



Q4 2025 Upcoming FDA Decision Dates (PDUFAs)

DATE	COMPANY NAME	DRUG NAME	USE/THERAPEUTIC AREA
10-07-2025	Boehringer Ingelheim	Jascayd (nerandomilast)	Idiopathic Pulmonary Fibrosis
10-07-2025	Jazz Pharmaceuticals	Zepzelca (lurbinectedin) and Atezolizumab (Tecentriq)	Extensive-Stage Small-Cell Lung Cancer
10-07-2025	Regeneron Pharmaceuticals	Libtayo (cemiplimab-rwlc)	High-risk cutaneous squamous cell carcinoma
10-19-2025	AstraZeneca and Amgen	Tezspire (tezepelumab)	Chronic Rhinosinusitis With Nasal Polyps
10-19-2025	Roche	Gazyva/Gazyvaro (obinutuzumab)	Lupus nephritis
10-20-2025	Glaukos	Epioxa	Keratoconus
10-23-2025	GSK	Blenrep combinations	Multiple myeloma
10-24-2025	Bayer	Elinzanetant	Moderate-to-severe vasomotor symptoms (VMS) associated with menopause
10-25-2025	Merck	Winrevair (sotatercept-csrk)	Pulmonary arterial hypertension

10-25-2025	Syndax Pharma	Revuforj	Relapsed or refractory mutant NPM1 acute myeloid leukemia
11-18-2025	Arrowhead Pharmaceuticals	Plozasiran	Familial chylomicronemia syndrome
11-25-2025	AstraZeneca	Durvalumab (IMFINZI)	Resectable, early-stage and locally advanced gastric and gastroesophageal junction (GEJ) cancers
11-28-2025	Bayer	Sevabertinib	Non-small cell lung cancer harboring HER2 activating mutations
11-28-2025	Otsuka Holdings	Sibeprenlimab	Immunoglobulin A Nephropathy (IgAN) in adults
11-30-2025	Ascendis Pharma	TransCon CNP	Children with achondroplasia
11-30-2025	Kura Oncology	Ziftomenib	Relapsed or refractory acute myeloid leukemia with a nucleophosmin 1 mutation
12-05-2025	Bristol Myers Squibb	Breyanzi	Relapsed or refractory marginal zone lymphoma
12-05-2025	AxoGen	Avance Nerve Graft	Surgical repair of severed peripheral nerves
12-07-2025	Agios Pharmaceuticals	Pyrukynd	Adult patients with non-transfusion-dependent and transfusion-dependent alpha- or beta-thalassemia
12-11-2025	GSK	Blujepa	Uncomplicated urogenital gonorrhoea in patients 12 years of age and older.
12-11-2025	Amgen	Uplizna	Generalized myasthenia gravis

12-12-2025	Biocryst Pharmaceuticals	ORLADEYO (berotralstat)	Hereditary angioedema (HAE) aged 2 to 11 years
12-13-2025	Milestone Pharmaceuticals	CARDAMYST (etripamil)	Paroxysmal supraventricular tachycardia
12-15-2025	Innoviva	Zoliflodacin	Uncomplicated gonorrhea in adults and pediatric patients 12 years and older
12-16-2025	GSK	Depemokimab	Asthma in adult and pediatric patients aged 12 years and older with type 2 inflammation
12-26-2025	Omeros Corp.	Narsoplimab	Hematopoietic stem cell transplant-associated thrombotic microangiopathy
12-26-2025	Cytokinetics	Aficamten	Obstructive hypertrophic cardiomyopathy
12-28-2025	Sanofi	Tolebrutinib	Non-relapsing secondary progressive multiple sclerosis
12-30-2025	Vanda Pharmaceuticals	Tradipitant	Motion sickness
12-30-2025	Corcept Therapeutics	Relacorilant	Endogenous hypercortisolism
Q4 2025	Amneal Pharmaceuticals, Inc.	Denosumab biosimilar to XGEVA	Bone Cancer
Q4 2025	Biohaven Ltd.	Troriluzole	Spinocerebellar Ataxia
Q4 2025	Regeneron Pharmaceuticals Inc	EYLEA HD	Macular edema