

PNC PHARMA & LIFE SCIENCES

Monthly News Brief

February 2021

COVID-19

[FDA Review Supports Safety, Efficacy of J&J Coronavirus Vaccine](#) *(BioPharma Dive)*

FDA reviewers affirmed the 66% overall efficacy previously reported by J&J. Clearance of J&J's single injection shot that can be stored at refrigerator temperatures will boost immunization efforts in the US that are currently limited by vaccine supply

[Developing Vaccines and Therapeutics for Virus Variants: FDA Releases New Guidance](#) *(Outsourcing-Pharma)*

FDA announces a modified vaccine against a SARS-CoV-2 variant would be authorized through an EUA amendment for the initial vaccine, and calls on companies to collaborate on antibody treatments that may be effective against variants

[AstraZeneca Joins with Care Access Research on COVID-19 Antibody Trial](#) *(Outsourcing-Pharma)*

The decentralized research organization (DRO) Care Access Research will assess the treatment's safety and efficacy in its Phase III trial, using its Mobile Sites On Demand model, deploying personnel, equipment, and supplies to strategic locations

M&A

[Zimmer Takes Electives Hit in Q4, to Spin Off Spine and Dental Units](#) *(MedTech Dive)*

The results continue a tough fourth quarter for orthopedics, with 4Q year-over-year sales down 1.9%. Zimmer plans to spin off its spine and dental businesses into a publicly-traded company in order to focus on higher-growth hip and knee markets

[Icon to Buy Contract Researcher PRA Health for \\$12B](#) *(BioPharma Dive)*

Icon reports PRA's mobile health platforms and data expertise will provide added benefits for customers, and complement its own network. The fifth and sixth largest CROs will combine to form the second largest CRO.

[Jazz Pharma to Buy GW Pharma, Maker of CBD-Based Epilepsy Drug, for \\$7.2B](#) *(BioPharma Dive)*

GW Pharma is the UK-based maker of the first FDA approved prescription cannabinoid medicine. Jazz pitched the deal as expanding its neuroscience research, and expects the acquisition to be accretive in the first full year following closing

FDA Approvals and Activities

[Regeneron and Sanofi Collab Picks Up Third FDA Drug Approval](#) *(BioSpace)*

Libtayo won FDA approval for first-line treatment of patients with advanced non-small cell lung cancer whose tumors have high PD-L1 expression. Phase III trial data showed the drug extended overall survival in patients compared to chemotherapy

[Bristol Myers Finally Wins FDA Approval for Cancer Cell Therapy](#) *(BioPharma Dive)*

The cancer cell therapy Breyanzi (previously called liso-cel) was approved for the treatment of late-stage lymphoma. The approval comes as the first in cell therapy for BMS and the fourth approved in the US for forms of non-Hodgkin lymphoma

Other News

[CGM, Insulin Pump Players Look to 2021 as Watershed Year for Diabetes Wearables Market](#) *(MedTech Dive)*

With the healthcare landscape continuing to move towards telehealth and digital health options, almost every major player in the continuous glucose monitoring (CGM) and insulin pump space have product launches this year

[Is Amazon's Healthcare Strategy Clear?](#) *(The Motley Fool)*

With the disbanding of Haven, the joint healthcare venture between Amazon, JPMorgan, and Berkshire Hathaway, Amazon continues to roll out services aimed at consumers such as the launch of its new online pharmacy

[McKinsey to Pay \\$573 Million to Settle Claims Over Opioid Crisis Role](#) *(Reuters)*

The consulting firm has agreed to the settlement payment to resolve claims by 40+ US states related to its role in the opioid pandemic and the advice it gave to Purdue Pharma, producer of OxyContin

[Chosen Wisely: Grail and Quest Team Up on Cancer Blood Test](#) *(Fierce Biotech)*

Grail's blood-based test should detect early signs of more than 50 types of cancer from a single sample. Quest Diagnostics will provide blood draws for the test at its 2,000+ locations, and through at-home visits via its mobile phlebotomist network

[Truvian Sciences Raises \\$105 Million for its Many-in-One Blood Testing Machine](#) *(Fierce Biotech)*

The new financing will support the biotech firm in the final development steps of its automated blood testing system, which could be used at a local pharmacy or a physician office to provide convenient access to high-quality blood tests

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