HIPRA
Avda. la Selva. 135, 17170 Amer (Girona), Spain
Tel.: (+34) 972 43 06 60 · hipra@hipra.com · www.hipra.com

HIPRA's COVID-19 vaccine shows an effective immunological response with no adverse effects in preclinical trials

It has also been demonstrated in trials with mice that the vaccine induces neutralising antibodies against the alpha, beta, gamma and delta variants of SARS-CoV-2, and confers cell memory in specific T lymphocytes

HIPRA's COVID-19 vaccine showed an effective immunological response, inducing the production of antibodies (IgG and neutralising), a T lymphocyte cell response, and no adverse effects. This is the most significant conclusion from the preclinical trials of the COVID-19 vaccine being developed by the biotechnological pharmaceutical company HIPRA. The objective of this first study was to confirm the immunogenicity, efficacy and safety of the adjuvanted recombinant protein vaccine (PHH-1V) based on a receptor-binding domain (RBD) fusion heterodimer containing the B.1.1.7 (alpha) and B.1.351 (beta) variants of SARS-CoV-2 in studies with mice.

In the preclinical Phase, the vaccine prototype was shown to work in animal models, with mice being immunised with different doses of RBD fusion heterodimer following a two-dose vaccine regimen. Following immunisation, it was concluded that HIPRA's vaccine **induces IgG and neutralising antibodies against the alpha, beta, gamma and delta variants of SARS-CoV-2**. In addition, the vaccine generated **$CD4^+$ (collaborative) and $CD8^+$** (cytotoxic) T cell memory with Th1 cytokine expression following *in vitro* restimulation of SARS-CoV-2 with RBD. It is important to highlight that **vaccination provided 100% efficacy in the prevention of death** after exposure to the SARS-CoV-2 virus in humanised mice. The study also showed that **no SARS-CoV-2 presence was detected in the lungs or brain** of mice immunised with the candidate vaccine and infected with the virus, with these being two of the organs most susceptible to infection. Vaccination did not cause adverse events in mice in any of the studies.

Timetable

On 15 November, HIPRA received authorisation from the Spanish Agency of Medicines and Medical Devices (Agencia Española de Medicamentos y Productos Sanitarios, AEMPS) to start Phase IIb of the clinical trial of HIPRA's COVID-19 vaccine. The trial it has been conducted at 10 Spanish hospitals.

HIPRA
Avda. la Selva. 135, 17170 Amer (Girona), Spain
Tel.: (+34) 972 43 06 60 · hipra@hipra.com · www.hipra.com

Phase IIb began after Phase I/IIa, approved by the AEMPS last August, demonstrated good tolerability and the absence of significant adverse effects in all participants, as well as a good immune response. If the results obtained in Phase IIb are favourable, Phase III could be started in January. It is expected that the vaccine could be available between the first and second quarters of 2022, subject to corresponding authorisations being obtained.

Preclinical results published on the bioRxiv preprint server

The complete manuscript containing these preclinical data is available on the bioRxiv preprint server. The HIPRA preclinical study benefited from the collaboration of IrsiCaixa, IRTA-CReSA, IGTP-CMCiB, ICREA, UAB, UVic and UPF.

20th December 2021