Biopharma Innovation at a Global Scale

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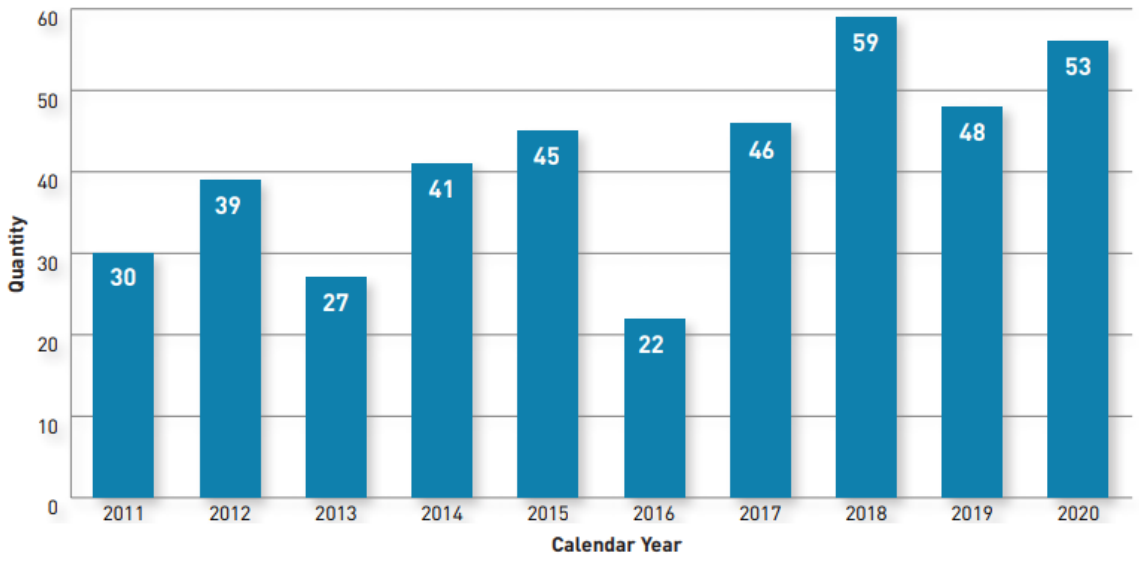
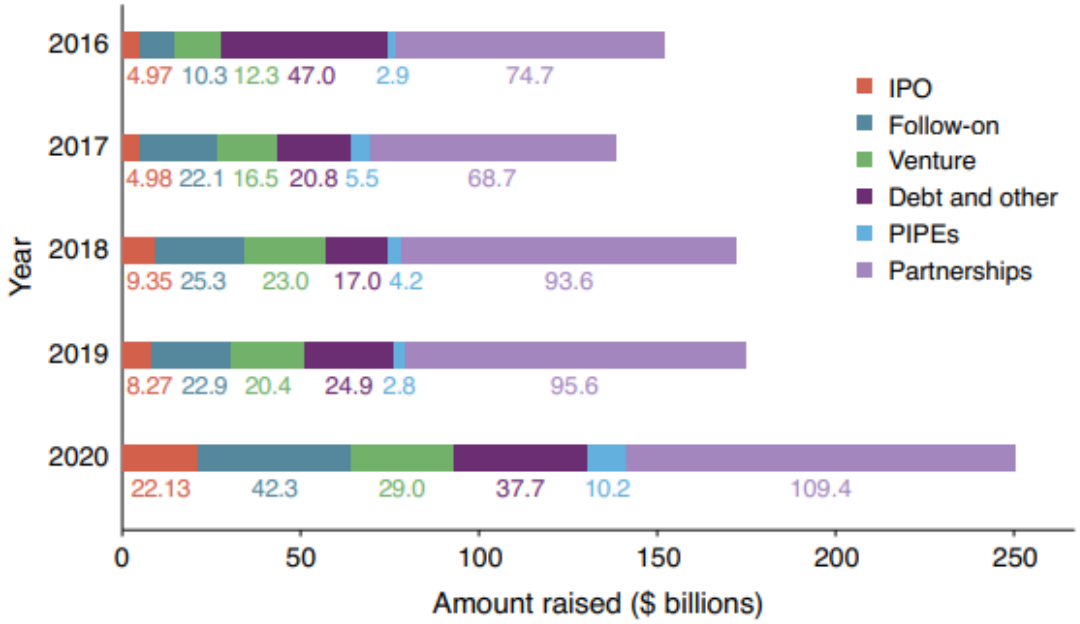
Better Health, Brighter Future

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

COVID R&D ALLIANCE

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Biopharmaceutical and Life Sciences Companies

Our members represent more than 20 leading life sciences companies, all working together to identify and accelerate promising therapeutic candidates for COVID-19 and its related symptoms.

