

US FDA approval tracker: April 2020



[Joanne Fagg](#)

Three oncology drugs gained early approval last month, but their developers' hardest task – launching during a pandemic – is yet to come. Immunomedics, which gained approval of Trodelvy in triple-negative breast cancer, [insisted that it was all set for launch](#) with virtual video conferencing and telesales in place. Elsewhere, Seattle Genetics said the past couple of months of virtual commercialisation with Adcetris and Padcev would help strategise the Tukysa launch in metastatic, Her2-positive breast cancer. Incyte too noted that it would build on past experience, in this case of selling Jakafi during the pandemic, when it comes to launching Pemazyre in cholangiocarcinoma. Neurocrine, on the other hand, delayed the launch of its add-on Parkinson's treatment Ongentys, owing to both the pandemic and supply chain issues [for partner Bial](#).

Notable first-time US approval decisions in April

Product	Company	2026e WW total sales (\$m)	Outcome
Trodelvy (sacituzumab govitecan)	Immunomedics	2,151	Approved (~1.5 months early)
Reblozyl	Bristol Myers Squibb/Acceleron	1,715	Approved
Tukysa (tucatinib)	Seattle Genetics	950	Approved (4 months early)
Ongentys (opicapone)	Neurocrine/Bial/Ono	344	Approved
Pemazyre (pemigatinib)	Incyte	335	Approved (1 month early)
Jelmyto (UGN-101/mitomycin gel)	Urogen	133	Approved
Koselugo (selumetinib)	Astrazeneca	84	Approved
Trevyent	United Therapeutics/Correvio	54	CRL
MenQuadfi	Sanofi	-	Approved

Source: EvaluatePharma, [Go or no go? Covid-19 upstages US regulatory decisions](#).

Supplementary and other notable approval decisions in April			
Product	Company	Indication (clinical trial)	Outcome
Braftovi + Erbitux	Pfizer	BRAF V600E-mutated Colorectal cancer (Beacon CRC)	Approved
Otezla	Amgen	Moderate to severe scalp psoriasis (Style)	Approved
Imbruvica	J&J	Imbruvia plus rituximab for the treatment of patients with CLL (E1912 study)	Approved
Keytruda	Merck	Every six-week dosing schedule	Approved
Zejula	Glaxosmithkline	First-line maintenance treatment for ovarian cancer regardless of BRCA mutational status (Prima)	Approved

Source: EvaluatePharma, [Go or no go? Covid-19 upstages US regulatory decisions.](#)

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