

US FDA approval tracker: May 2021



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Last month ended with a flurry of US FDA decisions and one, the green light for Amgen's Lumakras, came over two months early. The accelerated approval in NSCLC patients with a Kras G12C mutation was given to the 960mg dose; a [240mg dose is the subject of a postmarketing study](#) to see whether it has a similar clinical effect. Two other oncology drugs gained first-time accelerated approvals: [J&J's Rybrevant](#) and Bridgebio's Truseltiq. Both have confirmatory trials under way. After two previous complete response letters it was finally good news for Heron's pain therapy Zynrelef, an extended-release bupivacaine combined with the anti-inflammatory meloxicam. To try and gain market share Heron is pricing Zynrelef at a 22-28% discount to Pacira's Exparel; Evercore ISI analysts note that this price will also allow Heron's drug to compete with generic bupivacaine. With May now over all eyes rest on aducanumab's June 7 Pdufa, the biggest regulatory event of the year (*Go or no go? Aducanumab's day of reckoning, May 27, 2021*).

Notable first-time US approval decisions in May

Project	Company	Indication	2026e sales by indication (\$m)	Outcome
Lumakras (sotorasib)	Amgen	NSCLC with Kras G12C mutation after at least one systemic therapy	1,756	Approved (~2.5mth early, accelerated)
Myfembree (relugolix)	Myovant	Uterine fibroids	490	Approved
Zynrelef (HTX-011)	Heron Therapeutics	Post-op pain relief	471	Approved
Lybalvi (ALKS 3831)	Alkermes	Schizophrenia and bipolar 1 disorder	380	Approved
Empaveli (pegcetacoplan)	Apellis	PNH (including treatment naive)	309	Approved
Truseltiq (infigratinib)	Bridgebio Pharma	2L cholangiocarcinoma	253	Approved (accelerated)
Rybrevant (amivantamab)	J&J	NSCLC with EGFR exon 20 insertion mutations	250	Approved (~2mth early, accelerated)
Pylarify (PyL)	Lantheus Holdings	Prostate cancer diagnostic imaging agent	233	Approved
Zonisamide oral suspension	Eton/Azurity Pharmaceuticals	Partial seizures in epilepsy	-	No decision yet
Dehydrated alcohol injection (DS-100)	Eton	Methanol poisoning	-	CRL (CMC)
Camcevi	Foresee Pharmaceuticals	Advanced prostate cancer	-	Approved

Source: Evaluate Pharma & company releases.

Advisory committee meetings in May

Project	Company	2026e sales by indication (\$m)	Outcome	Note
Vynpenta (avacopan)	Chemocentryx	639	Efficacy vote split (9-9), safety profile and benefit-risk votes slightly in favour (10-8)	ANCA-associated vasculitis, Pdufa in July (Chemocentryx's future in doubt as avacopan foundation crumbles)
Teplizumab (PRV-031)	Provention Bio	-	Voted 10-7 that benefits outweigh risks in support of approval	Delay of clinical type 1 diabetes in at-risk individuals (Provention's diabetes project takes a tentative step forward)

Source: Evaluate Pharma & FDA adcom calendar

Supplementary and other notable approval decisions in May

Product	Company	Indication (clinical trial)	Outcome
Opdivo	Bristol Myers Squibb	Adjuvant oesophageal/gastroesophageal junction cancer (Checkmate-577)	Approved
Zeposia	Bristol Myers Squibb	Ulcerative colitis (True North)	Approved
Nurtec ODT	Biohaven	Prevention of migraine (Study 305 , 201)	Approved
Ferriprox	Chiesi	Transfusional iron overload due to sickle cell disease or other anaemias in adults and paediatrics aged 3 and older	Approved
Keytruda + Herceptin + chemo	Merck & Co	1L Her2+ gastric or gastroesophageal junction adenocarcinoma (Keynote-811)	Approved (accelerated)
Cosentyx	Novartis	Moderate-severe plaque psoriasis in children and adolescents (NCT03668613 , NCT02471144)	Approved
Nuzyra	Paratek	Oral only dosing regimen for the treatment of community-acquired bacterial pneumonia	Approved
MSB11455 (Neulasta biosimilar)	Fresenius	Reduce the incidence of infection associated with febrile neutropenia	No decision yet
Esbriet	Roche	Unclassifiable interstitial lung disease (NCT03099187)	No decision yet
Aubagio	Sanofi	Paediatric relapsing MS (Terikids)	No decision yet
Alecensa	Roche	First-line Alk-positive NSCLC (Bfast)	No decision yet

Source: Evaluate Pharma & company releases.

FDA Covid-19 EUAs

Product	Company	2026e sales by indication (\$m)	Note
Comirnaty	Pfizer	1,784	Expanded to include 12 to 15-year-olds
Sotrovimab (VIR-7831)	Vir/GSK	1,212	Treatment of mild-moderate Covid-19 in adults and paediatrics (<i>US appetite for Covid-19 treatments remains undiminished</i>)

Source: Evaluate Pharma & company releases.

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