The Executive Summary has been replaced with a weekly compendium of items relating to testing, immunity and vaccine development

INTERNATIONAL SOS WEEKLY SCIENTIFIC UPDATE Focussing on testing, immunity and vaccine development

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16 October 2020

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ASTRAZENECA EXEMPT FROM VACCINE LIABILITY CLAIMS IN MOST COUNTRIES

Reuters reports that “AstraZeneca has been granted protection from future product liability claims related to its COVID-19 vaccine hopeful by most of the countries with which it has struck supply agreements.

“This is a unique situation where we as a company simply cannot take the risk if in ... four years the vaccine is showing side effects,” Ruud Dobber, a member of Astra’s senior executive team, told Reuters.

“In the contracts we have in place, we are asking for indemnification. For most countries it is acceptable to take that risk on their shoulders because it is in their national interest,” he said, adding that Astra and regulators were making safety and tolerability a top priority.

The New Daily reports that, “The Australian Government has given “indemnity” to suppliers of coronavirus vaccines against liabilities.”

BRITAIN PREPARES VACCINATION CENTRES TO ROLL OUT COVID-19 VACCINE

"According to National Health Service (NHS) plans seen by The Economist, the UK has so far identified seven venues as possible "Nightingale Vaccination Centres" for what will be the country's biggest-ever vaccination programme."

Venues include: Leeds Town Hall, Woking Leisure Centre, a university sports centre in Hull, and the Olympic Copper Box Arena in London. The NHS plans to have some centres operational by the end of 2020.

UK LAUNCHES CLINICAL TRIAL OF BCG VACCINE

The University of Exeter is leading the UK arm of the trial of the BRACE TRIAL** to test if BCG vaccine could help protect against COVID-19. Other countries involved include Australia, the Netherlands, Spain, and Brazil. Together, the trial will recruit more than 10,000 healthcare staff.

BRACE seeks to determine whether the cheap and widely available BCG vaccine can boost the immune system enough to prevent healthcare workers from catching coronavirus.

**BRACE TRIAL: "BCG vaccination to Reduce the impact of COVID-19 in healthcare workers"

NEW TEST THAT CAN DETECT CORONAVIRUS IN FIVE MINUTES BEING DEVELOPED

Researchers, led by University of California, Berkeley's Dr Jennifer Doudna, who is the joint winner of this year's Nobel Prize for chemistry have used CRISPR gene-editing technology to develop a test that detects the pandemic coronavirus in just five minutes, Science Magazine reports.

The new test uses mobile phones and does not require expensive lab equipment. It could potentially be deployed at doctor's offices, schools, and office buildings.

In a new non-peer-reviewed publication on the preprint server medRix, the researchers report that uses a mobile phone camera with a portable device fitted with low-cost laser illumination and collection optics.

The South China Morning Post (Hong Kong) reports that "Doudna's team successfully combined multiple CRISPR strands in tandem, increasing the sensitivity of the test and making amplification unnecessary. This was the key behind the drastic reduction in testing time, from one hour to five minutes.

"As COVID-19 cases continue to shoot up in some of the world's largest countries like the US, India and Brazil, huge backlogs of tests have strained public health systems. Most COVID-19 tests currently take at least 24 hours, but sometimes backlogs can lead to delays spanning several days."

"It looks like they have a really rock-solid test," says Max Wilson, a molecular biologist at the University of California (UC), Santa Barbara. "It's really quite elegant."

MODERNA TO APPLY FOR EU'S ROLLING APPROVAL FOR COVID-19 VACCINE

On 7 October we advised that the European Medicines Agency (EMA) had begun a real-time rolling review of data on the AstraZeneca/Oxford vaccine candidate.

This week EMA has launched real-time reviews of U.S. drug maker Pfizer and Germany's BioNTech's vaccine candidate. In addition, Reuters reports that Moderna has applied to be enrolled in the review process.

Real-time reviews are used to speed up the process of approving a successful vaccine by allowing researchers to submit findings in real time, without waiting for studies to conclude.

EU'S POTENTIAL COVID-19 VACCINE DOSES TOP A BILLION WITH J&J DEAL

Reuters reports that “The European Union has sealed a deal with Johnson & Johnson to supply up to 400 million doses of its potential COVID-19 vaccine.”

