Evaluate Vantage

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# Go or no go? Covid-19 upstages US regulatory decisions

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**A Vantage analysis of FDA decisions expected in the next month and how the ongoing Covid-19 pandemic could affect these.**

Regulatory delays are growing ever more likely as the threat of coronavirus ramps up globally. The US FDA announced earlier this month that it was postponing certain manufacturing facility inspections, and some advisory committee meetings have been cancelled; drug approvals are surely next to be hit.

*Vantage* took a look at US regulatory decisions remaining for this month and those expected in April − bellwethers for the future regulatory landscape. Those most closely watched include the panel for Intercept's Nash project and an approval decision for Bristol's multiple sclerosis asset ozanimod.

Mizuho analysts note that ozanimod's manufacturing inspection probably occurred 5-6 months ago, so its review will likely be unaffected, while a website for the new product, named Zeposia, is already live. Celgene holders will be eager to hear of the decision as ozanimod is part of the contingent value right, which will only pay out if the drug is approved before the end of 2020.

The FDA told Mizuho that "CDER remains fully capable to continue daily activities, such as drug reviews". Business as usual for now, it seems, though presumably this could change should conditions worsen significantly in the US.

The EMA previously said all its committee meetings would be held virtually until the end of April, and the FDA has said that where possible it will host meetings remotely, but several have already been postponed.

Intercept's Ocaliva has a tentative panel date of April 22, and any timeline update would hit the PDUFA, which is scheduled for June.

| Notable first-time US approval decisions remaining in March | | | |
|---|---|---|---|
| **Project** | **Company** | **PDUFA date** | **2024e sales ($m)** |
| Ozanimod | Bristol-Myers Squibb | Mar 25 | 966 |
| Rizaport/RNG-103 | Intelgenx | Mar 26 (fourth review) | - |
| E-58425 | Esteve | Estimated Mar 31 (adcom voted 13 for and 13 against approval) | - |
| Travivo | Fabre-Kramer Pharmaceuticals | Q1 | - |
| *Sources: Company press releases & EvaluatePharma.* | | | |

| Supplementary and other notable approval decisions remaining in March | | | |
|---|---|---|---|
| **Product** | **Company** | **Event type** | **Date** |
| IV Triferic | Rockwell | sNDA for anaemia in chronic kidney disease | Mar 28 |
| Imfinzi | Astrazeneca | sBLA for first-line SCLC (Caspian) | Q1 |
| Vesicare | Astellas | sNDA for neurogenic detrusor overactivity in paediatric patients | Estimated Q1 |
| *Sources: Company press releases & EvaluatePharma.* | | | |

**And beyond**

Even with a delay to its second-quarter approval date Abbvie's uterine fibroid treatment Orilissa would still be ahead of the GnRH antagonist competition. Myovant previously announced that its antagonist relugolix would be submitted in April, while Obseva's rival project linzagolix in still in phase III.

Acceleron's Reblozyl is up for approval in early April to treat anaemia in adults with myelodysplastic syndrome (MDS). Reblozyl gained approval in beta-thalassemia at the end of last year, but MDS is more lucrative, accounting for nearly 80% of its $1.2bn forecast for 2024, according to *EvaluatePharma's* sales by indication data.

The biggest financial impact from delays would be seen with small companies that rely on just a handful of products for revenue. Urogen's biggest growth driver, UGN-101, for low-grade upper tract urothelial cancer, has a decision due next month. The company has hired a sales force and had expected to book revenues in the third quarter, but this could be pushed back if the FDA delays approval.

Meanwhile, Astrazeneca has several decisions upcoming. Due this month Imfinzi is looking to add small-cell lung cancer to its bow, and was filed on data from the Caspian study, which showed success in combination with chemo. The results, however, will be unlikely to challenge Roche's Tecentriq.

Also, the company's SGLT2 inhibitor Farxiga is due a decision in the second quarter in heart failure with reduced ejection fraction, an important step to moving Farxiga beyond diabetes. Without a delay an approval, based on the Dapa-HF trial, would keep Farxiga just ahead of Boehringer and Lilly's rival project Jardiance; results from the latter's Emperor-Reduced trial are expected later this year.

While uncertainty remains over near-term decisions even more surrounds those due later, and if the FDA need to shift timelines then companies, and investors, need to be prepared to weather the storm.

| Notable first-time US approval decisions due in April | | | |
|---|---|---|---|
| **Project** | **Company** | **PDUFA date** | **2024e sales ($m)** |
| Trevyent | United Therapeutics/Correvio | April (likely to be extended due to deficiences in NDA) | 38 |
| Reblozyl | Bristol-Myers Squibb/Acceleron | April 4 | 1,167 |
| UGN-101 (mitomycin gel) | Urogen | April 18 | 82 |
| Opicapone | Neurocrine/BIAL | April 26 | 246 |
| MenQuadfi | Sanofi | Q2 | - |
| Orilissa | Abbvie/Neurocrine | Q2 | 926 (408 in uterine fibroids) |
| Selumetinib | Astrazeneca | Q2 | 45 |
| *Sources: company press releases & EvaluatePharma.* | | | |

| Advisory committee meetings due in April | | | | |
|---|---|---|---|---|
| **Product** | **Company** | **Date** | **Indication (clinical trial)** | **2024e sales ($m)** |
| Trelegy Ellipta | GSK | April 21 | Mortality benefit in COPD (Impact) | 1,836 |
| Ocaliva | Intercept | April 22 | Nash (Regenerate) | 1,855 (1,236 in Nash) |
| *Sources: company press releases & EvaluatePharma.* | | | | |

| Supplementary and other notable approval decisions due in April | | | |
|---|---|---|---|
| **Product** | **Company** | **Indication (clinical trial)** | **Date** |
| Braftovi + Erbitux | Pfizer | BRAF V600E-mutated colorectal cancer (Beacon CRC) | April |
| Otezla | Amgen | Moderate to severe scalp psoriasis (Style) | April |
| Farxiga | Astrazeneca | Reduce the risk of CV death or the worsening of heart failure in adults with HFrEF with and without type 2 diabetes (Dapa-HF) | Q2 |
| Lynparza + Avastin | Astrazeneca | Advanced ovarian cancer maintenance with Avastin (Paola-1) | Q2 |
| Lynparza | Astrazeneca | mCRPC and germline or somatic HRR mutations (Profound) | Q2 |
| *Sources: company press releases & EvaluatePharma.* | | | |

*This story has been updated with a statement from the FDA.*

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