BIOBUSINESS BRIEFS

MARKET WATCH

FDA new drug approvals in Q3 2021

The biggest FDA approval of the third quarter was for a product that has already been used in more than 130 countries. August saw the full approval of Pfizer and BioNTech's COVID-19 vaccine Comirnaty for those aged 16 and over, 8 months after it was initially granted emergency use authorization. Comirnaty has already become the fastest selling new product in pharma history — 2021 sales are forecast to exceed US$30 billion, and with booster programmes being rolled out, revenues will continue to accrue in 2022.

The quarter brought in two other potential blockbusters: Ascendis Pharma's Skytrofa (lonapegsomatropin) and Bayer's Kerendia (finerenone). Skytrofa became the first approved once-weekly treatment for paediatric growth hormone deficiency, and Kerendia was approved for the treatment of chronic kidney disease associated with type 2 diabetes.

The competitive market for CGRP inhibitors for migraine had another entrant with the approval of AbbVie's Qulipta (atogepant). As only the second oral option in the migraine prevention setting though, challenging Biohaven's Nurtec (rimegepant), it has forecasted sales of $954 million in 2026.

The quarter was an exceptional one for pruritus, or itch, with three products gaining approval. First was Bylvay (odevixibat), an IBAT inhibitor, for pruritus in progressive familial intrahepatic cholestasis. This was followed by Korsuva (difelikefalin) for pruritus in haemodialysis patients and another IBAT inhibitor, Livmarli (maralixibat) for pruritus in Alagille syndrome. Three projects also made it to market in oncology — a quieter quarter than usual for this field, although all were first-in-class agents. Merck & Co.'s HIF2α inhibitor Welireg (belzutifan) was approved for VHL disease and could exceed current sales forecasts after being granted a wider-than-expected label. Sales forecasts for the other two agents — the antibody–drug conjugate Tivdak (tisotumab vedotin) for cervical cancer and the kinase inhibitor Exkivity (mobocertinib) for non-small-cell lung cancer with EGFR exon 20 insertion mutations — could be dimmed by safety issues, however.

Two further pioneering approvals were for the antiprotozoal agent fexinidazole for human African trypanosomiasis (sleeping sickness) and Saphnelo (anifrolumab), a type I interferon receptor antagonist for systemic lupus erythematosus (SLE). As the first oral drug for sleeping sickness, fexinidazole removes the need for infusions or injections, which can be hard for people living in remote areas to access, while anifrolumab is the first new drug for SLE in more than 10 years.

Other regulatory endorsements included Merck & Co.'s pneumococcal vaccine Vaxneuvance, Kadmon/BioNova's Rezurock (belumosudil) for graft versus host disease and Sanofi's Pompe disease therapy Nexviazyme (avalglucosidase alfa). With 13 new drug approvals (TABLE 1) in the quarter, if the FDA keeps up this pace, 2021 might just beat 2020's total of 53.

Table 1 | **Selected FDA new drug and vaccine approvals in Q3 2021**

Date	Drug (brand name; company)	Properties	Indication	2026 global sales forecast
9 Jul	Finerenone (Kerendia; Bayer)	Mineralocorticoid receptor antagonist	Diabetic nephropathy	$1,173 million
16 Jul	Fexinidazole (NA; Sanofi)	Antiprotozoal agent	Trypanosomiasis	NA
16 Jul	Belumosudil (Rezurock; Kadmon/ BioNova Pharma)	ROCK2 inhibitor	Graft versus host disease	$540 million
16 Jul	Pneumococcal 15-valent conjugate vaccine (Vaxneuvance; Merck & Co.)	Purified polysaccharides from 15 *Streptococcus pneumoniae* serotypes conjugated to CRM_{197}	Pneumococcal infection prophylaxis	$786 million
20 Jul	Odevixibat (Bylvay; Albireo Pharma)	IBAT inhibitor	Pruritus in patients with PFIC	$580 million
30 Jul	Anifrolumab (Saphnelo; AstraZeneca)	Type I interferon receptor antagonist	Systemic lupus erythematosus	$608 million
6 Aug	Avalglucosidase alfa (Nexviazyme; Sanofi)	Modified recombinant α-glucosidase	Pompe disease	$366 million
13 Aug	Belzutifan (Welireg; Merck & Co.)	HIF2α inhibitor	VHL disease	$386 million
23 Aug	Difelikefalin (Korsuva; Vifor Pharma/Cara Therapeutics)	κ-Opioid receptor agonist	Pruritus	$358 million
23 Aug	COVID-19 vaccine, mRNA (Comirnaty; BioNTech/Pfizer)	mRNA vaccine encoding SARS-CoV-2 S antigen	Prevention of COVID-19	$2,819 million
25 Aug	Lonapegsomatropin (Skytrofa; Ascendis Pharma)	GHRH receptor agonist	Short stature in children	$1,441 million
15 Aug	Mobocertinib (Exkivity; Takeda)	EGFR inhibitor	NSCLC with EGFR exon 20 insertion mutations	$436 million
20 Sep	Tisotumab vedotin (Tivdak; Genmab/ Seagen)	Tissue factor-specific ADC	Cervical cancer	$629 million
28 Sep	Atogepant (Qulipta; AbbVie)	CGRP receptor antagonist	Migraine	$954 million
29 Sep	Maralixibat (Livmarli; Mirum Pharmaceuticals)	IBAT inhibitor	Cholestatic pruritus in patients with Alagille syndrome	$598 million

ADC, antibody–drug conjugate; CGRP, calcitonin gene-related peptide; CRM_{197}, diphtheria cross-reactive material; GHRH, growth hormone-releasing hormone; HIF2, hypoxia-inducible factor 2; IBAT, ileal bile acid transporter; NA, not available; NSCLC, non-small-cell lung cancer; PFIC, progressive familial intrahepatic cholestasis; ROCK2, Rho-associated protein kinase 2. Source: EvaluatePharma October 2021, Evaluate Ltd.

Lisa Urquhart
Evaluate Vantage, London, UK.
e-mail: lisau@epvantage.com

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Competing interests
The author declares no competing interests.