The deal “by the European Commission is its third advance purchase contract with makers of COVID-19 vaccines after deals with AstraZeneca and Sanofi, bringing the number of doses secured by the EU for its population of 450 million to 1.1 billion.”

ELI LILLY TO SUPPLY COVID-19 ANTIBODY THERAPY TO LOW-INCOME COUNTRIES

Eli Lilly has announced an agreement with the Bill & Melinda Gates Foundation for potential supply of its experimental antibody treatments for COVID-19 to low and middle-income countries.

As part of the deal, Lilly said make antibody therapies available to lower-income countries prior to April 2021, but did not elaborate on the number of doses.

JOHNSON & JOHNSON PAUSES COVID-19 VACCINE TRIAL

Johnson & Johnson has temporarily paused its US COVID-19 vaccine clinical trial after a candidate succumbed to an "unexplained illness".

In an update on its website on 12 October, the pharmaceutical company said its Data Safety Monitoring Board (DSMB), an independent committee overseeing the trial, will now review and evaluate the individual's illness.

Some 60,000 participants are currently enrolled in the trial.

International SOS Comment:

AstraZeneca recently suspended all of its vaccine trials due to an unexplained illness in a person who had received the vaccine. Following safety analysis, the AstraZeneca trials have subsequently re-started in all countries except the USA, where the FDA (US Food and Drug Administration) has asked for more information. A ruling from the FDA is expected in coming weeks.

Pausing a trial when there is an unexplained illness in a vaccinee is a normal part of trial protocols. We await further information from Johnson & Johnson DSMB.

THAILAND DELAYS HUMAN TESTING FOR CORONAVIRUS VACCINE

Thailand’s Chulalongkorn University is developing an mRNA-based vaccine known as ChulaCov19.

Reuters reports that “Thailand will delay human trials of its coronavirus vaccine due to limited production capacity at overseas facilities.
“Thai health authorities had planned human testing of the vaccine by October but must delay that by several months. The delay will be a setback for Thailand’s push to quickly create its own vaccine.”

In an interview with the Bangkok Post, the leader of the project said that up to 30 million doses might be produced for Thailand and six other Asian countries if the vaccine proved to be safe and effective.

INDONESIA GUARDED ON TIMETABLE FOR COVID-19 VACCINE PRODUCTION

Anadolu Agency reports on "Phase 3 clinical trials of the Sinovac vaccine at Padjadjaran University's Medical Faculty in Bandung, West Java involving 1,620 volunteers.

"The vaccine is the result of a collaboration between PT Bio Farma, a leading biopharmaceutical company in Indonesia, and Chinese provider of biopharmaceutical products Sinovac Biotech Ltd. The two companies have also agreed to supply at least 40 million doses of the vaccine for Indonesia.

"In an exclusive interview with Anadolu Agency, Kusnandi Rusmil, head of the COVID-19 Vaccine Clinical Trial Research Team at the Medical Faculty of Padjadjaran University, said the efficacy or ability to form antibodies of the Sinovac vaccine candidate is likely to be concluded in March 2021.

"The Indonesian government aims to mass-produce the vaccine starting in December this year or early 2021."

COVID-19 VACCINE TRIAL IN SOUTH AFRICA INCLUDES HIV INFECTED VOLUNTEERS

Witwatersrand University (Wits) in Johannesburg, South Africa, began screening for a Phase 3 trial of COVID-19 Novavax vaccine in August 2020.

A US$15 million grant towards the trial was awarded to Novavax by the Bill & Melinda Gates Foundation. The trial involves 2,665 healthy adults and nearly 240 medically stable, HIV-positive adults.

"'The major motivation for COVID-19 vaccines being evaluated at an early stage in South Africa is to generate evidence in the African context on how well these vaccines work in settings such as our own', says principle investigator of the Novavax clinical trial Shabir Madhi, Wits Professor of Vaccinology."

COVID-19 ANTIBODIES PERSIST FOR AT LEAST 3 MONTHS AFTER INFECTION

Two recent studies published in Science Immunology have shown that SARS-CoV-2 antibodies were detectable for at least three months after COVID-19 symptom onset.

