BIOBUSINESS BRIEFS

MARKET WATCH

FDA new drug approvals in Q1 2020

In a quarter that was marked by the rapid spread of the COVID-19 pandemic, drug approvals continued (TABLE 1), but launching was a completely different matter. Zeposia (ozanimod), the most eagerly awaited new drug of the quarter, is not going to reach patients with multiple sclerosis soon, after Bristol-Myers Squibb announced that it would be delaying its debut.

Even if Zeposia's launch had gone to plan, the S1P receptor modulator would have faced commercial hurdles. Novartis's Gilenya (fingolimod), which has the same mechanism of action, is now off-patent, although it has safety issues related to its lack of selectivity. While Zeposia lacks these handicaps, it will have to square off against Roche's CD20 monoclonal antibody (mAb), Ocrevus (ocrelizumab). Ocrevus has demonstrated strong efficacy and is currently forecast to become the market-leading multiple sclerosis drug in 2024, according to EvaluatePharma.

For Lundbeck's Vyepti (eptinezumab) and Biohaven's Nurtec ODT (rimegepant), launching as the fourth and fifth CGRP-targeted migraine products to market would have been challenging enough, even without the movement restrictions on their sales forces. Vyepti, an intravenously delivered mAb, was approved ahead of Nurtec ODT, but Nurtec ODT is an oral small-molecule drug and so its convenience might make up for it being fifth to market. The drug is also differentiated as the only CGRP antagonist shown to work in both the acute and preventive setting. The market will be watching with interest Biohaven's virtual launch strategy, which involves remote education programmes for physician and key opinion leaders, direct-to-consumer advertising and social media ads.

Esperion received two approvals for its cholesterol-lowering product Nexletol (bempedoic acid): one as a monotherapy and the second in combination with ezetimibe. As an oral therapy, the drug has the advantage of being more convenient and much cheaper than the PCSK9 inhibitors it is expected to compete with. However, unlike these drugs, it cannot yet boast any cardiovascular benefits, and a 12,600-patient trial to investigate such benefits is not due to report before 2022.

The FDA kept up its recent approval pace, with Ayvakit (avapritinib) and Tepezza (teprotumumab) approved ahead of schedule. The kinase inhibitor Ayvakit is approved for gastrointestinal stromal tumours driven by a *PDGFRA* mutation, whereas the IGF1R mAb Tepezza became the first approved drug for thyroid eye disease, a rare autoimmune disorder.

Other firsts included Epizymes's Tazverik (tazemetostat) for epithelioid sarcoma, a rare cancer, and Aimmune Therapeutics' Palforzia, an oral immunotherapy for peanut allergy. However, being first might not be enough to make Palforzia a commercial success — its US$1.15 billion sales forecast in 2024 notwithstanding. The product comes with a black box warning over anaphylaxis and a strict risk mitigation programme, and a key question will be whether parents and patients think the benefits of the treatment and the annual $10,000 list price outweigh the risks.

Finally, other approvals included Sanofi's multiple myeloma treatment Sarclisa (isatuximab), the second approved CD38 mAb for multiple myeloma; Isturisa (osilodrostat), which joined four other treatments for Cushing syndrome; Barhemsys (amisulpride), which got approval for postoperative nausea and vomiting after two complete response letters; and Pizensy (lactitol), which was approved for constipation.

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Competing interests
The author declares no competing interests.

Table 1 | **Selected FDA new drug approvals in Q1 2020**

Date	Drug (brand name; company)	Properties	Indication	2024 global sales forecast
9 Jan	Avapritinib (Ayvakit; Blueprint Medicines)	KIT inhibitor; PDGFR D816V inhibitor	Gastrointestinal stromal tumours	$705 million
21 Jan	Teprotumumab (Tepezza; Horizon Therapeutics)	IGF1R antibody	Thyroid eye disease	$606 million
23 Jan	Tazemetostat (Tazverik; Epizyme)	EZH2 inhibitor	Epithelioid sarcoma	$566 million
31 Jan	Peanut (*Arachis hypogaea*) allergen powder (Palforzia; Aimmune Therapeutics)	Oral immunotherapy	Peanut allergy	$1,150 million
12 Feb	Lactitol for oral solution (Pizensy; Sebela International)	Intestinal motility regulator	Constipation	NA
21 Feb	Bempedoic acid (Nexletol; Esperion Therapeutics)	ACL inhibitor	Hyperlipidaemia	$716 million
21 Feb	Eptinezumab (Vyepti; Lundbeck)	CGRP antibody	Migraine	$470 million
26 Feb	Amisulpride (Barhemsys; Acacia Pharma)	Dopamine D_2/D_3 receptor antagonist	Surgery-induced emesis	$102 million
27 Feb	Rimegepant (Nurtec ODT; Biohaven Pharmaceutical)	CGRP receptor antagonist	Migraine	NA
2 Mar	Isatuximab (Sarclisa; Sanofi)	CD38 antibody	Multiple myeloma	$516 million
6 Mar	Osilodrostat (Isturisa; Recordati)	CYP11B1 inhibitor	Cushing syndrome	$40 million
25 Mar	Ozanimod (Zeposia; Bristol-Myers Squibb)	$S1P_1/S1P_5$ receptor modulator	Relapsing-remitting multiple sclerosis	$966 million

ACL, ATP-citrate lyase; CGRP, calcitonin gene-related peptide; CYP11B1, cytochrome 11β-hydroxylase; EZH2, enhancer of zeste homologue 2; IGF1R, insulin-like growth factor receptor 1; NA, not available; PDGFR, platelet-derived growth factor receptor; S1P, sphingosine 1-phosphate. Source: EvaluatePharma April 2020, Evaluate Ltd.