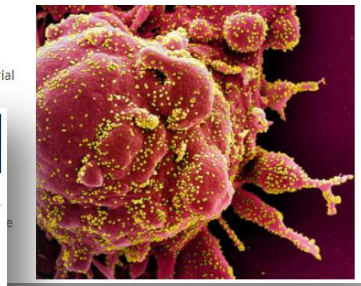
5AM VENTURES abbvie Alnylam BAYER Bristol-Myers Squibb Eisai Johnson & Johnson Lilly NOVARTIS Takeda Theravance Biopharma

NEWS RELEASES

Wednesday, April 29, 2020

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 1063 patients, which began on February 21. The trial (known as the Adaptive COVID-19 Treatment Trial, or ACTT), sponsored by



RECOVERY Randomised Evaluation of COVID-19 Therapy

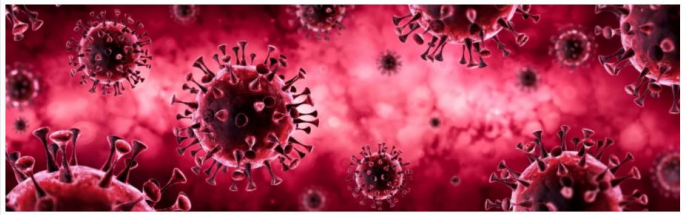
UNIVERSITY OF OXFORD

HOME FOR PATIENTS FOR SITE STAFF RESULTS NEWS Search

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

16 June 2020

Statement from the Chief Investigators of the Randomised Evaluation of COVid-19 thERapY (RECOVERY) Trial on dexamethasone, 16 June 2020



In March 2020, the RECOVERY (Randomised Evaluation of COVid-19 thERapY) trial was established as a randomised clinical trial to test a range of potential treatments for COVID-19, including low-dose dexamethasone (a steroid treatment). Over 11,500 patients have been enrolled from over 175 NHS hospitals in the UK.

On 8 June, recruitment to the dexamethasone arm was halted since, in the view of the trial Steering Committee, sufficient patients had been enrolled to establish whether or not the drug had a meaningful benefit.

A total of 2104 patients were randomised to receive dexamethasone 6 mg once per day (either by mouth or by intravenous injection) for ten days and were compared with 4321 patients randomised to usual care alone. Among the patients who received usual care alone, 28-day mortality was highest in those who required ventilation (41%), intermediate in those patients who required oxygen only (25%), and lowest among those who did not require any respiratory intervention (13%).

Pfizer

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NEWS / Pfizer and BioNTech to Provide 500 Million Doses of COVID-19 Vaccine to U.S. Government for Donation to Poorest Nations

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

Thursday, June 10, 2021 - 02:00am

- *U.S. government to purchase at not-for-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*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced plans to provide the U.S. government at a not-for-profit price 500 million doses of the companies' COVID-19 vaccine, 200 million doses in 2021 and 300 million doses in the first half of 2022, to further support the multilateral efforts to address the surge of infection in many parts of the world and to help end the pandemic. The government will, in turn, donate the Pfizer-BioNTech vaccine doses to low- and lower middle-income countries and organizations that support them.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20210609005930/en/

As part of the plan, the United States will allocate the vaccine doses to 92 low- and lower middle-income countries and economies as defined by Gavi's COVAX Advance Market Commitment (AMC) and the 55 member states of the African Union. The U.S. government and the companies will work with COVAX to ensure these vaccines are delivered to the specified countries around the world in a way that is most efficient and equitable.

