

PNC PHARMA & LIFE SCIENCES

Monthly News Brief

March 2021

COVID-19

[Johnson & Johnson Vaccine Partner Emergent Still Lacks FDA's Manufacturing Green Light](#) (*Fierce Pharma*)

The FDA is debating an EUA for Emergent Biosolutions, which was chosen in July 2020 to provide drug substance manufacturing for J&J's vaccine. Emergent has been shipping millions of doses to Catalent, J&J's US fill-finish partner, though these doses cannot be used until an EUA is granted

[GSK and Vir Biotechnology Announce Submission of Emergency Use Authorization Request for Early Treatment](#) (*GSK*)

The treatment is an investigational dual-action SARS-CoV-2 monoclonal antibody to treat adults and adolescents with mild-to-moderate cases, at risk for progression to hospitalization or death. Data demonstrates that the treatment maintains activity against the UK, South African, and Brazilian variants

[Pfizer-BioNTech Announce Positive Topline Results of Pivotal COVID-19 Vaccine Study in Adolescents](#) (*Pfizer*)

A phase III trial of 2,260 adolescents demonstrated 100% efficacy and robust antibody responses in adolescents ages 12-15. EUA is expected to be requested from the FDA and EMA (European Medicines Agency) as soon as possible

M&A

[Agilent Strikes \\$550M Resolution Buyout to Muscle in on Liquid Biopsy](#) (*MedTech Dive*)

Agilent is present in the market for profiling tumors, but is on the periphery of the liquid biopsy space. The acquisition of Resolution and their cancer Dx liquid biopsy assay platform will move Agilent to a prominent position in the sector

[Charles River Laboratories Completes the Acquisition of Cognate BioServices](#) (*TheStreet*)

Strategic benefits of the \$875 million acquisition include driving efficiency and accelerating clients' speed to market by integrating manufacturing and required analytical testing, and expansion into the high-growth cell and gene therapy sector

[Perrigo to Sell Generic Drugs Business for \\$1.55B](#) (*Yahoo Finance*)

Consumer healthcare products company will sell the business to PE firm Altaris Capital Partners, and sharpen focus on core business. Transaction proceeds will be used to advance consumer self-care strategy through prudent and revenue accretive M&A

[In Wake of Biopharma Mega Buyouts, FTC Kicks Off Review of Industry's Deal-Making](#) (*Fierce Pharma*)

The Biden Administration's Federal Trade Commission announced a review of its approach to biopharma M&A as a result of a high number of recent mergers, "skyrocketing" drug costs, and allegations of anticompetitive conduct within the industry

[Illumina Hits the Antitrust Wall – Again](#) (*Evaluate Pharma*)

Illumina's \$8 billion bid for liquid biopsy developer Grail is under FTC examination just over a year after another proposed acquisition by Illumina was blocked. The Agency says the Grail deal could create a monopoly for sequencing technology that makes multi-cancer screening tests possible, potentially leading to decreased quality and higher prices

FDA Approvals and Pipeline Activities

[FDA Advisers Reassert Case Against Approval of Biogen's Alzheimer's Drug](#) (*BioPharma Dive*)

By early June, FDA should have a decision made on the approval the first-of-its-kind treatment for Alzheimer's disease. The drug is meant to slow the cognitive decline that patients experience, rather than just alleviate symptoms as existing medications do. Data surrounding the new treatment has been under scrutiny from experts who don't think efficacy evidence is strong enough

[Regeneron and Sanofi Report Positive Data from Cervical Cancer Study](#) (*Clinical Trials Arena*)

Data from the Phase III trial investigating the PD-1 inhibitor Libtayo for treating cervical cancer has shown a reduction in the risk of death by 31% compared to chemotherapy in patients with recurrent or metastatic cervical cancer. This is the fourth patient population in which Libtayo has shown clinical benefit. Regulatory submissions are planned for this year

Other News

[Countering Payers, Drugmakers Say Net Prices Declined in 2020](#) (*BioPharma Dive*)

Three large drugmakers in the US report approximately half of their gross drug revenues earned is returned to insurers as rebates or discounts. While the average list price reported by Sanofi, Merck, and Novartis in 2020 increased by 0.2%, 3.1%, and 3.7% respectively, their net prices declined by 7.8%, 0.9% and 0.5%, respectively

[Insulin Pump Adoption Seen Climbing 21% in 2021 on Wearables Boom: Survey](#) (*MedTech Dive*)

A survey of health providers projects insulin pump adoption to outpace previous estimates, with 21% growth in 2021 and 17% in 2022 driven by a shift to wearables and virtual care as a result of the pandemic. As patient adoption increases, so will competition, as smaller pump makers like Insulet and Tandem have already started to take on medtech giants like Medtronic

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