

New Drug Report 1st Quarter 2022



First time generic approvals

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Generic Drug Name	Brand Name	Therapeutic Category	Indication / Use
Mixed Salts of a Single-Entity Amphetamine Product Extended-Release Capsules	Mydayis ExtendedRelease Capsules	Central Nervous System Stimulant	For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older
Brimonidine Tartrate Ophthalmic Solution	Alphagan P Ophthalmic Solution	Ophthalmic Agent	For the reduction of elevated intraocular pressure (IOP) in patients with openangle glaucoma or ocular hypertension
Sofosbuvir Tablets	Sovaldi Tablets	Antihepaciviral Agent	For the treatment of adult patients with genotype 1, 2, 3 or 4 chronic HCV infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen
Carbidopa, Levodopa and Entacapone Tablets	Stalevo Tablets	Anti-Parkinson's Agent	For the treatment of Parkinson's disease
Pirfenidone Tablets	Esbriet Tablets	Anti-inflammatory Agent; Antifibrotic Agent	For the treatment of idiopathic pulmonary fibrosis

New brand name drug approvals

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Drug Name	Manufacturer	Therapeutic Category	Indication / Use
Vonjo	CTI BioPharma	Antineoplastic Agent	To treat intermediate or high-risk primary or secondary myelofibrosis in adults with low platelets
Pyrukynd	Agios	Pyruvate Kinase Activator	To treat hemolytic anemia in pyruvate kinase deficiency
Enjaymo	Sanofi	Complement Inhibitor; Monoclonal Antibody	To decrease the need for red blood cell transfusion due to hemolysis in cold agglutinin disease
Vabysmo	Genentech	Ophthalmic Agent	To treat neovascular (wet) aged-related macular degeneration and diabetic macular edema
Kimtrak	Immunocore	Antineoplastic Agent	To treat unresectable or metastatic uveal melanoma
Cibinqo	Pfizer	Janus Kinase Inhibitor	To treat refractory, moderate-to-severe atopic dermatitis
Quviviq	Indorsia	Hypnotic; Orexin Receptor Antagonist	To treat insomnia

Key pipeline drugs with FDA approval decisions expected by the end of the 2nd Quarter (ss&c pipeline review q1 2022)

Drug Name	Manufacturer	Indication/ Use	Estimated Release Date
Fintepla	Zogenix	Lennox-Gastaut syndrome	3/25/2022
Reblozyl	Acceleron; Bristol-Myers Squibb; Celgene	Beta thalassemia*; Myelodysplastic syndromes*; Nontransfusion-dependent thalassemia (NTDT)	3/27/2022
Aliqopa	Bayer	Chronic lymphocytic leukemia; Waldenstrom's macroglobulinemia; Follicular lymphoma; Marginal zone lymphoma (MZL)	4/2022
Kymriah	Kymriah	Follicular lymphoma	4/2022
Yescarta	Gilead; Kite Pharma	B-cell lymphoma	4/1/2022
Opzelura	Incyte	Vitiligo	4/18/2022
Tyvaso	MannKind Corporation; United Therapeutics	Pulmonary arterial hypertension; Lung diseaseassociated pulmonary hypertension	5/2022
Vabysmo	Roche	Wet age-related macular degeneration*; Diabetic macular edema*; Diabetic retinopathy	5/2022
Radicava	Mitsubishi Tanabe	Lou Gehrig's disease (amyotrophic lateral sclerosis (ALS))	5/12/2022

Resources

SS&C PIPELINE REVIEW QUARTER 1 2022

<https://biopharma.media/quviviq-new-sleeping-pill-3201/>

<https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals>

<https://www.goodrx.com/abrocitinib/fda-approves-cibinqo>

<https://www.thepharmaletter.com/article/despite-hefty-price-immunocore-s-kimmtrak-will-dominate-uveal-melanoma-market>

<https://ir.immunocore.com/news-releases/news-release-details/immunocore-announces-fda-approval-kimmtrakr-tebentafusp-tebn#:~:text=The%20company%20is%20ready%20to,the%20FDA%20in%20February%202021.>

<https://www.biopharmadive.com/news/roche-vabysmo-fda-approval-eye-drug-regeneron/618032/>

<https://www.sanofi.com/en/media-room/press-releases/2022/2022-02-04-23-00-00-2379517#:~:text=Enjaymo%20is%20administered%20intravenously%20weekly,Enjaymo%20is%20%241%2C800%20per%20vial.>

<https://medcitynews.com/2022/02/sanofi-drug-enjaymo-wins-fda-approval-to-treat-anemia-from-rare-blood-disorder/#:~:text=Patients%20weighing%20between%2039%20kg,the%20therapy%20comes%20to%20%24280%2C800.>

<https://www.globenewswire.com/news-release/2022/02/17/2387542/0/en/Agios-Announces-FDA-Approval-of-PYRUKYND-mitapivat-as-First-Disease-Modifying-Therapy-for-Hemolytic-Anemia-in-Adults-with-Pyruvate-Kinase-Deficiency.html>

<https://www.evaluate.com/vantage/articles/news/pricing/agios-pricing-dilemma#:~:text=Agios%20has%20a%20newly%20approved,Pyrukynd%20at%20%24334%2C880%20a%20year.>

<https://www.fiercepharma.com/pharma/cti-clinches-long-awaited-approval-myelofibrosis-blockbuster-waiting-vonjo#:~:text=CTI%20is%20primed%20for%20Vonjo's,a%20call%20with%20investors%20Tuesday.>

<https://fco.factsandcomparisons.com/lco/action/home>

<https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022>

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