Pipeline Drugs to Watch Report

Q1 2025

Notable Upcoming Launches

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Specialty

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION AND MANUFACTURER[1]	PROPOSED INDICATION[1]	PHASE OF STUDY[1]	SELECT AVAILABLE FDA-APPROVED THERAPIES	COMMENTS
Cystic Fibrosis	**vanzacaftor/ tezacaftor/ deutivacaftor** Oral Vertex Pharmaceuticals	The treatment of cystic fibrosis in patients ages 6 years and older who have at least one F508del mutation or a mutation responsive to triple combination CFTR modulators	Pending FDA approval 01/02/2025	Kalydeco (ivacaftor) oral, Orkambi (lumacaftor/ ivacaftor) oral, Symdeko (tezacaftor/ivacaftor) oral, Trikafta (elexacaftor/ tezacaftor/ ivacaftor) oral	Vanzacaftor/tezacaftor/deutivacaftor would provide an alternative triple CFTR modulator to Trikafta. It may be priced at a slight premium to currently available CFTR modulators. **Anticipated impact:** Incremental spend, pharmacy benefit
Hemophilia, Von Willebrand Disease & Related Bleeding Disorders	**fitusiran** SC Genzyme/Sanofi	The prevention of bleeding episodes in patients ages 12 years and older with hemophilia A and B with and without inhibitors	Pending FDA approval 03/28/2025	**Hemophilia A:** Various factor VIII products IV, Hemlibra (emicizumab) SC, Roctavian (valoctocogene roxaparvovec-rvox) IV **Hemophilia B:** Various factor IX products IV, Hemgenix (etranacogene dezaparvovec-drlb) IV, Beqvez (fidanacogene elaparvovec-dzkt) IV **Hemophilia A and B:** FEIBA (anti-inhibitor coagulant complex) IV, Hympavzi (marstacimab-hncq) SC	Fitusiran was granted Breakthrough Therapy designation for patients with hemophilia B with inhibitors. It would be the first agent in a new class of drugs for hemophilia and would provide an additional therapy option for patients with hemophilia A or B regardless of inhibitor status. It is anticipated that fitusiran may require healthcare provider administration. **Anticipated impact:** Replacement spend, potential shift to medical benefit

A drug in the pipeline has the potential to become a new standard of care for cystic fibrosis, which affects more than 40,000 Americans. **Read our *Insights* post to learn more**.

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
Inflammatory Bowel Disease	**Omvoh** (mirikizumab-mrkz) IV & SC Eli Lilly	The treatment of moderately-to-severely active Crohn's disease (supplemental indication)	Pending FDA approval 01/15/2025	Adalimumab (e.g., Humira, biosimilars) SC, Cimzia (certolizumab pegol) SC, Entyvio (vedolizumab) IV/SC, infliximab (e.g., Remicade, biosimilars) IV, Rinvoq (upadacitinib) oral, Skyrizi (risankizumab-rzaa) IV/SC, ustekinumab SC (e.g., Stelara, biosimilars), Tysabri (natalizumab) IV, Zymfentra (infliximab-dyyb) SC	Omvoh would be the third IL-23 inhibitor for Crohn's disease and would provide an alternative SC option for patients with moderately-to-severely active Crohn's disease. **Anticipated impact:** Replacement spend, pharmacy benefit
Oncology - Injectable	**Enhertu** (fam-trastuzumab deruxtecan-nxki) IV AstraZeneca/ Daiichi Sankyo	The treatment of adults with unresectable or metastatic HR-positive, HER2-low or HER2-ultralow breast cancer who have received at least 1 endocrine therapy in the metastatic setting (supplemental indication)	Pending FDA approval 02/01/2025	Systemic chemotherapy, everolimus (e.g., Afinitor) oral + endocrine therapy (exemestane [e.g., Aromasin] oral, fulvestrant [e.g., Faslodex] IM, tamoxifen [e.g., Soltamox] oral)	Enhertu was granted Breakthrough Therapy designation. This approval would expand Enhertu use to chemotherapy-naïve patients in the metastatic setting, as well as to patients with HER2-ultralow tumors. **Anticipated impact:** Incremental spend, medical benefit
Oncology - Oral	**Calquence** (acalabrutinib) oral AstraZeneca/ Acerta Pharma	The first-line treatment of mantle cell lymphoma, in combination with bendamustine and rituximab (supplemental indication)	Pending FDA approval 02/03/2025	Systemic chemotherapy, bendamustine (e.g., Treanda) IV + rituximab (e.g., Rituxan, biosimilars) IV, lenalidomide (e.g., Revlimid) oral + rituximab IV, Calquence oral + rituximab IV	Calquence was granted Breakthrough Therapy designation. This approval would provide an additional regimen for previously untreated mantle cell lymphoma. **Anticipated impact:** Incremental spend, pharmacy benefit
	ensartinib oral Xcovery/Betta Pharmaceuticals	The treatment of metastatic ALK-positive non-small cell lung cancer in adults	Pending FDA approval 12/28/2024	Alecensa (alectinib) oral, Alunbrig (brigatinib) oral, Lorbrena (lorlatinib) oral, Xalkori (crizotinib) oral, Zykadia (ceritinib) oral	Ensartinib would provide an additional first- or second-line agent for metastatic ALK-positive non-small cell lung cancer. **Anticipated impact:** Replacement spend, pharmacy benefit

