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

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COMMONPASS 'PASSPORT' TO LET AIR TRAVELLERS BYPASS QUARANTINE

Yahoo News reports that “the world's first coronavirus ‘passport’ is being launched next Wednesday to enable people to travel without having to quarantine. Passengers using two of the world's biggest airlines – United Airlines and Cathay Pacific – and travelling through London Heathrow will be the first to test the technology, which is backed by the US government.

“The volunteer passengers will upload their coronavirus test results from a validated laboratory onto a digital health pass, the CommonPass, up to 72 hours before departure. The airlines, and airport and border officials, will be able to scan the digital data on the pass to see if a person is free of the virus.

“If the trials of the scheme are successful, it will allow passengers to reduce their time in quarantine in line with the self-isolation regulations and health requirements in whichever country they arrive. The aim is to create a standardised global testing system in which governments and airlines can trust passengers' results because they are from reputable laboratories and on a recognised health passport.

“The ‘CommonPass’ is being launched by the Commons Project, a non-profit trust, and the World Economic Forum, in collaboration with government representatives from 37 countries.

“The first UK passengers to use it will test it next week on United Airlines flights between London Heathrow and Newark Liberty International Airport, one of the major airports of the New York metropolitan area. The trials are being observed by US Customs and Border Protection (CBP) and US Centers for Disease Control and Prevention (CDC).

“Dr Bradley Perkins, the organisation's Chief Medical Officer, said: ‘Without the ability to trust COVID-19 tests – and eventually vaccine records – across international borders, many countries will feel compelled to retain full travel bans and mandatory quarantines for as long as the pandemic persists."

ASTRAZENECA EXPECTS TRIAL UPDATE WITHIN TWO WEEKS

The Phase 3 trial of the Oxford/AstraZeneca vaccine has been on hold in the US pending an FDA investigation into a possible serious neurological side-effect. Bloomberg reports today that AstraZeneca expects an update from the FDA in the next one to two weeks and believes the study could resume this year.

The Phase 3 trials have been continuing in other countries and AstraZeneca expects global approval will be determined by results in tests outside the U.S, and that the US trial will be more confirmatory of results from other countries.

ELI LILLY HAS APPLIED TO THE FDA FOR AN EUA FOR COVID-19 ANTIBODY THERAPY

Bloomberg reports that Eli Lilly has asked the US FDA for emergency use authorization of its experimental COVID-19 single antibody therapy after data showed the treatment reduced hospitalizations. Authorisation would allow high-risk patients recently diagnosed with mild-to-moderate COVID-19 to receive the therapy.

Regeneron’s REGN-COV2 antibody therapy, given to President Trump, which contains two antibodies, REGN10933 and REGN10987, is currently being studied in the Phase 3 Recovery trial of hospitalized COVID-19 patients in the UK, and a Phase 3 trial for the prevention of COVID-19 in uninfected people who are at high-risk of exposure to a COVID-19 patient, such as the patient’s housemate.

Eli Lilly is also studying a cocktail of two antibodies and expects to approach regulators for authorization in November and seek full approval in the second quarter of 2021.

SOME US STATES INDICATE THEY WILL VET COVID-19 VACCINES THEMSELVES

Kaiser Health News reports that “at least six states and the District of Columbia have indicated they intend to review the scientific data for any vaccine approved to fight COVID-19.

However, Dr. Michael Osterholm, Director of the Center for Infectious Disease Research and Policy at the University of Minnesota, said “Separate state vaccine reviews would be unprecedented and disruptive, and a robust regulatory process already exists. States should stay out of the vaccine review business.”

COVID-19 VACCINE TRIALS NEED ONLY A FRACTION OF PEOPLE TO GET SICK

The Wall St Journal reports “that just 150 or so of the 30,000 or more subjects enrolled in the Phase 3 trials of the leading COVID-19 vaccines need to be infected, and show symptoms, to provide the data to assess” the efficacy (protective ability) four most advanced vaccine candidates.

“’It just takes a while to get enough events (infections), so you need to have a lot of people in the trial,’ said Angela Rasmussen, a virologist at Columbia University.

“Moderna and Pfizer executives have said they could see initial data in late October or November.”

Once the number of COVID-19 infections required by a vaccine testing protocol has been reached, the study will be “unblinded” to show if it was vaccinated, un-vaccinated, or a combination of the two who became infected.

If most or all of the infected volunteers had received the placebo (i.e. were not vaccinated), this would be strong evidence that infection had been prevented by the vaccine and would allow an early estimate of the vaccine "efficacy". This information, along with safety / side effect data, may inform an EUA (Emergency Use Authorization) for the vaccine.

FAUCI SAYS MASKS AND SOCIAL DISTANCING MAY BE NEEDED UNTIL LATE 2021

WJZ CBS Baltimore reports that Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, speaking at a virtual discussion with Maryland doctors, explained that it is "unclear what percentage of the population would need to either be infected with the virus or receive a vaccine in order for herd immunity to be effective."

Fauci continued, "Let's assume 75% of the population is protected either from already being infected and/or having a vaccine. I think it's going to be well into next year before we get there, so I don't think people are going to be able to get rid of the masks and not worry about social distancing and avoiding crowds until we get into the third quarter or fourth quarter of 2021.

"Still, people won't be able to throw caution to the wind," Fauci warned. "The public assuming they can do whatever they want once a vaccine hits the market would be "very dangerous."

