Evaluate Vantage

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Covid-19 adds a new danger to drug launches

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Launch phase is a challenging time for drug developers, so consider the likes of Biohaven, Esperion and, most recently, Urogen, as they brave locked-down markets.

Urogen won its first US approval this week, for a treatment for a rare form of urothelial cancer, but executives could be forgiven for feeling pangs of regret at the timing. The small developer faces making its debut in an incredibly tough market, largely locked down by the coronavirus pandemic.

Urogen is preparing for a “virtual launch” and insists that this can still be carried out successfully: Jelmyto will arrive on June 1. The company is certainly not alone in braving uncertain territories, and *Evaluate Vantage* has identified 16 products launched in the past couple of months that the sellside believes hold significant revenue potential – sales that are now at risk.

None will escape disruption, though the pandemic will hurt some launches more than others. Jelmyto, for example, treats low-grade upper tract urothelial cancer, an orphan disease that afflicts only 6,000-7,000 patients a year, so a targeted marketing campaign to specialists that Urogen no doubt already has in its sights could probably still have an impact.

Treatment of cancer and other life-threatening illnesses is continuing throughout the pandemic, another advantage of sorts for companies with this focus. However, the cancellation of medical conferences will be a big blow to those hoping to roll out a medicine to a captive physician audience.

And treating a rare disease is certainly no shield; Bluebird Bio, which released its beta-thalassemia gene therapy in Germany in January, said earlier this month that it now expected the first patients not to be dosed until later in the year. It also warned that the pandemic would hinder its ability to launch in other European markets.

Feeling most pain?

Launches targeting the primary care market are thought particularly vulnerable to the global shutdown. Aside from the widespread disruptions to healthcare systems, sales teams will be physically unable to reach front-line physicians.

In this category Biohaven looks particularly exposed. The company launched its migraine treatment Nurtec ODT in March, and presumably its marketing team has been grounded. Esperion’s cholesterol-lowering drug Nexletol also arrived on US pharmacy shelves at the end of last month; the company has resorted to setting up

telephone lines and email addresses, and asking physicians to get in touch with questions.

Aimmune's peanut allergy treatment was another March debut, and in a further hindrance to uptake Palforzia needs to be administered in-office by allergists. Like Biohaven and Esperion, Aimmune is due to report first-quarter earnings in May, at which point the lockdown's ramifications on these launches will be revealed.

Investors should be braced for disappointing numbers, and the hope has to be that the results will reflect delays rather than permanent commercial setbacks. Big drug developers are also being affected: Bristol-Myers Squibb, on receiving approval for its new multiple sclerosis treatment Zeposia in March, said it would hold off a launch.

Bristol's motivation was presumably to give a product entering a highly competitive market the best start possible. Smaller companies, however, which typically will have invested heavily ahead of a launch, will be less willing or able simply to hit the pause button. For those with a closer eye on cash flow this will be a very difficult time.

Note: with projected sales of $76m in 2024, according to *EvaluatePharma*'s consensus, Urogen's Jelmyto falls just outside the $100m threshold selected as a cut-off for the analysis below.

Hitting the market or hitting the skids? 2020's biggest drug approvals so far

Product	Company	Status	2020e sales ($m)	2024e sales ($m)
Enhertu	Daiichi Sankyo/Astrazeneca	January US launch	219	2,738
Palforzia	Aimmune	March US launch	46	1,150
Caplyta	Intracellular Therapeutics	March US launch	51	974
Zeposia (ozanimod)	Bristol-Myers Squibb	US approved March, launch delayed	52	966
Nurtec ODT/rimegepant*	Biohaven	March US launch	59	893
Zynteglo	Bluebird Bio	EU approved but initial treatments delayed	23	888
Nexletol	Esperion	March US launch	42	716
Ayvakit	Blueprint Medicines	January US launch	12	705
Tepezza	Horizon Therapeutics	February US launch	37	606
Tazverik	Epizyme	February US launch	29	566
Sarclisa (isatuximab)	Sanofi	March US launch	50	516
Vyepti	Lundbeck	April US launch	41	470
Reyvow	Lilly	February US launch	70	304
Ubrelvy	Allergan	January US launch	25	302
Amzeeq	Menlo Pharmaceuticals	January US launch	37	174
Barhemsys	Acacia Pharma	US launched planned H2 2020	1	102

**Forecasts include use in preventative setting, for which the drug is not yet approved. Source: EvaluatePharma.*

For an in-depth look at how the Covid-19 pandemic is impacting the biopharma and medtech sectors, check out our free report.