Pipeline Drugs to Watch Report

Q3 2023

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
Atopic Dermatitis (AD)	**lebrikizumab** SC Eli Lilly	The treatment of moderate-to-severe AD in patients ages 12 years and older	Pending FDA approval 09/20/2023	**SC:** Adbry (tralokinumab-ldrm), Dupixent (dupilumab) **Oral:** Cibinqo (abrocitinib), Rinvoq (upadacitinib) Numerous topical therapies may be used.	Lebrikizumab would provide an additional SC option with the potential for less frequent maintenance dosing as compared to Dupixent. **Anticipated impact:** Replacement spend, pharmacy benefit
Lysosomal Storage Disorders	**cipaglucosidase alfa** IV Amicus Therapeutics **miglustat** oral Amicus Therapeutics	The combination treatment of late-onset Pompe disease (glycogen storage disease type II) in adults	Pending FDA approval 08/15/2023	Lumizyme (alglucosidase alfa) IV, Nexviazyme (avalglucosidase alfa-ngpt) IV	The combination of cipaglucosidase alfa and miglustat was granted Breakthrough Therapy designation and would provide an additional therapy option. **Anticipated impact:** cipaglucosidase alfa: Replacement spend, medical benefit miglustat: Incremental spend, pharmacy benefit
Mental Health Disorders	**zuranolone** oral Biogen/Sage Therapeutics	The treatment of major depressive disorder (MDD) when an acute rapid response is needed, in combination with new standard antidepressant therapy The episodic treatment of MDD The treatment of severe postpartum depression	Pending FDA approval 08/05/2023	Spravato (esketamine) intranasal Oral: Numerous agents, including SSRIs and SNRIs Zulresso (brexanolone) IV	Zuranolone was granted Breakthrough Therapy designation for MDD. It would provide an oral, rapid-acting option for short course therapy (14 days). Specialty designation TBD **Anticipated impact:** Incremental spend, pharmacy benefit

Specialty (continued)

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Movement Disorders	**Ingrezza** (valbenazine) oral Neurocrine Biosciences	The treatment of chorea in patients with Huntington's disease (supplemental indication)	Pending FDA approval 08/20/2023	Austedo/Austedo XR (deutrabenazine) oral, Xenazine (tetrabenazine) oral	Ingrezza would provide an additional once-daily therapy option that lacks boxed warnings. **Anticipated impact:** Replacement spend, pharmacy benefit
Oncology – Oral	**quizartinib** oral Daiichi Sankyo	The treatment of newly diagnosed acute myeloid leukemia in patients with the FLT3-ITD mutation, in combination with induction and consolidation chemotherapy	Pending FDA approval 07/24/2023	Rydapt (midostaurin) oral	Quizartinib would provide an alternative therapy option to Rydapt. **Anticipated impact:** Replacement spend, pharmacy benefit
Psoriasis	**Cosentyx** (secukinumab) SC Novartis	The treatment of moderate-to-severe hidradenitis suppurativa (supplemental indication)	Pending FDA approval 09/15/2023	adalimumab SC (e.g., Humira, Amjevita and other biosimilars)	Cosentyx would provide an additional SC therapy option with the potential for less frequent dosing. **Anticipated impact:** Replacement spend, pharmacy benefit
Respiratory Syncytial Virus (RSV)	**Beyfortus** (nirsevimab) IM AstraZeneca/Sanofi	The prevention of RSV infection in newborns and infants entering or during their first RSV season, and for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season	Pending FDA approval 07/05/2023	Synagis (palivizumab) IM: prevention of RSV in high-risk premature or immunocompromised infants	Beyfortus was granted Breakthrough Therapy designation and would provide the first preventive therapy option for use in all infants, regardless of risk status, across the RSV season with a single dose. **Anticipated impact:** Incremental spend, pharmacy benefit

RSV cases in infants and children have risen in recent years, and have become more serious, causing 58,000–80,000 hospitalizations each year. Currently there is no vaccine approved for use in young children in the United States, but promising research is underway.

Read our Insights post, **"Protecting Infants and Young Children from RSV,"** to learn more.

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
Anaphylaxis Treatment Agents	**Neffy** (epinephrine) intranasal Recordati/ARS Pharmaceuticals	The emergency treatment of type I allergic reactions including anaphylaxis in adults and children weighing at least 30 kg	Pending FDA approval 06/21/2023	Intramuscular epinephrine products: Auvi-Q, EpiPen, Symjepi, Adrenaclick and generics	Neffy would provide the only epinephrine product for acute management of allergic reactions that does not require an injection for administration. **Anticipated impact:** Replacement spend, pharmacy benefit
Antidiabetics	**Jardiance** (empagliflozin) oral Boehringer Ingelheim/ Eli Lilly	The risk reduction of kidney disease progression and cardiovascular death in adults with chronic kidney disease (supplemental indication)	Pending FDA approval 09/20/2023	Farxiga (dapagliflozin) oral, Invokana (canagliflozin) oral, Kerendia (finerenone) oral, numerous oral angiotensin converting enzyme inhibitors and angiotensin receptor blockers	Jardiance will provide an additional oral therapy option for the prevention of the progression of kidney disease. **Anticipated impact:** Replacement spend, pharmacy benefit
Contraceptives	**Opill** (norgestrel) oral HRA Pharma/Perrigo Pharmaceuticals	The prevention of pregnancy	Pending FDA approval 08/11/2023	Numerous oral, implanted, injectable, intravaginal, and topical hormonal contraceptive products available by prescription only	Opill would be the first hormonal contraceptive agent available over the counter (without a prescription). **Anticipated impact:** Replacement spend (potential for decreased spend), pharmacy benefit
Ophthalmic – Anti-infectives	**lotilaner** ocular Tarsus Pharmaceuticals	The treatment of *Demodex* blepharitis	Pending FDA approval 08/25/2023	None	Lotilaner would be the first FDA-approved treatment for *Demodex* blepharitis. **Anticipated impact:** New spend, pharmacy benefit