The first study showed antibodies specific to the SARS-CoV-2 spike protein's receptor binding domain for up to 122 days after symptom onset.

The second study found a similar duration of antibody response.

Neither study extended beyond four months, however both suggest that people who have had COVID-19 may be protected against re-infection.

CELLTRION TO BEGIN MASS PRODUCTION OF COVID-19 ANTIBODY TREATMENT

HospiMedica.com reports that the Celltrion Group in South Korea will soon begin commercial production of its experimental COVID-19 antiviral antibody treatment while continuing with clinical trials.

Celltrion has completed a Phase 1 trial involving 32 volunteers in South Korea and is enrolling an additional nine participants. Later-stage will start soon; regulatory reviews are underway.

“The company is conducting separate overseas human trials in the UK, which will be followed by global second and third stage trials in COVID-19 patients with mild and moderate symptoms.”

APOLLO HOSPITALS PREPARING TO GIVE ONE MILLION COVID-19 VACCINES A DAY

The Hindustan Times reports that the Apollo Hospitals Group, a leading healthcare provider in India, is preparing to be able to administer one million doses of COVID-19 vaccine daily.

“’The group will work with the government to ensure that the largest number of people get the vaccine safe and fast,’ Apollo Hospitals Group Executive Vice-Chairperson Shobana Kamineni said in a virtual media conference.

“’Apollo Hospitals have been strengthening its vaccine cold chain and gearing up all Apollo facilities for efficient and fast administration with the highest safety standards’, she added.

“The group has the capability and has trained 10,000 professionals which will be stationed in all the group’s pharmacies, clinics, in hospitals across the country.

“’Almost 30% of India is 30 minutes away from an Apollo facility. Every facility will have the capability and the professionals to administer a vaccine based on the government’s directive,’ she added”.

RUSSIA APPROVES 2ND CORONAVIRUS VACCINE, 3RD ON THE WAY

The Times of Moscow reports that Russia has approved its second coronavirus vaccine, EpiVacCorona.

This is a “peptide vaccine” – these vaccines are usually composed of 20–30 amino acids containing the specific epitope (part of) of an antigen. According to the New York Times Coronavirus Vaccine Tracker, this is the only coronavirus peptide vaccine in development.

The vaccine is being developed by Siberian biotech Vektor in Novosibirsk. Early trials on 100 volunteers were said to have been successful. Vektor is preparing for large-scale post-registration trials that will involve 40,000 persons across Russia.

Vektor is a former Soviet bio-weapons research lab and, in addition to the U.S. Centers for Disease Control and Prevention (CDC), is one of two sites in the world that houses smallpox stockpiles. Vektor also houses Ebola samples.

A third Russian candidate coronavirus vaccine is likely to receive government approval in December.

VAXART ORAL CORONAVIRUS VACCINE BEGINS PHASE 1 TRIAL

Vaxart, a San Francisco-based biotech company, has announced that the first volunteer in their Phase 1 trial of oral coronavirus vaccine, VXA-CoV2-1, has been given the vaccine. VXA-CoV2-1 is a recombinant adenoviral mucosal vaccine.

Pre-clinical data showed that the vaccine induces both a robust systemic immune response (humoral and cellular) and a strong mucosal immune response, specifically in the lungs.

The Phase 1 trial will enrol 48 healthy adult volunteers aged 18 to 54 years. Participants will receive the low or high dose of the VXA-CoV2-1 oral tablet at days 1 and 29. Safety, reactogenicity and immunogenicity assessments will be performed at set times during the trial.

CHINA CONSIDERING VACCINATING STUDENTS PRIOR TO OVERSEAS STUDY

Bloomberg reports that CNBG (China National Biotec Group Co.) is in talks with the Chinese government regarding vaccinating students before they go abroad to study. No final decision has been made. CNBGs coronavirus vaccines are yet to receive regulatory approval.

The CNBG vaccine, which requires two doses, is undergoing Phase 3 testing. It has been authorized for emergency use in China and has been administered to hundreds of thousands of people there, including medical workers and employees of state-owned companies working in high-risk countries.

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