



Q3 2025 Upcoming FDA Decision Dates (PDUFAs)

DATE	COMPANY NAME	DRUG NAME	USE/THERAPEUTIC AREA
07-10-2025	Regeneron Pharmaceuticals	Linvoseltamab	Relapsed/Refractory Multiple Myeloma
07-22-2025	Replimune	RP1 (vusolimogene oderparepvec)	Advanced melanoma
07-24-2025	Sobi North America	Avatrombopag	Immune thrombocytopenia
07-27-2025	Ascendis Pharma & Royalty Pharma	Skytrofa	Growth hormone deficiency
07-28-2025	Apellis Pharmaceuticals	Empaveli (pegcetacoplan)	C3G and primary IC-MPGN
07-29-2025	PTC Therapeutics	Sepiapterin	Phenylketonuria (PKU)
07-30-2025	Regeneron Pharmaceuticals	Odronextamab	Follicular lymphoma
07-31-2025	Novo Nordisk	Alhemo (concizumab)	Hemophilia A or B without inhibitors
08-06-2025	Jazz Pharmaceuticals	Dordaviprone (Modeyso)	H3 K27M-mutant diffuse midline glioma

08-08-2025	LENZ Therapeutics	LNZ100	Presbyopia
08-09-2025	PharmaTher	Ketamine	Anesthesia, sedation, pain, mental health, and neurological indications
08-12-2025	Insmed	Brensocatib	Bronchiectasis
08-15-2025	Tonix Pharmaceuticals	TNX-102 SL	Fibromyalgia
08-18-2025	Ultragenyx & Abeona Therapeutics	UX111	Treat Sanfilippo Syndrome Type A (MPS IIIA)
08-19-2025	Regeneron Pharmaceuticals & Bayer	EYLEA HD® (aflibercept) Injection 8 mg	Macular Edema Following Retinal Vein Occlusion (RVO)
08-19-2025	PTC Therapeutics	Vatiquinone	Friedreich's ataxia
08-21-2025	Ionis Pharmaceuticals & Theratechnologies	Donidalorsen	Hereditary Angioedema
08-27-2025	Precigen	PRGN-2012 (zopapogene imadenovec)	Recurrent Respiratory Papillomatosis (RRP)
08-27-2025	Outlook Therapeutics	ONS-5010	Wet age-related macular degeneration
08-28-2025	Traverse Therapeutics	Filspari	Immunoglobulin A nephropathy (IgAN)
08-29-2025	Sanofi	Rilzabrutinib	Immune thrombocytopenia (ITP)

08-31-2025	Capricor Therapeutics	Deramiocel	Duchenne muscular dystrophy
08-31-2025	Biogen & Eisai	LEQEMBI subcutaneous autoinjector	Early Alzheimer's
09-12-2025	BioCryst Pharmaceuticals	Orladeyo (berotralstat)	UHereditary Angioedema (HAE)
09-19-2025	Incyte Corporation	Ruxolitinib cream	Atopic Dermatitis in pediatric patients
09-22-2025	Scholar Rock	Apitegromab	Spinal muscular atrophy
09-22-2025	Biogen	SPINRAZA	Spinal muscular atrophy
09-23-2025	Merck & Co Inc.	Subcutaneous Keytruda	Non-small cell lung cancer (NSCLC)
09-25-2025	Omeros Corp.	Narsoplimab	Hematopoietic stem cell transplant-associated thrombotic microangiopathy
09-25-2025	Crinetics Pharmaceuticals	Paltusotine	Acromegaly
09-28-2025	Sanofi	Tolebrutinib	Multiple sclerosis
09-30-2025	Fortress Biotech and Cyprium Therapeutics	CUTX-101 (Copper Histidinate)	Menkes disease