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2020 Drug Launches, Like Everything, Will Be Remembered For COVID-19

by Jessica Merrill

Gilead's Veklury for the treatment of COVID-19 was a clear commercial standout among new drugs in 2020, but cancer drugs like Seagen's Padcev and Tukysa are poised for long-term potential.

Like most things in 2020, new drug launches faced the unexpected consequences of a world weighed down by the pandemic. The outbreak of COVID-19 early in the year led to stay-at-home orders and public health concerns that kept many patients and industry sales reps out of doctor's offices and curtailed non-essential medical procedures, widely impacting the global drug launch environment.

The raging health crisis also demonstrated the resiliency of pharma and the importance of having research-based innovation engines that could develop new drugs and vaccines against COVID-19. *Gilead Sciences, Inc.*'s antiviral Veklury (remdesivir), *Eli Lilly and Company*'s and *Regeneron Pharmaceuticals, Inc.*'s respective monoclonal antibodies, bamlanivimab and casirivimab/imdevimab, and especially *Pfizer Inc.*/*BioNTech SE*'s and *Moderna, Inc.*'s COVID-19 vaccines are expected to provide near-term revenue upside for the drug manufacturers, though a lot of uncertainty remains about how the market will play out long-term.

While the focus on COVID-19 diverted some of the attention of drug developers and regulators, the US Food and Drug Administration kept pace with work on new drug approvals in other therapeutic areas. The FDA approved 53 new molecular and biologic entities (plus 5 therapeutic biologics out of CBER) and granted another four emergency use authorizations (EUAs) for drugs and vaccines for COVID-19. (Also see "*US FDA 2020 Novel Approval Count Rises To 53 At CDER, Plus 5 New CBER Biologics*" - Pink Sheet, 1 Jan, 2021.)

The number of approvals was remarkable given the challenges FDA and industry faced from COVID-19 and is not far off the record year of 2018 when 59 drugs and biologics were approved. (Also see "*2018 Saw Record Launches, But No Big Splash*" - Scrip, 5 Apr, 2019.) The 2020 class of

novel drugs include potential blockbusters in cancer, multiple sclerosis and rare diseases (*see chart*).

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"What is remarkable to me is how much innovation, we are seeing, especially as both sponsors and regulators deal with COVID-19," PwC Principal Greg Rotz said. "When you pull it back, what we are talking about is rare disease advances, mRNA, rapid antibody development, gene therapy, cell therapy. These are real advances in the care of patients."

COVID-19 Curveball

Nonetheless, like just about everything that took place in 2020, launch activities and promotions around new drugs were curtailed, made virtual and even postponed.

Bristol Myers Squibb Company held off on launching its multiple sclerosis drug Zeposia (ozanimod) until June after FDA approval in late March, as the first wave of COVID-19 in the US took hold. The company waited for doctors to recalibrate to the new environment before launching the S1P receptor modulator, which joins a crowded category for MS treatments and will compete against Novartis's Gilenya (fingolimod). (Also see "*Bristol Launches Zeposia For MS, Sees Advantages In The COVID-19 Environment*" - Scrip, 1 Jun, 2020.)

Others proceeded with new drug launches in the first half of the year but pivoted to virtual outreach to doctors and health care providers. (Also see "*'Business Unusual': COVID-19 Brought Commercial Changes To Pharma And It May Stick*" - Scrip, 27 May, 2020.) *Biohaven Pharmaceutical Holding Company Ltd.*, for example, launched its oral calcitonin gene-related peptide (CGRP) inhibitor Nurtec ODT (rimegepant), the first fast-dissolving tablet in the class, for acute migraine in March. Biohaven adapted its commercial plan to a largely virtual effort. (Also see "*Biohaven's Oral CGRP Inhibitor Nurtec ODT Approved In The US For Acute Migraine*" - Scrip, 27 Feb, 2020.)

"We utilized Zoom, FaceTime, phone calls and online media to engage with physicians, while also arranging the remote delivery of samples and co-pay cards," chief commercial officer William Jones outlined during the company's second quarter earnings call in August. Nurtec ODT generated $28.6m through the third quarter.

Eli Lilly and Company also moved forward with the immediate launch of Retevmo (selpercatinib) following its approval in May for certain types of cancers driven by rearranged during transfusion (RET) alternations, citing the seriousness of the rare cancers. But Lilly modified its outreach to patients given the COVID-19 dynamics, reaching out via email, telephone and virtual webinars.

(Also see "*Lilly Moves Ahead With Retevmo Launch In A Challenging Environment*" - Scrip, 8 May, 2020.)

Pivoting to virtual communications with health care providers has been a big change for the industry.

"The challenge is not just moving the engagement from in-person to virtual, but sponsors have needed to think about that virtual experience in a fundamentally new way, the timing of that, content of that, the visual experience, the audio experience of how you talk and engage," PwC's Rotz said. "In addition to having field personnel learn new remote selling capabilities and technologies, there is a new art to virtual engagement that I think has been a challenge this year and that I think the industry is working through."

