La science pour la santé
From science to health

Paris, February 1, 2021

Press information

COVID-19 Vaccine Trials: Janssen's Vaccine Candidate to be Tested by Covireivac

The Phase 3 clinical trial of a COVID-19 vaccine is to be launched via Covireivac, a platform set up under the auspices of Inserm and the university hospitals to centralize COVID-19 vaccine trials in France. Janssen, the pharmaceutical division of the Johnson & Johnson group, has obtained the authorizations1 needed for ENSEMBLE 2, a trial evaluating the efficacy and safety of vaccine candidate Ad26.COV2.S in the prevention of COVID-19 in adults. In France, 1175 volunteers out of those registered on Covireivac will enroll in this clinical trial that will be conducted in 30,000 people across the world.

To conduct the French component of the trial, eight centers2 have been selected to enroll the 1175 volunteers, representing around 147 per center. The frequency of the disease will be compared between those having received the vaccine and those having received placebo. The aim is to determine whether the administration of two doses of the study vaccine is effective against COVID-19 and whether the vaccine protects against SARS-CoV-2 infection and disease.

The candidate developed by Janssen is based on an attenuated version of a virus that causes rhinopharyngitis in humans (adenovirus) in order to:

- Produce just part of the COVID-19 virus, the spike "S" protein, which will be recognized by the immune system and induce an immune response
- Block the multiplication of SARS-CoV-2 in the human body

This "non-replicating viral vector" vaccine is based on technology used in one of the Ebola vaccines, a product approved by the European Medicines Agency. It will be administered in the form of two intramuscular injections, with the second to be given 57 days (8 weeks) after the first. Details of the trial protocol are published on ClinicalTrials, a database of clinical studies conducted around the world.

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1 From France's drugs regulator (ANSM) and the Île-de-France institutional review board (CPP)

2 2 centers in the Île-de-France region (Cochin Hospital AP-HP and Saint Antoine Hospital AP-HP); 3 in Occitanie, 1 in Nouvelle Aquitaine, 1 in Auvergne Rhône Alpes and 1 in Grand Est.

The initial results available show that tolerability of the vaccine is good and that it induces the production of SARS-CoV-2 neutralizing antibodies in over 90% of the participants 29 days after vaccination and in almost 100% of them after 57 days. Preliminary data show the vaccine to be 66% effective against COVID-19 and that the two-dose regimen (vs. the single-dose regimen) multiplied by 2 to 3 the quantity of antibodies produced against SARS-CoV-2.

The volunteers registered on Covireivac who have been selected to participate in this trial have already been contacted or will be shortly. To be eligible, the volunteers must, for example:

- Be at least 18 years of age, healthy or with pre-existing medical conditions that are stable at the time of enrollment.
- Be affiliated to a social security system.
- Be capable of accepting and respecting the trial procedures and be capable of giving their free and informed consent.
- For women of childbearing age, a negative pregnancy test is required before vaccine administration.

Ineligible for the trial are, for example, volunteers:

- With unstable medical conditions.
- Presenting with an acute illness or temperature ≥ 38°C within 24 hours before the first injection.
- Having previously received a COVID-19 vaccine.
- Having received a live attenuated vaccine within 28 days before the vaccination visit or another type of vaccine within 14 days before the vaccination visit.
- Having received a clinical trial drug within 30 days to 6 months before enrollment, depending on its type.

"*Once a vaccine becomes available in France, it is legitimate that volunteers ask themselves whether they wish to participate in a trial in which some of them will receive placebo*. *For obvious ethical reasons, for those who will soon be able to access the national vaccination campaign, the answer is that these eventualities will be taken into account in the upcoming protocol amendments and that the option will be there to get vaccinated as part of that campaign should they so wish, even if they have already been enrolled in the trial."* declares Odile Launay, Scientific Manager of Covireivac*,* whose coordination team is based at Hôtel-Dieu Hospital - AP-HP.

Even if vaccines are already approved in France, continuing the trials is essential if we are to further scientific knowledge, particularly regarding length of vaccine protection and quality of immune response. Furthermore, in order to meet worldwide demand and the needs of the different populations, it is imperative to develop and have at our disposal several vaccines. Continued research also enables the development of products whose efficacies complement each other, are easier to administer, and possibly also cheaper to produce.

About

Inserm:

Created in 1964, the French National Institute of Health and Medical Research (Inserm) is a public science and technology institute, jointly supervised by the Ministry of Higher Education, Research and Innovation (MESRI) and the Ministry of Solidarity and Health (MSS). Inserm is France's only public institute dedicated to biomedical research and human health, and is involved in the entire range of activities from the laboratory to the patient's bedside. The mission of its scientists is to study all diseases, from the rarest to the most common.

Covireivac:

At the request of MSS and MESRI, Inserm has, in coordination with the hospitals and general practitioners, been tasked with setting up infrastructure to conduct clinical trials on COVID-19 vaccines in France. Driven by Inserm, this platform, named Covireivac, federates 24 clinical investigation centers (CICs) located in university hospitals across France, in close collaboration with the College of teachers in general practice. The clinical operational aspects of the various university hospitals are coordinated by the Paris hospital group AP-HP.

Covireivac is based on I-REIVAC, the existing national network for clinical investigation in vaccinology, which has been reinforced and extended for the occasion. This network has been labeled a network of excellence by F-Crin (France's national clinical research infrastructure). The platform's infrastructure is funded by MSS and MESRI.

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