pending FDA approval 04/20/2025	adalimumab (e.g., Humira, biosimilars) SC, Cimzia (certolizumab pegol) SC, Entyvio (vedolizumab) IV/SC, infliximab (e.g., Remicade, biosimilars) IV, Omvoh (mirikizumab-mrkz) IV/SC, Rinvoq (upadacitinib) oral, Skyrizi (risankizumab-rzaa) IV/SC, Tysabri (natalizumab) IV, ustekinumab IV/SC (e.g., Stelara, biosimilars), Zymfentra (infliximab-dyyb) SC	Tremfya would be the fourth IL-23 inhibitor approved for Crohn's disease and would provide an alternative option for patients with moderately-to-severely active Crohn's disease. **Anticipated impact:** Replacement spend, pharmacy benefit

Specialty (continued)

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION AND MANUFACTURER	PROPOSED INDICATION	PHASE OF STUDY	SELECT AVAILABLE FDA-APPROVED THERAPIES	COMMENTS
Neuromuscular	**nipocalimab** IV Johnson & Johnson/ Momenta Pharmaceuticals	The treatment of generalized myasthenia gravis in adults	Pending FDA approval 04/29/2025	eculizumab (e.g., Soliris, biosimilars) IV, Rystiggo (rozanolixizumab-noli) SC, Ultomiris (ravulizumab-cwvz) IV, Vyvgart (efgartigimod alfa) IV, Vyvgart Hytrulo (efgartigimod alfa/ hyaluronidase-qvfc) SC, Zilbrysq (zilucoplan) SC **Pipeline agent:** Uplizna (inebilizumab-cdon, supplemental indication) IV, Phase III; 1Q 2026	Nipocalimab would provide an additional add-on therapy option for patients with refractory myasthenia gravis. **Anticipated impact:** Replacement spend, medical benefit
Oncology – oral/topical	**taletrectinib** Oral AnHeart Therapeutics/ Nuvation Bio	The treatment of locally advanced or metastatic ROS1-positive non-small cell lung cancer in adults	Pending FDA approval 06/23/2025	Augtyro (repotrectinib) oral, Rozlytrek (entrectinib) oral, Xalkori (crizotinib) oral Additional guideline supported therapies: Zykadia (ceritinib) oral, Lorbrena (lorlatinib) oral – later-line option only	Taletrectinib was granted Breakthrough Therapy designation. This approval would provide an additional first-line or later therapy option for patients with ROS1-positive non-small cell lung cancer. **Anticipated impact:** Replacement spend, pharmacy benefit
Pulmonary disorders	**Nucala (mepolizumab)** SC GlaxoSmithKline	The adjunctive treatment of severe chronic obstructive pulmonary disease (COPD) in patients with an eosinophilic phenotype (supplemental indication)	Pending FDA approval 05/07/2025	Biologics: Dupixent (dupilumab) SC	Nucala would provide an alternative biologic therapy option for patients with COPD. It would be used as an add-on to triple (or maximally tolerated) controller therapy. **Anticipated impact:** Replacement spend, pharmacy benefit

Specialty (continued)

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION AND MANUFACTURER	PROPOSED INDICATION	PHASE OF STUDY	SELECT AVAILABLE FDA-APPROVED THERAPIES	COMMENTS
Renal disease	**atrasentan** Oral AbbVie/Novartis	The treatment of immunoglobulin A nephropathy	Pending FDA approval 04/01/2025	Fabhalta (iptacopan) oral, Filspari (sparsentan) oral, Tarpeyo (budesonide) oral	Atrasentan would provide an alternative, later-line add-on therapy option in patients with inadequate proteinuria reduction from first-line angiotensin-converting enzyme inhibitor or angiotensin receptor blocker treatment. **Anticipated impact:** Replacement spend, pharmacy benefit
Rheumatoid arthritis	**Rinvoq (upadacitinib)** Oral AbbVie	The treatment of giant cell arteritis (supplemental indication)	Pending FDA approval 05/12/2025	tocilizumab (e.g., Actemra, biosimilars) IV/SC **Pipeline agent:** Cosentyx (secukinumab, supplemental indication) SC, Phase III; 3Q 2026	Rinvoq would be the first Janus kinase inhibitor approved to treat giant cell arteritis and would provide an oral therapy option. **Anticipated impact:** Incremental spend, pharmacy benefit

