MARKET WATCH

FDA new drug approvals in Q1 2021

Any fears that COVID-19 could affect drug approvals should be put to rest by the 14 new drugs greenlighted by the FDA in the first three months of 2021 (TABLE 1). This total beats the 12 approvals recorded this time last year and far exceeds the 7 approvals in Q1 2019.

Oncology products continue to dominate, with five approvals. Among these, the CDK4/6 inhibitor Cosela (trilaciclib) is notable because it was approved to mitigate the side effects of chemotherapies, initially for patients being treated for small cell lung cancer. Merck KGaA's Tepmetko (tepotinib) will provide competition to Novartis's MET inhibitor Tabrecta (capmatinib) following its approval for patients with lung cancer with MET exon 14 skipping mutations, a particularly aggressive form of the disease. Although Tabrecta has a 9-month head start and is forecast to sell more than Tepmetko in 2026, the convenience of its once-daily dosing versus Tabrecta's twice-daily dosing might support gains in market share.

One cancer drug for which market uptake could be challenging is AVEO Oncology's VEGFR inhibitor Fotivda (tivozanib), which was finally approved after 5 years of trying. The renal cell carcinoma space it is entering has changed dramatically in this time, with anti-PD1/PDL1 drugs in combination with other products now dominating treatment. This could explain why Fotivda is only forecast to have sales of US$155 million in 2026.

Other products approved in Q1 that face strong existing marketed competitors include Janssen's Ponvory (ponesimod) for multiple sclerosis. The S1P receptor modulator is not only up against Bristol Myers Squibb's Zeposia (ozanimod) and Novartis's Gilenya (fingolimod) from the same drug class, but also Roche's Ocrevus (ocrelizumab); last year sales of the CD20-targeted antibody increased by 24% to $4.6 billion. The guanylate cyclase agonist Verquvo (vericiguat) will also enter a fiercely competitive landscape for the treatment of symptomatic chronic heart failure with reduced ejection fraction, a market where Novartis's Entresto (sacubitril and valsartan) is becoming the standard of care, and where AstraZeneca's Farxiga (dapagliflozin) gained approval earlier this year.

The only product approved this quarter that is expected to achieve blockbuster sales 5 years post-launch is Aurinia Pharmaceuticals' Lupkynis (voclosporin). The calcineurin inhibitor is the first oral therapy for lupus nephritis, which could help distinguish it from GlaxoSmithKline's Benlysta (belimumab) and has led to speculation that Aurinia could be an acquisition target.

There were three approvals for rare diseases. Sarepta racked up its third approval for Duchenne muscular dystrophy (DMD), with Amondys 45 (casimersen), an antisense oligonucleotide to treat patients with a mutation of the *DMD* gene amenable to exon 45 skipping. The product was approved based on increases in dystrophin protein levels from baseline after 48 weeks of treatment, but, as with Sarepta's analogous products for other subsets of patients with DMD, there is currently a lack of clear evidence that dystrophin production leads to clinical benefits. The other two approvals were first-in-class agents: the homozygous familial hypercholesterolaemia treatment Evkeeza (evinacumab); and Nulibry (fosdenopterin) to treat the genetic metabolic disorder molybdenum cofactor deficiency type A.

Although potential blockbusters are thin on the ground, FDA approvals have made a strong start. With the impact of COVID-19 on the FDA's work likely to diminish, 2021 could be record-breaking if the pace continues.

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Competing interests
The author declares no competing interests.

Table 1 | **Selected FDA new drug approvals in Q1 2021**

Date	Drug (brand name; company)	Properties	Indication	2026 global sales forecast
19 Jan	Vericiguat (Verquvo; Bayer/Merck & Co.)	Guanylate cyclase receptor agonist	Chronic heart failure	$760 million
21 Jan	Cabotegravir sodium; rilpivirine hydrochloride (Cabenuva; GlaxoSmithKline)[a]	HIV-1 integrase inhibitor; HIV-1 NNRTI	HIV treatment	$960 million
22 Jan	Voclosporin (Lupkynis; Aurinia Pharmaceuticals)	Calcineurin inhibitor	Systemic lupus erythematosus	$1,063 million
3 Feb	Tepotinib (Tepmetko; Merck KGaA)	MET inhibitor	Non-small-cell lung cancer	$468 million
5 Feb	Umbralisib (Ukoniq; TG Therapeutics)	CK1ε inhibitor; PI3Kδ inhibitor	Non-Hodgkin lymphoma	$296 million
11 Feb	Evinacumab (Evkeeza; Regeneron Pharmaceuticals)	ANGPTL3 antibody	Familial hypercholesterolaemia	NA
12 Feb	Trilaciclib (Cosela; G1 Therapeutics)	CDK4/6 inhibitor	Small cell lung cancer	$773 million
25 Feb	Casimersen (Amondys 45; Sarepta Therapeutics)	Exon 45-binding oligonucleotide	Duchenne muscular dystrophy	$202 million
26 Feb	Fosdenopterin (Nulibry; BridgeBio Pharma)	Molybdenum cofactor stimulant	Molybdenum cofactor deficiency type A	$30 million
1 Mar	Melphalan flufenamide (Pepaxto; Oncopeptides)	Peptide-conjugated DNA alkylator	Multiple myeloma	$494 million
2 Mar	Serdexmethylphenidate chloride; dexmethylphenidate (Azstarys; KemPharm)	Dopamine transporter inhibitor, noradrenaline transporter inhibitor	Attention deficit hyperactivity disorder	NA
10 Mar	Tivozanib (Fotivda; AVEO Oncology)	VEGFR1/2/3 inhibitor	Renal cell carcinoma	$155 million
18 Mar	Ponesimod (Ponvory; Janssen Pharmaceuticals)	S1P receptor 1 modulator	Relapsing–remitting MS	NA
22 Mar	Dasiglucagon (Zegalogue; Zealand Pharma)	Glucagon receptor agonist	Hypoglycaemia	$268 million

ANGPTL3, angiopoietin-like 3; CDK, cyclin-dependent kinase; CK1, casein kinase 1; MS, multiple sclerosis; NA, not available; NNRTI, non-nucleoside reverse transcriptase inhibitor; S1P, sphingosine 1-phosphate; VEGFR, vascular endothelial growth factor receptor. [a]Co-packaged for intramuscular administration. The FDA simultaneously approved cabotegravir sodium tablets alone (Vocabria) to be taken in combination with oral rilpivirine. Source: EvaluatePharma April 2021, Evaluate Ltd.