MARKET WATCH

FDA new drug approvals in Q2 2021

Among the 13 FDA approvals during the second quarter of 2021, one has undoubtedly been the biggest talking point. Biogen's Alzheimer disease drug Aduhelm (aducanumab) has become one of the most controversial authorizations for some time, with much debate about whether the FDA was justified in granting accelerated approval on the basis of an unvalidated surrogate end point. Efficacy data painted a questionable picture, and the US$56,000 per year list price of the amyloid-targeted antibody divided opinion further.

Beyond Aduhelm though, it was business as usual; oncology continued to dominate, with seven agents gaining approval (TABLE 1). Particularly notable among these was Amgen's Lumakras (sotorasib) as the first approved drug to directly target KRAS, a target that was once considered 'undruggable', which gained a green light for non-small-cell lung cancer (NSCLC) driven by the *KRAS*^{G12C} mutation. Johnson & Johnson's bispecific antibody Rybrevant (amivantamab) also received accelerated approval for a niche NSCLC population: patients with EGFR exon 20 insertion mutations.

Other anticancer drugs to receive accelerated approval included ADC Therapeutics' antibody–drug conjugate Zynlonta (loncastuximab tesirine) for diffuse large B cell lymphoma, BridgeBio's FGFR kinase inhibitor Truseltiq (infigratinib) for cholangiocarcinoma with FGFR2 fusion or rearrangement and GlaxoSmithKline's Jemperli (dostarlimab), the seventh PD1/PDL1 blocker to win a US green light. Jemperli will be launched in a very rare tumour type: mismatch repair-deficient endometrial cancer.

This quarter's crop of oncology approvals highlight how developers are targeting rare cancer settings, which can be lucrative. For example, Amgen's Lumakras is forecast to have sales of almost $2 billion by 2026 (TABLE 1). Competition could soon be arriving from Mirati's adagrasib, however, which is expected to be filed by the end of this year.

Outside of oncology, two women's health products were approved, providing firsts in an often neglected area of health care. Oral contraceptive pill Nextstellis (drospirenone and oestetrol) contains E4, a naturally occurring oestrogen, marking one of the first alternatives to synthetic oestrogen in more than 50 years. Brexafemme (ibrexafungerp) for vaginal yeast infections is the first of a novel class of antifungals.

Other notable approvals included Apellis Pharmaceuticals' Empaveli (pegcetacoplan) and Alkermes' Lybalvi (olanzapine; samidorphan). The novel part of the combination therapy, samidorphan, is a μ-opioid receptor antagonist, and trials showed that the combination reduced unwanted weight gain associated with use of the antipsychotic olanzapine. Empaveli, the first complement C3 inhibitor to be approved, will compete with Soliris (eculizumab), formerly the world's most expensive drug, in treating the rare blood disorder paroxysmal nocturnal haemoglobinuria, and has already beaten Solaris in a head-to-head trial.

So, while the noise around the Aduhelm approval dominated, it should not mask the fact that the FDA kept up the pace of approvals despite the coronavirus pandemic, putting the year on track to be another fruitful one.

Table 1 | **Selected FDA new drug approvals in Q2 2021**

Date	Drug (brand name; company)	Properties	Indication	2026 global sales forecast
1 Apr	Viloxazine hydrochloride (Qelbree; Supernus Pharmaceuticals)	Noradrenaline reuptake inhibitor	Attention deficit hyperactivity disorder	$321 million
14 Apr	Drospirenone; oestetrol (Nextstellis; Mayne Pharma)	Progestin and oestrogen	Female contraception	NA
21 Apr	Dostarlimab (Jemperli; GlaxoSmithKline)	PD1-targeted antibody	dMMR endometrial cancer	$553 million
21 Apr	Loncastuximab tesirine (Zynlonta; ADC Therapeutics)	CD19-targeted ADC	Diffuse large B cell lymphoma	$1,025 million
13 May	Pegcetacoplan (Empaveli; Apellis Pharmaceuticals)	Complement C3 inhibitor	PNH	$513 million
21 May	Amivantamab (Rybrevant; Johnson & Johnson)	EGFR×MET bispecific antibody	NSCLC with EGFR exon 20 insertion mutations	$250 million
27 May	Piflufolastat F-18 (Pylarify; Lantheus Holdings)	PSMA-targeted imaging agent	Detection of prostate cancer	$119 million
28 May	Sotorasib (Lumakras; Amgen)	KRAS-G12C inhibitor	NSCLC with *KRAS*^{G12C} mutation	$1,756 million
28 May	Infigratinib (Truseltiq; BridgeBio Pharma)	FGFR1–3 kinase inhibitor	Cholangiocarcinoma with FGFR2 fusion or rearrangement	$561 million
1 Jun	Olanzapine; samidorphan (Lybalvi; Alkermes)	$5\text{-HT}_{2A}/D_1/D_2$ receptor antagonist; MOR antagonist	Schizophrenia; bipolar disorder	$380 million
1 Jun	Ibrexafungerp (Brexafemme; Scynexis)	Glucan synthase inhibitor	Candidiasis	$351 million
7 Jun	Aducanumab (Aduhelm; Biogen/Eisai)	Amyloid-β antibody	Alzheimer disease	$3,908 million
30 Jun	Asparaginase erwinia chrysanthemi (Rylaze; Jazz Pharmaceuticals)	Asparaginase	Acute lymphocytic leukaemia; non-Hodgkin lymphoma	$33 million

ADC, antibody–drug conjugate; dMMR, mismatch-repair deficient; EGFR, epidermal growth factor receptor; FGFR, fibroblast growth factor receptor; MOR, μ-opioid receptor; NA, not available; NSCLC, non-small-cell lung cancer; PNH, paroxysmal nocturnal haemoglobinuria; PSMA, prostate-specific membrane antigen.
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Competing interests
The author declares no competing interests.