Non-Specialty

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION AND MANUFACTURER	PROPOSED INDICATION	PHASE OF STUDY	SELECT AVAILABLE FDA-APPROVED THERAPIES	COMMENTS
Dry eye disease	**acoltremon** Ocular Alcon Laboratories	The treatment of dry eye disease	Pending FDA approval 05/30/2025	Pharmacologic management of dry eye disease includes ocular lubricants (e.g., artificial tears, ointments), cyclosporine ocular (e.g., Restasis), Eysuvis (loteprednol etabonate) ocular, Miebo (perfluorohexyloctane) ocular, Tyrvaya (varenicline) nasal spray and Xiidra (lifitegrast) ocular.	Acoltremon and reproxalap would provide additional therapy options in novel drug classes for dry eye disease. **Anticipated impact:** Replacement spend, pharmacy benefit
	reproxalap Ocular Aldeyra Therapeutics		Pending FDA approval 04/02/2025		
Respiratory syncytial virus (RSV)	**clesrovimab** IM Merck	The prevention of lower respiratory tract infection due to RSV infection in patients ages birth to 1 year	Pending FDA approval 06/10/2025	Beyfortus (nirsevimab-alip) IM, Synagis (palivizumab) IM	Clesrovimab would provide an alternative to Beyfortus for the prevention of RSV lower respiratory tract disease in both healthy and at-risk infants entering their first RSV season and an alternative to Synagis in those who are at increased risk of severe RSV disease. Clesrovimab is intended to be administered in a single fixed dose, regardless of patient weight. **Anticipated impact:** Replacement spend, pharmacy benefit

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
Oncology – injectable and osteoporosis	**Jubbonti and Wyost** (denosumab-bbdz) SC Sandoz	**Prolia and Xgeva** (denosumab) [Amgen]	**Prolia** (denosumab) • Osteoporosis in postmenopausal women • Osteoporosis in men • Glucocorticoid-induced osteoporosis • Men receiving androgen deprivation therapy for nonmetastatic prostate cancer • Women receiving adjuvant aromatase inhibitor therapy for breast cancer **Xgeva** (denosumab) • Multiple myeloma and bone metastases from solid tumors • Giant cell tumor of bone • Hypercalcemia of malignancy	**Jubbonti, Ospomyv, Stoboclo** • Osteoporosis in postmenopausal women • Osteoporosis in men • Glucocorticoid-induced osteoporosis • Men receiving androgen deprivation therapy for nonmetastatic prostate cancer • Women receiving adjuvant aromatase inhibitor therapy for breast cancer **Wyost, Xbryk, Osenvelt** • Multiple myeloma and bone metastases from solid tumors • Giant cell tumor of bone • Hypercalcemia of malignancy	05/31/2025	Jubbonti and Wyost may be the first Prolia and Xgeva biosimilars to launch in May 2025. At least 10 additional biosimilars are awaiting FDA approval. Jubbonti, Wyost, Ospomyv and Xbryk are approved as interchangeable biosimilars. Unbranded versions may also be available from Samsung Bioepis. Specialty products **Anticipated impact:** Replacement spend (potential for decreased spend), pharmacy benefit
	Ospomyv and Xbryk (denosumab-dssb) SC Samsung Bioepis				2Q 2025	
	Stoboclo and Osenvelt (denosumab-bmwo) SC Celltrion				2Q 2025	
	denosumab SC Fresenius Kabi			Pending FDA approval 03/27/2025 Indications TBD	2Q 2025	

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FDA (U.S. Food and Drug Administration), SC (subcutaneous), IM (intramuscular), IV (intravenous).

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Source: RxPipeline, CVS Health Clinical Affairs. Information current as of March 17, 2025.

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