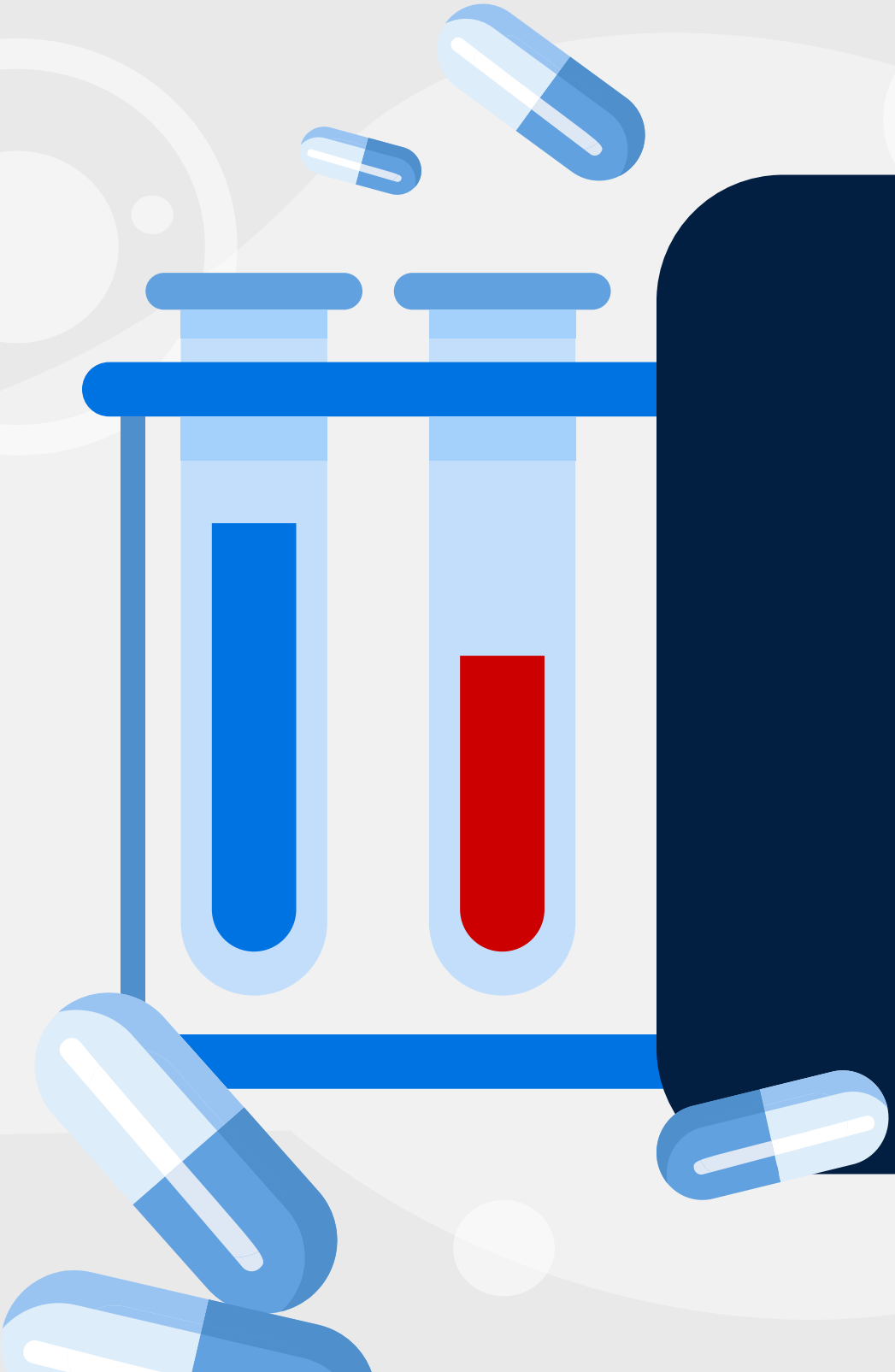

Pipeline Drugs to Watch Report

Q1 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
Alzheimer's Disease (AD)	**donanemab** intravenous (IV) Eli Lilly	The treatment of early symptomatic Alzheimer's disease	Pending FDA approval 03/15/2024	Aduhelm (aducanumab-avwa) IV, Leqembi (lecanemab-irmb) IV	Donanemab was granted Breakthrough Therapy designation and would provide an additional disease-modifying therapy for early AD. Donanemab requires less frequent administration (every 4 weeks) than Leqembi (every 2 weeks) and demonstrated improved plaque clearing as compared to Aduhelm. Like Aduhelm and Leqembi, donanemab would require brain MRI prior to, and during, therapy. **Anticipated impact:** Replacement spend, medical benefit
Gastrointestinal Disorders – Other	**budesonide** oral (new formulation) Takeda	The short-term treatment of eosinophilic esophagitis (EoE) in patients ages 11 years and older	Pending FDA approval 03/06/2024	Dupixent (for patients ≥12 years and weighing ≥40 kg) **Off-label:** proton pump inhibitors, topical glucocorticoids (e.g., swallowed fluticasone or budesonide)	Budesonide was granted Breakthrough Therapy designation and would be the first corticosteroid approved for the short-term treatment of EoE. **Anticipated impact:** Replacement spend, pharmacy benefit
	Dupixent (dupilumab) SC Regeneron/Sanofi	The treatment of EoE in patients ages 1 to 11 years (supplemental indication)	Pending FDA approval 01/31/2024		Dupixent would provide a biologic therapy option for pediatrics with EoE in this age range. **Anticipated impact:** Incremental spend, pharmacy benefit
	resmetirom oral Madrigal Pharmaceuticals	The treatment of non-alcoholic steatohepatitis (NASH) with liver fibrosis	Pending FDA approval 03/14/2024	None **Off-label:** vitamin E, Actos (pioglitazone) oral Weight loss is a key strategy	Resmetirom was granted Breakthrough Therapy designation and would be the first approved therapy to treat NASH. **Anticipated impact:** New 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	**lifileucel** IV Iovance Biotherapeutics	The treatment of unresectable or metastatic melanoma in adults who progressed on or after prior PD-1/L1 inhibitor therapy	Pending FDA approval 02/23/2024	**Second-line or later regimens:** Keytruda (pembrolizumab) IV or Opdivo (nivolumab) IV + Yervoy (ipilimumab) IV, Yervoy IV, high-dose Proleukin (aldesleukin) IV Oral combination regimens may be considered for patients with BRAF V600 mutations	Lifileucel is a novel cellular therapy that was granted Regenerative Medicine Advanced Therapy designation. It would provide a second-line or later therapy for metastatic disease after failure of PD-1/L1 and BRAF/MEK inhibitors, if applicable. **Anticipated impact:** Replacement spend, medical benefit
