

US FDA approval tracker: December



[Joanne Fagg](#)

The FDA's run of speedy approvals continued in the last month of 2019. Two antibody-drug conjugates, Seattle's Padcev and Astra/Daiichi's Enhertu, came early, alongside Newlink/Merck's Ebola vaccine Ervebo. Approval of Sarepta's second Duchenne's therapy, Vyondys 53, came out of the blue mid-month, reversing a previous complete response letter, while Intracellular's shares rocketed 193% after its schizophrenia treatment Caplyta got the green light despite mixed clinical data. Amarin's Vascepa gained a broad cardiovascular label including a primary prevention setting; however, [risk from litigation](#) and upcoming competition overhangs this drug. Allergan's Ubrelvy became the first oral CGRP antagonist for acute migraine, but Biohaven's competing offering has its own [PDUFA date set for early 2020](#). Meanwhile, Enzyvant's RVT-802, a regenerative tissue therapy in development for congenital athymia, was knocked back owing to manufacturing concerns - not a great start to the [\\$3bn strategic alliance Sumitomo Dainippon signed with Roivant](#), Enzyvant's holding company, back in September.

Notable first-time US approval decisions in December

Project	Company	Product NPV (\$m)*	Outcome	Vantage coverage
Subcutaneous Entyvio**	Takeda	13,353 (franchise)	CRL	
Enhertu (trastuzumab deruxtecan)**	Astrazeneca/Daiichi Sankyo	6,502	Approved (4 mths early)	<i>Go or no go? Enhertu's destiny revealed and FDA decisions due for Epizyme, Novo</i>
Padcev (enfortumab vedotin)**	Seattle Genetics/Astellas	4,693	Approved (3 mths early)	
Caplyta (lumateperone)	Intra-Cellular Therapeutics	2,069	Approved	<i>Intra-cellular triples on schizophrenia approval</i>
Cabotegravir & Rilpivirine	Shionogi/GSK	1,837	CRL	
Ubrovelvy (ubrogepant)	Allergan	708	Approved	<i>Ubrovelvy's a winner, but not for long</i>
Dayvigo (lemborexant)	Eisai	625	Approved	
Brinavess	Correvio Pharma	510	CRL	
Vyondys 53 (golodirsen)**	Sarepta	359	Approved	<i>Sarepta proves the doubters wrong - again</i>
AV001	Avadel	7	Approved	
RVT-802	Enzyvant	-	CRL	
Arazlo (tazarotene)	Bausch Health Companies	-	Approved	
Ervebo/Zaire Ebola virus vaccine V920**	Newlink/Merck	-	Approved (3 mths early)	

*NPV data as of December 30, via *EvaluatePharma*. **Not in December story. Source: [*Go or no go? Vascepa's finale and Allergan's pain relief, December 2, 2019.*](#)

Supplementary and other notable approval decisions in December

Product	Company	Event type	Outcome	Vantage coverage
Tecentriq	Roche	sBLA + Abraxane for first-line non-squamous NSCLC (Impower-130)	Approved	
Avsola/ABP 710	Amgen	Biosimilar Remicade	Approved	
Vascepa	Amarin	sNDA for Cardiovascular outcomes (Reduce-It)	Approved	<i>Litigation risk still overhangs the Amarin takeover thesis</i>
Xtandi	Astellas Pharma	sNDA for metastatic hormone sensitive prostate cancer (Arches)	Approved	
Lynparza	Astrazeneca	sNDA for BRCAm pancreatic cancer (Polo)	Approved	<i>Asco 2019 - Polo reveals an overall survival hole</i>

Source: [Go or no go? Vascepa's finale and Allergan's pain relief](#), December 2, 2019.