MONOCLONAL ANTIBODY TREATMENT TO ENTER PHASE 3 TRIALS

GlaxoSmithKline and Vir Biotechnology announced on 6 October that their monoclonal antibody, VIR-7831, will progress to Phase 3 trials.

The worldwide trial will assess the ability of a single intravenous infusion of VIR-7831 to prevent hospitalisation in approximately 1,300 non-hospitalised patients who have symptomatic COVID-19 infection. The antibodies for VIR-7831 are produced, or cloned, from immune cells in the laboratory.

Vir Biotechnology has identified unique antibodies from COVID-19 survivors that may work by blocking the virus from infecting new cells (neutralisation) and or by recruiting the immune system to eliminate infected cells (effector function).

Initial Phase 3 results may be available by the end of 2020.

CROSS-REACTIVE IMMUNITY TO COMMON COLD DOES NOT EQUAL PROTECTIVE IMMUNITY

An article in Nature describes a recent study using human blood samples obtained donor prior to the pandemic that provides evidence that previous infection with one of the endemic "common cold" coronaviruses (HCoVs OC43, 229E, HKU1 and/or NL63.1) can produce cross-reactive T-cell responses to SARS-CoV-2. [The role of T8-lymphocytes is to kill infected cells and tumor cells.]

However, there is no evidence that this T-cell response provides "protective immunity" against SARS-CoV-2; in fact it unknown whether this T-cell response may ameliorate or worsen clinical COVID-19.

Also, a recent study in the American Society of Microbiology suggests that a history of the common cold may carry some immunity against SARS-CoV-2 infection via memory B cells. [Memory B cells remember the same (or very similar) pathogen (in this case, virus) for faster antibody production in future infections.]

Understanding the role of T-cells and memory B cells in COVID-19 disease severity is crucial to inform vaccine design and evaluation.

EU REGULATOR RAPIDLY REVIEWING ASTRAZENECA'S COVID-19 VACCINE

The European Medicines Agency (EMA) has started a “rolling review” of the data on AstraZeneca and Oxford University's potential COVID-19 vaccine, aimed at speeding up any approval process in the region for a vaccine.

At this time, the Agency has started evaluating the first batch of non-clinical data on the vaccine. It is yet to receive data from the Phases 1, 2 and 3 trials.

FRANCE TO ENROLL 25,000 IN COVID-19 VACCINES CLINICAL TRIALS

Reuters reports that France has called for 25,000 adult volunteers to enroll in a series of large-scale clinical trials aimed at evaluating the safety and efficacy of several COVID-19 vaccine candidates.

“The Phase II and III trials, which could start as soon as this month, will take place at 24 hospitals across the country.

“France’s public research body “Inserm”, which is in charge of the project, did not name the vaccines that would be assessed and said it was currently holding discussions with drug makers, adding it would pick the “most promising” candidates for the trials.”

LESS THAN HALF UK POPULATION TO RECEIVE CORONAVIRUS VACCINE

Kate Bingham, head of the UK Government’s Vaccine Task Force, told the Financial Times that vaccinating everyone in the country was “not going to happen”, adding: “We just need to vaccinate everyone at risk.”

“Ms Bingham said the government was aiming to vaccinate about 30m people, compared with a UK population of about 67m, if a successful vaccine against COVID-19 was found.

“People keep talking about ‘time to vaccinate the whole population’, but that is misguided,” she said. “There’s going to be no vaccination of people under 18. It’s an adult-only vaccine, for people over 50, focusing on health workers and care home workers and the vulnerable.”

MODERNA VACCINE TRIAL CONTRACTORS FAIL TO ENROLL ENOUGH MINORITIES

CNBC reports that “private contractors hired by Moderna to recruit volunteers for its coronavirus vaccine trial failed to enroll enough Black, Latino and Native American participants.

To make up for the shortfall, Moderna has slowed enrollment of its late-stage trial and instructed research centers to focus on increasing participation among minority volunteers.

Several researchers said they struggled to overcome the entrenched barriers that traditionally limit minority enrollment.”

NEW GLOBAL LAB NETWORK WILL COMPARE AND SELECT COVID-19 VACCINES

The Director of Vaccine R&D at the CEPI (Coalition for Epidemic Preparedness Innovations) has told Reuters that CEPI has set up a global laboratory network to assess data from potential COVID-19 vaccines. This should allow scientists and drug makers to compare vaccines and speed up selection of the most effective ones.

The network of laboratories will span Europe, Asia and North America and will centralise analysis of samples from trials of COVID-19 candidates "as though vaccines are all being tested under one roof", the Director said.

Front-runners from Pfizer, Moderna and AstraZeneca are likely to have Phase 3 trial results before the end of 2020.

CORONAVIRUS VACCINE TRIAL PARTICIPANTS REPORT SIDE EFFECTS

CNBC reports that three patients taking part in Moderna's Phases 3 trial and two in Pfizer's study have experienced significant side effects, including high fever, pounding headaches, intense chills, and exhaustion.

The CNBC article identified one of the participants in the Moderna study, a man named Luke Hutchison. After being given the second of two COVID-19 vaccine shots during the trial, he said he awoke late at night with chills and a fever.

However, in interviews, all five participants said they thought the discomfort was worth it to protect themselves against coronavirus.

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