

US FDA approval tracker: July



[Joanne Fagg](#)

Last month saw three early FDA approvals, including that of [Morphosys and Incyte's Monjuvi](#), an anti-CD19 antibody that last week won a better-than-expected second line label to treat large B-cell lymphoma. With the filgotinib verdict yet to emerge for Gilead and Galapagos, Monjuvi becomes the most notable new approval in terms of sales potential for July - filgotinib received a positive opinion in Europe and hopes are high for a green light in the US in August. A second Car-T approval also arrived early for Gilead. KTE-X19, now branded Tecartus, was waved through in mantle cell lymphoma. Other big decisions in the US last month included Jazz's new narcolepsy treatment, Xywav; this is a low sodium follow-on to Xyrem, which will see generic competition in 2023, so Jazz needs to make the most of the Xyway opportunity. GW Pharma meanwhile added tuberous sclerosis to the label for Epidiolex, putting more ground between it and competitor Zogenix. And GSK's anti-BCMA ADC, belantamab mafadotin, [got a positive adcom vote for myeloma](#), despite underwhelming efficacy and safety issues. This makes an approval likely in August, although black box warnings and a REMS programme will likely be required ([Go or no go? Valuable drugs set for FDA decisions, July 29, 2020](#)).

Notable first-time US regulatory verdicts in July

Project	Company	2026e sales by indication (\$m)	Outcome
Filgotinib	Gilead/Galapagos	1,290	No decision yet
Belantamab mafodotin	GSK	1,240	Positive, voted 12-0. PDUFA due in August
Monjuvi (tafasitamab) + lenalidomide	Morphosys/Incyte	687	Approved (~1 month early)
Dostarlimab	GSK/ Anaptysbio	507	No decision yet
Xywav (JZP-258)	Jazz	420	Approved
Somapacitan/ NN8640	Novo Nordisk	319	No decision yet
Upneeq/ RVL-1201	Osmotica	309	Approved
Rukobia (fostemsavir)	GSK/Bristol Myers Squibb	282	Approved
Byfavo	Cosmo/ Paion/ Acacia Pharma	269	Approved
VP-102	Verrica	260	CRL
Inqovi (C-Dec/ASTX727)	Otsuka	77	Approved (~1 month early)
Ryanodex	Eagle	4	Postponed to Aug 8
Camcevi	Foresee Pharmaceuticals	-	No decision yet
E-58425	Esteve	-	No decision yet
Vocabria (cabotegravir)	Shionogi/GSK	-	No decision yet
Wynzora	MC2 Therapeutics	-	Approved
Tecartus (brexucabtagene autoleucel/ KTE-X19)	Gilead/Kite	-	Approved (~2 weeks early)
Xeglyze	Dr. Reddy's Laboratories	-	Approved

Sources: EvaluatePharma, [Go or no go? Pandemic looms over FDA timelines](#), company releases

Supplementary and other notable approval decisions in July

Product	Company	Indication (clinical trial)	Outcome
Xiaflex/Qwo	Endo	Cellulite (Release 1 and 2)	Approved
Qutenza	Averitas	Neuropathic pain associated with diabetic peripheral neuropathy	Approved
Epidiolex	GW Pharmaceuticals	Tuberous sclerosis (GWPCare6)	Approved
Spravato	Johnson & Johnson	Major depressive disorder who have active suicidal ideation with intent	Approved
Trelegy Ellipta	GSK	Asthma (Captain)	No decision yet
Tremfya	Johnson & Johnson	Psoriatic arthritis (Discover-1 and -2)	Approved
Xolair	Novartis	Nasal polyps (Polyp 1 and 2)	No decision yet
Bavencio	Merck KGaA /Pfizer	Locally advanced or metastatic urothelial carcinoma that has not progressed with first-line platinum-containing chemotherapy (Javelin Bladder 100)	Approved
Hulio (Humira biosimilar)	Mylan	RA, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis and plaque psoriasis	Approved
Keytruda + Lenvima	Merck	1L liver cancer (Keynote-524)	CRL
Botox	Abbvie	Spasticity in paediatric patients aged ≥ 2 years, including those with lower limb spasticity caused by cerebral palsy	Approved
Dysport	Ipsen	Spasticity in paediatric patients aged ≥ 2 years, including those with lower limb spasticity caused by cerebral palsy	Approved
Breztri Aerosphere	Astrazeneca	COPD (Ethos)	Approved
Tecentriq + Cotellic + Zelboraf	Roche/Exelixis	Braf V600 mutation-positive advanced melanoma patients (Imspire150)	Approved

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