

US FDA approval tracker: October



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The Covid-19 pandemic saw the FDA give full approval to [Gilead's Veklury last month despite contradictory evidence](#) of its efficacy in hospitalised patients. Sales of the drug are forecast to peak at \$3bn next year according to sellside consensus from *EvaluatePharma*, but with [Covid-19 increasingly affecting younger, healthier patients Veklury's use could be limited](#). Elsewhere, Kala received the greenlight for its dry eye treatment, Eysuvis. The next hurdle for Kala will be launching during a pandemic given most patients would likely avoid in-person physician visits for non-essential treatment. Avenue Therapeutics, meanwhile, received a knockback for its intravenous version of the opioid painkiller tramadol due to safety concerns. Avenue's shares plummeted 59% on the news. Zosano also got a complete response letter for its migraine treatment Qtrypta, a transdermal microneedle system that delivers zolmitriptan. Due to differences observed in zolmitriptan exposures in trial subjects the FDA requested a repeat bioequivalence study between three of the product lots used during development.

Notable first-time US approval decisions in October

Project	Company	2026e sales by indication (\$m)	Outcome
Veklury (remdesivir)	Gilead	1,729	Approved
Eysuvis	Kala Pharmaceuticals	1,118	Approved
Rolontis/ eflapegrastim	Spectrum	314	Action deferred due to Covid-19 travel restrictions
Qtrypta	Zosano	286	CRL
IV tramadol	Avenue Therapeutics/Fortress Biotech	281	CRL
Inmazoleb (REGN-EB3)	Regeneron	-	Approved

Sources: *EvaluatePharma* & company releases.

October advisory committee meeting outcomes

Project	Company	2026e sales by indication (\$m)	Outcome	Vantage story
ALKS 3831	Alkermes	362	Positive	Could Alkermes' new antipsychotic punch below its weight?
AR19 (immediate release amphetamine capsule)	Arbor	-	Negative	-
Vaccines and related biological products	-	NA	-	US panel puts the spotlight on pivotal Covid vaccine readouts

Sources: FDA ad com calendar, EvaluatePharma.

Supplementary and other notable approval decisions in October

Product	Company	Indication (clinical trial)	Outcome
Keytruda	Merck & Co	2nd line treatment R/R classical HL (Keynote-204 vs Seattle's Adcetris)	Approved
Opdivo + Yervoy	Bristol Myers Squibb	Untreated unresectable malignant pleural mesothelioma (Checkmate-743)	Approved
Generic Nuvaring	Mayne Pharma Group	Contraception	CRL
Wakix	Harmony Biosciences	Cataplexy in adult patients with narcolepsy (Harmony CTP , Harmony 1)	Approved

Sources: EvaluatePharma & company releases.