Non-Specialty (continued)

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Vaccines	**Arexvy** (RSV vaccine, recombinant, adjuvanted) IM GlaxoSmithKline	The prevention of lower respiratory tract disease (LRTD) due to RSV infection in patients ages 60 years and older	Approved 05/03/2023	Abrysvo, Arexvy	Arexvy and Abrysvo were granted Breakthrough Therapy designation and are the first vaccines approved for the prevention of RSV-associated LRTD in older adults. **Anticipated impact:** New spend; mixed medical/pharmacy benefit
	Abrysvo (RSV vaccine) IM Pfizer		Approved 05/31/2023		
		The prevention of RSV-associated LRTD in infants from birth up to 6 months of age by active immunization of pregnant women	Pending FDA approval 08/21/2023	Synagis (palivizumab) IM: for certain high-risk patients ages 2 years and younger	Abrysvo was granted Breakthrough Therapy designation and would provide an option to prevent RSV-associated LRTD in all infants prior to birth and regardless of risk status. **Anticipated impact:** New spend; mixed medical/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, Psoriasis, Rheumatoid Arthritis	**Abrilada** (adalimumab-afzb) SC Pfizer	Humira (adalimumab) AbbVie	The treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, and plaque psoriasis in adults, the treatment of juvenile idiopathic arthritis and uveitis in patients ages 2 years and older, the treatment of Crohn's disease in patients ages 6 years and older, and the treatment of hidradenitis suppurativa in patients ages 12 years and older	The treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, and plaque psoriasis in adults, the treatment of juvenile idiopathic arthritis in patients ages 2 years and older, and the treatment of Crohn's disease in patients ages 6 years and older	July 2023	Amjevita (adalimumab-atto, Amgen) was the first biosimilar to launch in January 2023. Eight additional adalimumab biosimilar products have been approved and at least one other is awaiting FDA approval. All of these biosimilars may be available in 2023. Cyltezo is approved as an interchangeable biosimilar. Abrilada and adalimumab [Alvotech/Teva] are pending FDA approval for interchangeable status. Specialty products **Anticipated impact:** Replacement spend (potential for decreased spend), pharmacy benefit
	Hadlima (adalimumab-bwwd) SC Samgsung Bioepis/ Organon				07/01/2023	
	Hulio (adalimumab-fkip) SC Biocon/Viatris				07/31/2023	
	Idacio (adalimumab-aacf) SC Fresenius Kabi				July 2023	

Nine biosimilars are expected to launch in the U.S. in July 2023.

First-time Biosimilars (continued)

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Inflammatory Bowel Disease, Psoriasis, Rheumatoid Arthritis	**Cyltezo** (adalimumab-adbm) SC Boehringer Ingelheim	Humira (adalimumab) AbbVie	The treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, and plaque psoriasis in adults, the treatment of juvenile idiopathic arthritis and uveitis in patients ages 2 years and older, the treatment of Crohn's disease in patients ages 6 years and older, and the treatment of hidradenitis suppurativa in patients ages 12 years and older	The treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, plaque psoriasis, and hidradenitis suppurativa in adults, the treatment of juvenile idiopathic arthritis in patients ages 2 years and older, and the treatment of Crohn's disease in patients ages 6 years and older	07/01/2023	Amjevita (adalimumab-atto, Amgen) was the first biosimilar to launch in January 2023. Eight additional adalimumab biosimilar products have been approved and at least one other is awaiting FDA approval. All of these biosimilars may be available in 2023. Cyltezo is approved as an interchangeable biosimilar. Abrilada and adalimumab [Alvotech/Teva] are pending FDA approval for interchangeable status. Specialty products **Anticipated impact:** Replacement spend (potential for decreased spend), pharmacy benefit
	Hyrimoz (adalimumab-adaz) SC Novartis/ Sandoz				07/01/2023	
	Yuflyma (adalimumab-aaty) SC Celltrion				July 2023	
	Yusimry (adalimumab-aqvh) SC Coherus BioSciences				07/01/2023	
	adalimumab SC Alvotech/ Teva			Pending FDA approval 06/28/2023 Indications TBD	07/01/2023	

Visit our website for more insights on the active drug pipeline.

1. RxPipeline, May 2023.

*U.S. Food and Drug Administration

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