Trends & Technology

Trends

FDA grants emergency use authorization for monoclonal antibodies COVID-19 treatment

The FDA issued an emergency use authorization (EUA) on February 9, 2021, for monoclonal antibodies bamlanivimab and etesevimab administered together for mild to moderate COVID-19 treatment in adults and children age 12 years or older weighing at least 88 pounds who test positive for SARS-CoV-2 and are at high risk for progression to severe COVID-19.

Monoclonal antibodies are laboratory-made proteins able to fight off viruses by imitating the immune system. Bamlanivimab and etesevimab attack the spike protein of SARS-CoV-2, blocking the virus' attachment and entry into human cells.

EUA was based on results of a clinical trial of 1,035 non-hospitalized adults with mild to moderate COVID-19 symptoms who were at high risk for progressing to severe COVID-19, in which a single I.V. infusion of bamlanivimab and etesevimab administered together significantly reduced COVID-19-related hospitalization and death compared with placebo.

Scientists are still evaluating the safety and efficacy of this treatment. Bamlanivimab and etesevimab have not yet been studied in patients hospitalized with COVID-19 and so are not yet authorized in this patient population; monoclonal antibodies could potentially worsen outcomes for patients requiring high-flow oxygen or mechanical ventilation.

Source: **asamonitor.pub/2ZKhfuo**

Adjuvant Capital raises $300M for overlooked diseases

Several charitable organizations and pharmaceutical companies have united to raise a $300 million venture round for Adjuvant Capital, which will pursue solutions for neglected diseases around the world.

Participating donors include Merck, Novartis, IFC, the Bill & Melinda Gates Foundation, the Children's Investment Fund Foundation, Dalio Philanthropies, the Doris Duke Charitable Foundation, ELMA Investments Ltd., the Ford Foundation, the MacArthur Foundation, Global Health Investment Corporation, CDC Group, Anthos Fund & Asset Management, and others.

This group will join forces to take on some of the biggest global disease threats that are often overlooked in the West, such as malaria, shigella, hookworm, tuberculosis, and Lassa fever. These diseases predominately impact poorer regions but can quickly travel to wealthier countries across the globe, as experienced with Ebola, Zika, and SARS-CoV-2. A vigorous global health system is beneficial to all.

Adjuvant, which officially launched in 2019, has already backed several companies developing technologies for rare conditions such as melioidosis to widespread global emergencies such as COVID-19.

Source: **asamonitor.pub/2NxfUVs**

Google strengthens Mayo Clinic partnership with Rochester office

Back in September 2019, Google and the Mayo Clinic formed a partnership establishing Google Cloud as the home for all Mayo Clinic data. Google is now supporting this venture with the opening of its first dedicated offices in Minnesota. The new office space is located about a block away from the Mayo Clinic's downtown Rochester campus.

In addition to supporting their cloud-computing collaboration, the move will help facilitate the second aspect of Google and Mayo Clinic's partnership – developing machine learning models for different diseases, artificial intelligence-powered diagnostics, and virtual care platforms.

The health network's data has so far been migrated to Google's servers, and the pair have embarked on an AI project to guide cancer radiotherapy while also responding to the spread of COVID-19. Google will officially open its new office space later in 2021, in accordance with state and local health orders.

Source: **asamonitor.pub/2NpzcMB**

USDA, FDA affirm COVID-19 transmission through food or food packaging is unlikely

In February 2021, Acting USDA Secretary Kevin Shea and Acting FDA Commissioner Janet Woodcock, MD, released a statement that more than one year since the COVID-19 outbreak was declared a global health emergency, there is still no credible evidence of viral transmission of SARS-CoV-2, the virus behind COVID-19, through food or food packaging.

The USDA and FDA continue reassuring consumers that all current epidemiologic and scientific information indicates that foods and food packaging are highly unlikely to spread SARS-CoV-2. Although gastrointestinal viruses can infect people through contaminated food, COVID-19 is a respiratory illness spread from person to person. There exist relatively few reports of the virus detected on food packaging. In addition, the amount of virus of particles that can be transferred from contact with an infected surface is very small and extremely unlikely to be enough for infection by oral inhalation.

Source: **asamonitor.pub/3khOT4s**

Technology

Amgen's Corlanor could find new purpose treating COVID-19 long-haulers

Researchers at the University of California, San Diego (UCSD) say they may have found a way to repurpose Corlanor (ivabradine) – originally intended for chronic heart failure treatment – as a COVID-19 long-hauler treatment.

Amgen's FDA approval of ivabradine in 2015 didn't generate the desired enthusiasm in the cardiology industry and quickly met competition from Novartis' Entresto (sacubitril/valsartan), which eventually overtook sales of ivabradine; sacubitril/valsartan was perceived to have a better risk-benefit profile.

A recent UCSD study now promises a new legacy for ivabradine. Scientists studied the efficacy of ivabradine in 22 patients with postural orthostatic tachycardia syndrome (POTS), a disorder that causes a spike in heart rate while standing along with other symptoms like fatigue, weakness, and brain fog. Similar symptoms can also be observed in some COVID-19 patients months after they have recovered from the virus. Study patients receiving ivabradine saw a significant drop in heart rate compared with the placebo group. These patients reported an increased quality of life with no significant side effects.

Since this drug is capable of reducing heart rate without impacting blood pressure, researchers are now recommending its off-label use in COVID-19 long-haulers.

Vocalis Health wins European approval for its voiceprint COVID-19 screener

Vocalis Health has received CE Mark approval for the use of its digital COVID-19 screening programs in Europe. The screening tool uses AI software to analyze voice recordings and detect small changes in a person's voice caused by the coronavirus. These voice changes are too subtle for the human ear to detect but can be identified on a computer.

VocalisCheck users record themselves counting up from 50 to 70 on a smartphone while the software analyzes their voice quality for signs associated with the virus. In a clinical study of 288 participants run by the Municipal Corporation of Greater Mumbai, VocalisCheck identified speakers with COVID-19 with 81.2% accuracy.

Vocalis Health says the tool should not be considered a diagnostic but can be used to screen populations and identify those with the highest risk of infection so they may be sent to the clinic for further testing, such as polymerase chain reaction (PCR) testing. Vocalis Health hopes its voiceprint screener can cut down on the high costs and resources associated with PCR testing.

Vocalis is now collaborating with the Mayo Clinic on voiceprint screening systems for pulmonary hypertension.

Adagio Therapeutics begins phase 1 trial of COVID-19 antibody targeting variants

In mid-February, the first subject was dosed with Adagio Therapeutics' anti-SARS-CoV-2 antibody, ADG20, in the U.S. phase 1 trial to assess safety, tolerability, and pharmacokinetics of the new antibody in healthy adults. After satisfactory safety data has been collected, the biotech firm plans to begin global pivotal trials assessing if ADG20 can treat and prevent COVID-19.

Adagio Therapeutics says it expects ADG20 to be effective against coronavirus variants and plans to conduct test sites in countries with high levels of resistant variants, such as the B.1.351 virus initially found in South Africa. Preclinical evidence in mice saw effective neutralization of emerging variants.

Some have doubts regarding the significance of anti-SARS-CoV-2 antibodies when the speedy development of multiple COVID-19 vaccines has already provided high levels of protection against the coronavirus. The emergence of coronavirus variants, which appear to be somewhat resistant to antibody neutralizing, raised even greater doubts. ■