

PNC PHARMA & LIFE SCIENCES

Monthly News Brief

June 2021

Novel Medicine

[**Grail Delivers Final Study Results Showing its Blood Test's Accuracy in Spotting 50 Different Cancers**](#) (*Fierce Biotech*)

The prescription diagnostic known as Galleri was launched in the US earlier this month, offering the ability to screen for 50 different cancers and uncover their original organ sites from a blood sample, with an overall false-positive rate of 0.5%

[**Intellia Delivers a 'Landmark' for CRISPR Gene Editing**](#) (*BioPharma Dive*)

Developed in collaboration with Regeneron Pharmaceuticals, an experimental CRISPR gene editing medicine dramatically lowered the levels of a misshapen protein that causes the disease transthyretin amyloidosis. These results prove to be the first clinical evidence that CRISPR technology can be used successfully inside a person's body to treat disease

[**FDA Approval of KRAS Inhibitor Sotorasib for Lung Cancer Hailed as Milestone**](#) (*National Cancer Institute*)

Mutations in a gene known as KRAS are the root cause of cancer for many people. Amgen's sotorasib is the first KRAS-blocking treatment to receive FDA accelerated approval. The drug can be used to treat patients with locally advanced or metastatic non-small cell lung cancer, opening a new treatment option for those whose previous treatments have been unsuccessful

Alzheimer's Therapeutic Developments

[**FDA Documents Show how Controversial Alzheimer's Drug Decision was Reached**](#) (*BioPharma Dive*)

Staff at the FDA were not in agreement as the agency granted accelerated approval to Biogen's Aduhelm. A team of statisticians opined that there was not enough evidence to prove that patients' lives are improved by the treatment. They were overruled by every other office, as the drug proved successful at clearing a brain plaque that has long been viewed as the root cause of disease

[**Lilly Rushes Through Wide-Open US Alzheimer's Floodgates**](#) (*Evaluate Vantage*)

Lilly will file its Alzheimer's antibody treatment donanemab later this year, after Biogen's approval for a similar treatment with breakthrough therapy designation has moved the goalposts and made it more likely to gain approval. Lilly's confirmatory trial is due to read out in early 2023, but with early safety data extraction, approval could come as soon as mid-2022

[**Bristol Myers Squibb Re-joins Alzheimer's Push, Paying \\$80M for Prothena's Tau Antibody**](#) (*pharmaphorum*)

Prothena's PRX005 antibody currently in phase 1 testing could be worth up to \$2.2 billion if it reaches the market. The purchase by BMS comes almost 10 years after the company's exit in the Alzheimer's space after abandoning their amyloid-targeting drug

[**Medicare Faces a Massive Bill for Biogen's Aduhelm – Even if it Limits Coverage**](#) (*Fierce Pharma*)

The first FDA-Approved Alzheimer's drug in nearly two decades will be listed at \$56K for a year's worth of treatment. As thousands of Medicare beneficiaries line up for the drug, the bill could cost Medicare up to \$29 billion in just one year

Legal Proceedings

[**Viatis Gets a Win in Long-Running EpiPen Antitrust Suit**](#) (*Competition Policy International*)

The US District Court for Kansas ruled in the company's favor over a case dating back to 2017 where charges of a number of anticompetitive strategies related to the EpiPen brand were brought against Mylan. All claims related to the Racketeer Influenced and Corrupt Organizations act, as well as claims that Mylan prevented competition by paying off PBMs were dismissed

[**Teva Reaches \\$925K Settlement with Mississippi in Price-Fixing Case – Hopes Other States will Follow Suit**](#) (*Fierce Pharma*)

After years of price-fixing allegations, the settlement between Teva and the state of Mississippi is the first, as the company works to "replicate these results" through ongoing settlement discussions with other states

[**The World's Biotech Sector Unites to Oppose IP Waiver**](#) (*BIO*)

Nearly 300 global biotechnology companies and associations have come together to oppose the waiving of IP protections for COVID-19 vaccines and treatments, citing the ineffectiveness and counterproductivity of the World Trade Organization's proposed "waiver," harming patients and future cures

[**J&J to Pay \\$263 Million in New York Opioid Settlements, Avoids Trial**](#) (*Reuters*)

In addition to the halt of manufacturing and distributing of opioid medications, J&J will pay \$230 million to the state over 9 years. This settlement removes J&J from another NY jury trial where several big opioid makers and distributors are defendants. Other opioid-related trials are already underway in California and West Virginia

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