Oncology – Oral	**Tagrisso** (osimertinib) oral AstraZeneca	The first-line treatment of adults with locally advanced or metastatic EGFR-mutated non-small cell lung cancer, in combination with chemotherapy (supplemental indication)	Pending FDA approval 02/16/2024	**First-line regimens:** Tagrisso monotherapy, Tarceva (erlotinib), Gilotrif (afatinib), Iressa (gefitinib), Vizimpro (dacomitinib)	Tagrisso in combination with chemotherapy was granted Breakthrough Therapy designation and would provide a more effective combination regimen alternative to Tagrisso monotherapy for first-line use. **Anticipated impact:** Replacement spend, pharmacy benefit
Pulmonary Arterial Hypertension (PAH)	**sotatercept** SC Merck	The treatment of symptomatic PAH in adults, as an add-on to stable background therapy	Pending FDA approval 03/26/2024	**Inhaled:** Ventavis (iloprost), Tyvaso/ Tyvaso DPI (treprostinil) **Injectable:** epoprostenol (e.g., Flolan, Veletri), Remodulin (treprostinil) **Oral:** Adempas (riociguat), Letairis (ambrisentan), Opsumit (macitentan), Orenitram (treprostinil), Tracleer (bosentan), sildenafil (e.g., Liqrev, Revatio), tadalafil (e.g., Adcirca, Tadliq), Uptravi (selexipag)	Sotatercept was granted Breakthrough Therapy designation and would provide the first potentially disease-modifying therapy in PAH; it would be used in addition to standard background therapy. **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
Sickle Cell Disease (SCD)	**exagamglogene autotemcel** IV CRISPR Therapeutics/ Vertex Pharmaceuticals	The treatment of sickle cell disease in patients ages 12 years and older with recurrent vaso-occlusive crises	Pending FDA approval 12/08/2023 Launch anticipated Q1 2024	Adakveo (crizanlizumab-tmca) IV, Endari (L-glutamine) oral, hydroxyurea (e.g., Droxia, Siklos) oral, Oxbryta (voxelotor) oral HLA-matched sibling allogeneic hematopoietic stem cell transplantation (HSCT)	Exagamglogene autotemcel and lovotibeglogene autotemcel would be the first gene therapies approved for SCD. Both agents were granted Regenerative Medicine Advanced Therapy designation. They would represent potentially curative options for patients who have severe disease despite treatment with hydroxyurea and do not have a matched donor for HSCT. **Anticipated impact:** Incremental spend, medical benefit
	lovotibeglogene autotemcel IV bluebird bio		Pending FDA approval 12/20/2023 Launch anticipated Q1 2024		

Sotatercept has the potential to reverse the characteristic vascular remodeling commonly seen in patients with Pulmonary Arterial Hypertension (PAH). It could alter the course of PAH for 45,000 U.S. patients.

Read our Insights post, "**A New Breakthrough Therapy for Pulmonary Arterial Hypertension**," to learn more.

1. RxPipeline, December 2023.

*U.S. Food and Drug Administration

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