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
Analgesics	**suzetrigine** oral Vertex Pharmaceuticals	The treatment of moderate-to-severe acute pain	Pending FDA approval 01/30/2025	Opioid-containing analgesics (e.g., codeine +/- acetaminophen, fentanyl, hydrocodone +/- acetaminophen, hydromorphone, morphine, oxycodone +/- acetaminophen), tramadol oral	Suzetrigine was granted Breakthrough Therapy designation. Suzetrigine would provide a non-addictive, nonopioid alternative for the treatment of moderate-to-severe acute pain. **Anticipated impact:** Incremental spend, pharmacy benefit
Antidiabetics, Incretin Mimetic Agents	**Ozempic** (semaglutide) SC Novo Nordisk Pharmaceuticals	The treatment of diabetic nephropathy (supplemental indication)	Pending FDA approval 01/15/2025	Farxiga (dapagliflozin), Invokana (canagliflozin), Jardiance (empagliflozin), Kerendia (finerenone)	Ozempic would be the first GLP-1 receptor agonist approved to reduce the risk of progression of chronic kidney disease in patients with type 2 diabetes and would be added on to standard of care therapy. **Anticipated impact:** Incremental spend, pharmacy benefit
Antipsychotics	**Rexulti** (brexpiprazole) oral Lundbeck/ Otsuka America Pharmaceutical	The treatment of post-traumatic stress disorder in adults, in combination with sertraline (supplemental indication)	Pending FDA approval 02/08/2025	Fluoxetine (e.g., Prozac), paroxetine (e.g., Paxil), sertraline (e.g., Zoloft), venlafaxine (e.g., Effexor)	Rexulti would be the first antipsychotic approved for post-traumatic stress disorder, and would be added on to standard of care antidepressant therapy. **Anticipated impact:** Incremental 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
Inflammatory Bowel Disease	**Otulfi** (ustekinumab-aauz) IV/SC Fresenius Kabi/ Formycon	**Stelara** (ustekinumab) Biogen	Adults with: • Moderate-to-severe plaque psoriasis • Active psoriatic arthritis • Moderately-to-severely active Crohn's disease • Moderately-to-severely active ulcerative colitis Pediatrics ages 6 years and older with: • Moderate-to-severe plaque psoriasis • Active psoriatic arthritis	Adults with: • Moderate-to-severe plaque psoriasis • Active psoriatic arthritis • Moderately-to-severely active Crohn's disease • Moderately-to-severely active ulcerative colitis Pediatrics ages 6 years and older with: • Moderate-to-severe plaque psoriasis • Active psoriatic arthritis	02/22/2025	Wezlana may be the first Stelara biosimilar to launch in January 2025. Four additional biosimilars have been approved and at least 3 others are awaiting FDA approval. Up to 6 of these biosimilar products may be available in 1Q 2025. Wezlana and Pyzchiva are approved as interchangeable biosimilars. Specialty products **Anticipated impact:** Replacement spend (potential for decreased spend), pharmacy benefit
	Pyzchiva (ustekinumab-ttwe) IV/SC Sandoz/ Samsung Bioepis				02/22/2025	
	Selarsdi (ustekinumab-aekn) IV/SC Alvotech/Teva				02/21/2025	
	Wezlana (ustekinumab-auub) IV/SC Amgen				01/01/2025	
	Yesintek (ustekinumab-kfce) IV/SC Biocon				02/22/2025	
	ustekinumab IV/SC Celltrion			Pending FDA approval 12/30/2024 Indications TBD	03/07/2025	

First-time Biosimilars (continued)

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
Neuromuscular	**Bkemv** (eculizumab-aeeb) IV Amgen	**Soliris (eculizumab)** **Alexion/ AstraZeneca**	• Paroxysmal nocturnal hemoglobinuria • Atypical hemolytic uremic syndrome • Generalized myasthenia gravis • Neuromyelitis optica spectrum disorder	• Paroxysmal nocturnal hemoglobinuria • Atypical hemolytic uremic syndrome	03/01/2025	Two Soliris biosimilars could launch as early as 1Q 2025. Bkemv is approved as an interchangeable biosimilar. Specialty products **Anticipated impact:** Replacement spend (potential for decreased spend), medical benefit
	Epysqli (eculizumab-aagh) IV			• Paroxysmal nocturnal hemoglobinuria • Atypical hemolytic uremic syndrome • Generalized myasthenia gravis	1Q 2025	

Abbreviations

FDA - U.S. Food and Drug Administration

SC - Subcutaneous

IM - Intramuscular

IV - Intravenous

1. RxPipeline, November 2024.

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