



Q2 2025 Upcoming FDA Decision Dates (PDUFAs)

DATE	COMPANY NAME	DRUG NAME	USE/THERAPEUTIC AREA
04-02-2025	Aldeyra Therapeutics, Inc.	Reproxalap	Dry eye disease
04-02-2025	Novartis	Vanrafia (atrasentan)	IgA nephropathy
04-03-2025	Exelixis, Inc.	CABOMETYX	Advanced neuroendocrine tumors
04-03-2025	Amgen Inc.	Uplizna	Immunoglobulin G4-related disease
04-10-2025	argenx SE	VYVGART SC pre-filled syringe	Generalized myasthenia gravis and chronic inflammatory demyelinating polyneuropathy
04-21-2025	Bristol-Myers Squibb Co.	Nivolumab plus ipilimumab	Hepatocellular carcinoma (HCC)
04-26-2025	Telix Pharmaceuticals Limited	TLX101-CDx	Imaging of glioma
04-29-2025	Abeona Therapeutics	Prademagene zamikeracel (pz-cel)	Recessive Dystrophic Epidermolysis Bullosa
04-29-2025	Stealth BioTherapeutics	Elamipretide	Barth syndrome

04-30-2025	Johnson & Johnson	Nipocalimab	Generalized myasthenia gravis
05-07-2025	GSK	Nucala	Chronic obstructive pulmonary disease (COPD) with an eosinophilic phenotype
05-19-2025	Novavax Inc.	NVX-CoV2705 (Nuvaxovid)	COVID-19 vaccine for individuals aged 12 to 64 years with at least one underlying condition, such as asthma, cancer, diabetes, obesity, or smoking
05-22-2025	Arcutis Biotherapeutics Inc.	ZORYVE (roflumilast)	Scalp and body psoriasis in adults and adolescents ages 12 and over
05-24-2025	Liquidia Corporation	Yutrepia	Pulmonary arterial hypertension
05-26-2025	Merck	WELIREG (belzutifan)	Advanced Pheochromocytoma and Paraganglioma (PPGL)
05-28-2025	Eton Pharmaceuticals, Inc	ET-400	Pediatric adrenal insufficiency
05-31-2025	Moderna	mRNA-1283	Respiratory COVID-19 vaccine
06-10-2025	Merck	Clesrovimab	RSV Disease
06-12-2025	Moderna, Inc	mRNA-1345	Respiratory syncytial virus (RSV) vaccine in high-risk adults aged 18-59
06-13-2025	UroGen Pharma Ltd.	UGN-102	Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer
06-17-2025	KalVista Pharmaceuticals, Inc.	Sebetralstat	Hereditary Angioedema

06-19-2025	Gilead Sciences Inc.	Lenacapavir	HIV prevention
06-20-2025	Sanofi & Regeneron	Dupixent	Bullous Pemphigoid
06-20-2025	GSK	Shingrix	Shingles (herpes zoster)
06-23-2025	Nuvation Bio	Taletrectinib	Advanced ROS1-positive non-small cell lung cancer
06-23-2025	Merck & Co Inc.	Keytruda (pembrolizumab)	Resectable Locally Advanced Head and Neck Squamous Cell Carcinoma
06-28-2025	Unicycive Therapeutics, Inc.	Oxylanthanum Carbonate	Hyperphosphatemia in patients with Chronic Kidney Disease on Dialysis
06-30-2025	Verastem, Inc.	Avmapki Fakzynja Co-Pack	KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC)