Biopharma
Innovation at a
Global Scale

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The Biopharma Innovation Boom Continues

FDA CDER Averages ~40 Annual Novel Drug Approvals In Last Decade

2020 A Banner Year for Biotech Financing
We Need to Harness and Apply Our COVID Learnings Broadly

**NEWS RELEASE**

**NIH clinical trial shows Remdesivir accelerates recovery from advanced COVID-19**

Hospitalized patients with advanced COVID-19 and lung involvement who received Remdesivir recovered faster than similar patients who received placebo, according to a preliminary data analysis from a randomized, controlled trial involving 1,065 patients, which began on February 21. The trial, known as the Adaptive COVID-19 Treatment Trial or ACTT, sponsored by NIH’s National Institute of Allergy and Infectious Diseases Clinical Trials Network, involved 1,065 patients across 12 countries. The study is still ongoing, and final results will be reported at a later date.

**PFIZER AND BIONTECH TO PROVIDE 500 MILLION DOSES OF COVID-19 VACCINE TO U.S. GOVERNMENT FOR DONATION TO POOREST NATIONS**

Thursday, June 18, 2020 - 02:00am

- U.S. government to purchase at non-profit price 200 million doses in 2021 and 300 million in the first half of 2022
- Doses to be donated to approximately 100 low- and lower-middle-income countries including those in the African Union via the COVAX Facility
- Effort is part of the companies’ recent pledge of two billion doses to ensure global equitable access to the vaccine

**RECOVERY**

Low-cost dexamethasone reduces death by up to one third in hospitalised patients with severe respiratory complications of COVID-19

Statement from the Chief Investigator of the Randomised Evaluation of Covid-19 Therapy (RECOVERY) Trial on dexamethasone, 16 June 2020

- A new analysis of the RECOVERY trial shows that dexamethasone reduces death by about a third in severely ill hospitalised patients with COVID-19.
- Dexamethasone is a low-cost drug commonly used as a non-specific anti-inflammatory treatment. It has been available in the UK for use in hospitalised patients with COVID-19 since early May.

**FDA NEWS RELEASE**


Action Follows Thorough Evaluation of Available Safety, Effectiveness, and Manufacturing Quality Information by FDA Career Scientists, Input from Independent Experts

Takeda

Pfizer

COVID-19

BioNTech
Human Genetic Data is a Key Lever for Target Discovery and Validation – And Improving Development Success

We’re at the Beginning of the Cell & Gene Therapy Journey....

We’re entering a new frontier in medical innovation with the ability to reprogram a patient’s own cells to attack a deadly cancer. New technologies such as gene and cell therapies hold out the potential to transform medicine and create an inflection point in our ability to treat and even cure many intractable illnesses.”

— Scott Gottlieb
Former FDA Commissioner
August 30, 2017

TiGenix and Takeda announce Alofisel® (darvadstrocel) receives approval to treat complex perianal fistulas in Crohn’s disease in Europe

March 23, 2018 | Leuven, Belgium, March 23, 2018 and Osaka, Japan, March 24, 2018, 18:00 CET

- First allogeneic stem cell therapy to receive central marketing authorization approval in Europe
- Alofisel offers a new treatment option for patients who do not respond to current available therapies and may be subject to numerous invasive surgeries

TiGenix NV (Euronext Brussels and NASDAQ: TIG) (“TiGenix”) and Takeda Pharmaceutical Company Limited (TSE: 4502) (“Takeda”) today announced that the European Commission (EC) has approved Alofisel (darvadstrocel), previously Cx601, for the treatment of complex perianal fistulas in adult patients with nonactive/mildly active luminal Crohn’s disease, when fistulas have shown an inadequate response to at least one conventional or biologic therapy.

Kymriah (CART-19), licensed by Novartis from UPenn, granted FDA approval September 2017
Healthcare Innovation Must Be Driven Globally

Focusing Across the Healthcare Ecosystem Is Critical

- Ensure data sharing between industry, regulators, academia, providers, payers, and policy makers
- Align with regulatory policies around the world
- Establish incentives to reduce manufacturing costs across the supply chain
- Embrace data and digital technologies
Rapidly Emerging As a Player on the Global Stage

- Overhauled regulations to comply with global standards
- Narrowing gaps in the time between new drug launches in the U.S. and China
- Rapid growth in local biopharma innovation