

2023 Drug Pipeline

(current as of 2/7/2023)

Drug Name	Disease	Manufacturer	Details
Lecanemab	Alzheimer's	Eisai/Biogen	Awaiting Approval
Donanemab	Alzheimer's	Eli Lilly	Awaiting Approval
Gantenerumab	Alzheimer's	Genentech	Primary Endpoint Unmet
CTX001™	Severe sickle cell anemia and transfusion dependent beta thalassemia	Vertex and CRISPR Therapeutics	For sickle cell anemia patients, this could help reduce or eliminate vaso-occlusive crisis, a painful complication of the disease. For transfusion-dependent beta thalassemia, the medication may help reduce the need for lifelong, regular blood transfusions.
Hemgenix	Hemophilia B	CSL Behring	One of the first approvals in the blood disorder category, specifically for Hemophilia B.
Roctavian	Hemophilia A	Biomarin Pharmaceuticals	Awaiting Approval (Spring)
Lenacapavir	HIV	Gilead	First-in-class capsid inhibitor without any known cross-resistance to other existing drug classes. The long-acting injectable will need to be administered by a health care professional every 6 months.
Zuranolone	Major Depressive Disorder and Post-Partum Depression	Sage Therapeutics and Biogen	Awaiting Approval If approved, this will be the first oral medication to be indicated to treat post-partum depression.

Omidubicel	Blood Cancer	Gamida Cell	Omidubicel has received "Breakthrough Therapy Designation" and "Orphan Drug Designation" from the FDA. This will be the first allogeneic advanced stem cell therapy donor source for patients with blood cancers who are unable to find a stem cell transplant match.
Amjevita	Rheumatoid arthritis; psoriatic arthritis; ankylosing spondylitis; Crohn's disease; ulcerative colitis; plaque psoriasis	Amgen	FDA-approved biosimilar version of adalimumab (Humira). Citrate Free. Possible U.S. Launch Date: 01/31/2023
Hadlima	Rheumatoid arthritis; juvenile idiopathic arthritis; psoriatic arthritis; ankylosing spondylitis; Crohn's disease; ulcerative colitis; plaque psoriasis	Organon/ Samsung Bioepis	FDA-approved biosimilar version of adalimumab (Humira). Citrate Free. High concentration. (Another version also available that is not Citrate free) Possible U.S. Launch Date: 6/30/2023
Hukyndra	Rheumatoid arthritis; juvenile idiopathic arthritis; axial spondylarthritis; psoriatic arthritis; psoriasis; pediatric plaque psoriasis; hidradenitis suppurativa; Crohn's disease; ulcerative colitis; uveitis	Alvotect/Teva	Under review- PDUFA Date: Dec 2022 biosimilar version of adalimumab (Humira). Citrate Free. Possible U.S. Launch Date: 07/01/2023
Cyltezo	Rheumatoid arthritis; polyarticular juvenile idiopathic arthritis; psoriatic arthritis; ankylosing spondylitis; Crohn's disease; ulcerative colitis; plaque psoriasis	Boehringer Ingelheim	FDA-approved biosimilar version of adalimumab (Humira). Citrate Free. Possible U.S. Launch Date: 07/01/2023
Yusimry	Rheumatoid arthritis; juvenile idiopathic arthritis; psoriatic arthritis; ankylosing spondylitis; Crohn's disease; ulcerative colitis; plaque psoriasis	Coherus BioSciences	FDA-approved biosimilar version of adalimumab (Humira). Citrate Free Possible U.S. Launch Date: 07/01/2023

Hulio	Rheumatoid arthritis; ankylosing spondylitis; psoriatic arthritis; plaque psoriasis; hidradenitis suppurativa; Crohn's disease; ulcerative colitis; uveitis; polyarticular juvenile idiopathic arthritis	Viartis	FDA-approved biosimilar version of adalimumab (Humira). Citrate Free. Possible U.S. Launch Date: 07/31/2023
Hyrimoz	Ankylosing spondylitis; Crohn's disease, plaque psoriasis; polyarticular juvenile idiopathic arthritis; psoriatic arthritis; rheumatoid arthritis; ulcerative colitis	Novartis/Sandoz	FDA-approved biosimilar version of adalimumab (Humira). Not Citrate Free. (A Citrate free version is under review.) Possible U.S. Launch Date: 07/01/2023
MSB11022 (Idacio in Europe)	Rheumatoid arthritis; plaque psoriasis; Crohn's disease, ulcerative colitis; psoriatic; hidradenitis suppurativa; ankylosing spondylitis, juvenile idiopathic arthritis; uveitis	Fresenius Kabi	Under review-PDUFA Date: Jan-Feb 2023 biosimilar version of adalimumab (Humira). Citrate information unavailable. Possible U.S. Launch Date: 09/30/2023
Simlandi	Rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa; plaque psoriasis; uveitis	Alvotech and JAMP	FDA-approved biosimilar version of adalimumab (Humira). High Concentration. Citrate Free. Possible U.S. Launch Date: TBD
Yuflyma	Rheumatoid arthritis; axial spondylarthritis; psoriasis; psoriatic arthritis; Crohn's disease, hidradenitis suppurativa; ulcerative colitis; uveitis; plaque psoriasis	Celltrion	Under review-PDUFA Date: Aug 2023 biosimilar version of adalimumab (Humira). High Concentration. Citrate Free. Potential U.S. Launch Date: 12/15/2023
Abrilada	Rheumatoid arthritis; idiopathic arthritis; psoriatic arthritis; ankylosing spondylitis; Crohn's disease; ulcerative colitis; hidradenitis suppurativa; uveitis	Pfizer	FDA-approved biosimilar version of adalimumab (Humira). Citrate Free. Possible U.S. Launch Date: 07/01/2023