Horizon's Tepezza Stands Out

Some launches proved particularly resilient to the pandemic environment, like *Horizon Therapeutics plc*'s Tepezza (teprotumumab), which launched in February for thyroid eye disease, a rare condition, and generated $476.3m through the third quarter. Sales outpaced analyst expectations, pointing partly to the successful groundwork Horizon laid ahead of the pandemic and also the seriousness of the condition, which is associated with proptosis (eye bulging), diplopia (double vision), blurred vision and pain. (Also see "*Horizon Heralds Stellar Launch Of TED Drug Tepezza*" - Scrip, 6 Aug, 2020.)

The strong launch led Horizon to raise its peak US sales estimates for Tepezza to more than $3bn and raise its 2020 consolidated net sales guidance by more than 30% to $1.85bn-$1.9bn.

The launch reflects the resiliency of therapeutics that address a high unmet medical need for which there are no currently marketed drugs – even in challenging commercial conditions. Other new drugs for advanced cancer also got off to a strong start, including two from Seagen (formerly Seattle Genetics), which had something of a breakout year powered by two new drugs launches.

Its antibody-drug conjugate Padcev (enfortumab vedotin-ejfv), partnered with *Astellas Pharma, Inc.*, was approved late in December 2019 for advanced or metastatic urothelial cancer, and the tyrosine kinase inhibitor Tukysa (tucatinib) was approved in April for advanced unresectable or metastatic HER2-positive breast cancer, including in patients with brain metastases. Padcev generated $153.5m in nine months on the market, while Tukysa generated $58.1m from its April launch through September.

Tukysa is expected to be a blockbuster, as is another drug from AstraZeneca and Daiichi Sankyo, Enhertu (fam-trastuzumab deruxtecan), that also launched in January for HER2-positive breast cancer. Enhertu generated $63m in its first nine months on the market.

AstraZeneca oncology business unit head David Fredrickson, in a recent interview, said the company focused in 2020 on leveraging its commercial and medical field forces virtually to educate physicians on Enhertu.

"It is a difficult time to be launching new drug, and educating and changing paradigms, but I'm happy to see that we have been able to make progress despite those challenges," Fredrickson said.

Launch success was even harder to judge in 2020 than usual with launches early in the year roiled by the pandemic. Even without the complexities of COVID-19, launch timelines have generally become lengthier as the industry has pivoted increasingly to rare disease, cancer and niche indications, and focused on building blockbuster commercial winners over time through indication expansion.

Generally, $200m in first-year sales is a benchmark for predicting an eventual blockbuster contender, though the industry has turned increasingly to metrics around market access and new prescriptions to judge launch success.

"We have seen a lot of our clients relooking at the activity measures in particular that are sometimes used to assess sales force performance in light of these dynamics," Rotz said. "At the high level, the result measures in terms of the number of patients on therapy, the access of drugs across the different segment of the population, new prescriptions – those results measures are still very much in play and on the scorecard."

Industry Sets Out To Beat COVID-19

The COVID-19 pandemic spawned a new and unexpected therapeutic field for drug manufactures to tackle in less than one year as industry rushed to help solve the public health crisis; 2020 will be remembered for those efforts more than anything else. Two vaccines from Pfizer and Moderna were granted emergency use authorizations in December in the most closely watched drug development race in modern history.

The launch of the two vaccines – Pfizer and BioNTech's BNT162b2 and Moderna's mRNA1273 – marked the start of a historic large-scale vaccination effort, though the commercial results will be felt in 2021. The vaccines are expected to be blockbusters, but how commercially significant each one will be depends on how many vaccines ultimately reach the market and when and how durable they prove to be against COVID-19.

The successful development of vaccines for COVID-19 is a high-water mark in the industry's multi-year effort to turn the tide of public approval in its favor. Helping to end the pandemic could help the industry build goodwill with the public after decades of lost trust, though a lot may depend on how industry and governments execute a mass vaccination plan. (Also see "*Can*

Pharma Rebuild Its Reputation? COVID-19 Means A Big Responsibility, And Opportunity" - Scrip, 30 Oct, 2020.)

Only one COVID-19 treatment secured full FDA approval in 2020, Gilead's antiviral Veklury (remdesivir), which was granted emergency use authorization in May and a final approval in October for the treatment of hospitalized COVID-19 patients. (Also see "*Gilead's Veklury Approval Shows US FDA's Existing Regulatory Tools Are Up To The COVID-19 Challenge*" - Pink Sheet, 22 Oct, 2020.)

Veklury generated $873m in the third quarter – a substantial windfall for Gilead – but revenues still fell short of the $1bn some analysts had forecast. And with monoclonal antibody treatments and vaccines poised to become more widely available, Veklury's commercial prospects are expected to fade.

All-in-all, the drugs that launched in 2020 were plentiful and could include several commercial standouts. New drugs were generally overshadowed by the COVID-19 drug development landscape, but their commercial potential will play out in 2021 and well beyond the COVID-19 crisis.