These doses are part of Pfizer and BioNTech's previously announced pledge to provide two billion doses of the COVID-19 vaccine to low- and middle-income countries over the next 18 months.

dly as possible.
thank President
and equitable

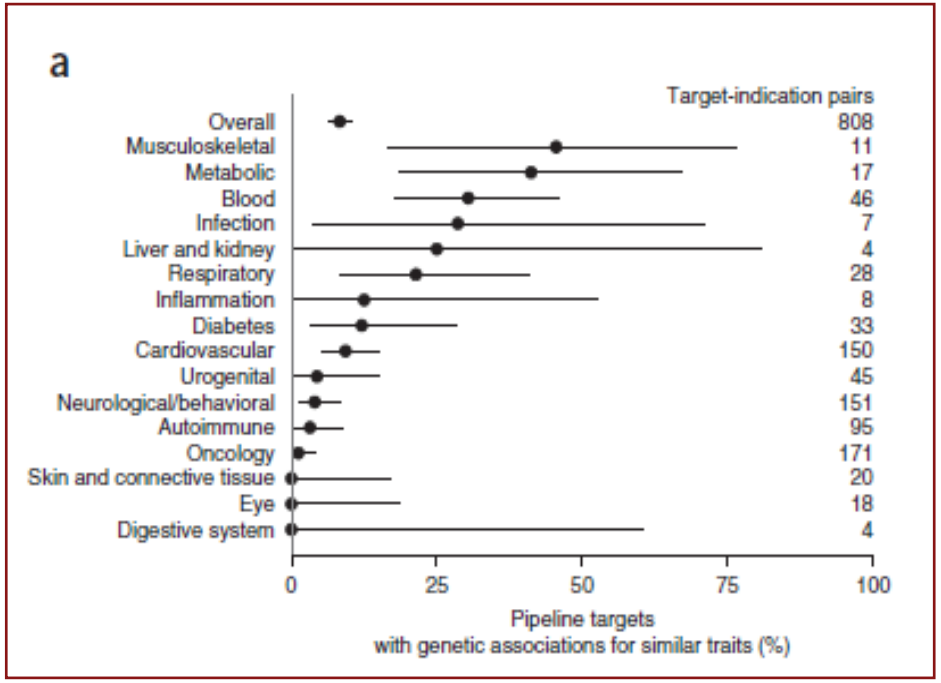
FDA NEWS RELEASE

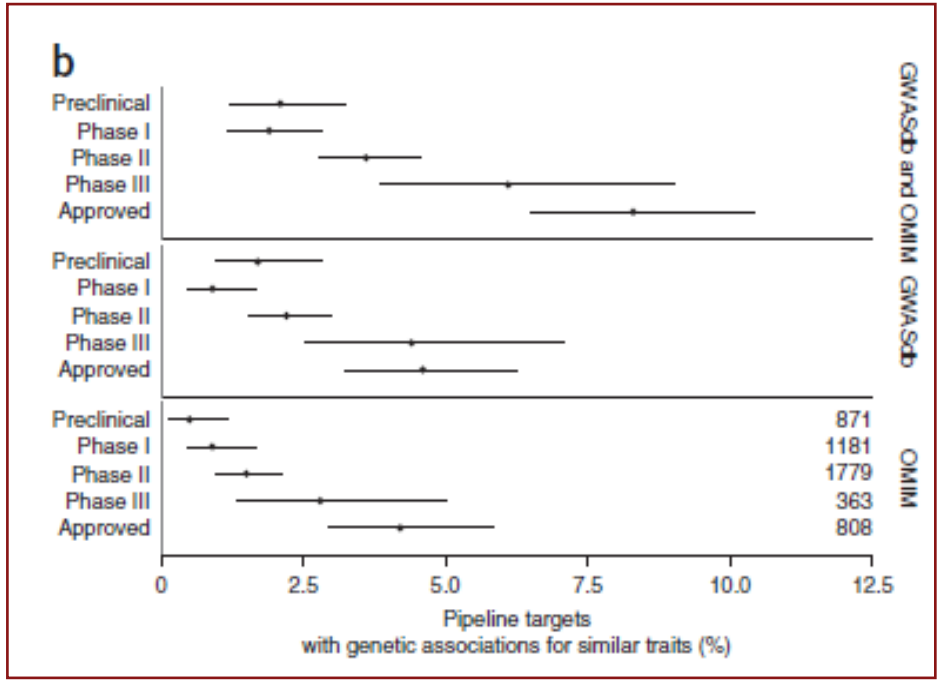
FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine

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

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

nature genetics





|Nelson, M, Tipney, H, et al. The Support Of Human Genetic Evidence For Drug Indications. Nature Genetics. 47.8 (2015): 856-860.

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[1]**

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

China: A Case Study In Biopharma Globalization

Rapidly Emerging As a Player on the Global Stage[1]

- ❑ 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

1. McKinsey: The Dawn of China Biopharma Innovation, October 2021

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