Evaluate Vantage

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US FDA approval tracker: November

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Last month was big on FDA knockbacks, with the coronavirus pandemic playing a major part. Five complete response letters were disclosed due to chemistry, manufacturing and control issues, and there were two Pdufa delays as travel restrictions hampered manufacturing inspections. The new Pdufa date for one of the delayed projects, Bristol's lisocabtagene maraleucel, has not yet been announced and the company is edging ever closer to the CVR deadline of December 31. On the approval side, Alnylam's Oxlumo was given the green light a week early; it is used to treat primary hyperoxaluria type 1, a rare genetic disease. Another rare disease player, Rhythm, received its first ever approval: Imcivree gained the thumbs up in pro-opiomelanocortin deficiency obesity and leptin receptor deficiency obesity. However, only around 30 patients have been identified and Rhythm does not plan to deploy a salesforce yet. Phase III data are due soon in the bigger indication of Bardet-Biedl syndrome and there are plans for a basket trial to expand into additional genetically defined obesities. Three emergency use authorisations were granted for Covid-19 treatments last month, but all eyes are on December when two vaccines could get FDA backing.

Notable first-time US approval decisions in November

Project	Company	2026e sales by indication ($m)	Outcome	Reason for CRL/delay?
Liso-cel/JCAR017/Breyanzi	Bristol Myers Squibb	1,155	Delayed (no new date disclosed)	Manufacturing inspection delay
Imcivree (setmelanotide)	Rhythm	955	Approved	-
Dostarlimab	Glaxosmithkline	571	No decision yet (Q4 date)	-
Sutimlimab	Sanofi	553	CRL	CMC
LIQ861	Liquidia Technologies	476	CRL	CMC
ALKS 3831	Alkermes	362	CRL	CMC
RT002/ DaxibotulinumtoxinA/ DAXI	Revance	350	Delayed (no new date disclosed)	Manufacturing inspection delay
SPN-812	Supernus	279	CRL	CMC
Oxlumo (lumasiran)	Alnylam	253	Approved ~1 week early	-
Danyelza (naxitamab)	Y-mabs	247	Approved	-
Zimhi	Adamis	174	CRL	CMC
Zokinvy (lonafarnib)	Eiger	99	Approved	-
AR19	Arbor	-	Not disclosed (private company)	-

Sources: EvaluatePharma & company releases.

Advisory committee meetings in November				
Project	**Company**	**2026e sales by indication ($m)**	**Outcome**	**Note**
Aducanumab	Biogen/Eisai	4,757	Negative	Positive briefing docs but negative panel meeting, Pdufa set for March 5 2021 (*Aducanumab: this time it's personal*)
Hydexor (CL-108)	Charleston Laboratoris/ Olas Pharma	-	Negative	Received first CRL in 2017 and negative adcom in 2018, second CRL afterwards
Sources: FDA ad com calendar, EvaluatePharma.				

FDA issued EUAs to treat Covid-19			
Project	**Company**	**2026e sales by indication ($m)**	**Setting**
Olumiant plus Veklury	Eli Lilly	1,729*	Confirmed Covid-19 in hospitalised patients
Bamlanivimab (LY-CoV555)	Eli Lilly	-	Mild-to-moderate Covid-19
Casirivimab plus imdevimab (REGN-COV2)	Regeneron	31	Mild-to-moderate Covid-19 (*The pandemic response roars on*)
**Veklury received full FDA approval as a single agent in October. Sources: FDA.gov, EvaluatePharma.*			

Supplementary and other notable approval decisions in November			
Product	**Company**	**Indication (clinical trial)**	**Outcome**
Xofluza	Roche	Three decisions: 1) new formulation as one-dose granules for oral suspension, 2) for the treatment of acute uncomplicated influenza in children aged 1-12, 3) post-exposure prophylaxis of influenza in people aged 12 and over (miniStone-2 and Blockstone)	Approved for 1) and 3), not yet approved in paediatric setting
Keytruda + chemo	Merck & Co	Triple-negative breast cancer (≥10% PD-L1 expressers) (Keynote-355)	Approved
Brilinta	Astrazeneca/ Merck & Co	Acute ischaemic stroke or transient ischaemic attack (Thales)	Approved
Imfinzi	Astrazeneca	Four-week fixed-dose regimen for NSCLC and bladder cancer (several trials, incl Caspian)	Approved
Sources: EvaluatePharma & company releases.			