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HIPRA's COVID-19 vaccine induces a good neutralising antibody response against the BA.2, BA.4 and BA.5 subvariants of Omicron

The latest studies confirm the broad spectrum of protection offered by the vaccine against the SARS-CoV-2 variants currently circulating in Europe.

Longer-lasting neutralising antibody titres were also observed following a heterologous booster dose of the HIPRA vaccine, suggesting a longer duration of protection compared to currently available booster shots.

Recent studies have shown that the adjuvanted bivalent recombinant protein vaccine against COVID-19 developed by the biotechnology company HIPRA **also confers protection against the BA.2, BA.4 and BA.5 Omicron subvariants** behind the latest surge in cases.

An increase in neutralising antibodies against BA.2, BA.4 and BA.5 was observed 14 days after administration of the HIPRA vaccine as a booster dose in participants previously vaccinated with two doses of the Pfizer/BioNTech mRNA vaccine. An increase in neutralising antibodies against BA.4/BA5 was also observed 14 days after a *booster* dose of the HIPRA vaccine in a subgroup of participants previously vaccinated with the Moderna mRNA vaccine.

In addition, the recently published results of the Phase IIb trial show that the HIPRA vaccine as a **heterologous booster dose** elicits a potent neutralising antibody response (greater than 10-fold increase) against all variants studied (Wuhan, Beta, Delta and Omicron (BA.1) at 14 and 98 days. These increases were statistically significantly higher than those induced by a booster dose of the Pfizer-BioNTech vaccine at 98 days against the Beta, Delta and Omicron (BA.1) variants, and at 14 days against the Beta and Omicron (BA.1) variants). These outcomes indicate that **the HIPRA vaccine generates a more sustained neutralising antibody response over time than the Pfizer-BioNTech mRNA vaccine, suggesting more durable and effective protection against the newly circulating variants.**

As has been done each time new variants of SARS-CoV-2 have appeared, the IrsiCaixa research center, with which HIPRA has collaborated since the beginning of the project, has been in charge of designing and

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producing the necessary pseudoviruses to test the efficacy of the HIPRA vaccine against these new variants. The technology that successfully analyzes the levels of neutralizing antibodies in the sera of people who have been vaccinated has been perfected by IrsiCaixa and has made it possible to carry out the analyzes in the clinical trials of the HIPRA vaccine.

The HIPRA vaccine also showed **good safety and tolerability** in clinical trials**, with no relevant adverse effects recorded** in study participants (the most common adverse effects were pain at the injection site, headache and fatigue which at no time interfered with activities of daily living and resolved within a few days). Note that recombinant protein vaccines have already been used for many years in other diseases and that the safety and efficacy of the type of **adjuvant** used (oil-in-water emulsion -like SQBA is-) have already been demonstrated in other vaccines.

Extension study: effectiveness of the vaccine as a 4th dose

To expand on the data collected in clinical trials and, in parallel to the rolling review of the European Medicines Agency (EMA), the company plans to conduct an extension of the Phase IIb trial (HIPRA-HH-2). The objective is to evaluate the safety and immune response of a 4th booster dose of the HIPRA vaccine. A total of 200 volunteers from 10 hospitals in Spain are expected to participate in the study. Of these participants, half will have previously received two doses of the Pfizer-BioNTech vaccine + one dose of the HIPRA vaccine. The other half will have received three doses of the Pfizer-BioNTech vaccine.

The study, which is scheduled to start at the end of the summer, will launch once it has been approved by the Ethics Committee of the Hospital Clínic de Barcelona and the Spanish Agency of Medicines and Medical Devices (AEMPS).

Final Phase of the HIPRA Vaccine

On 29 March, the European Medicines Agency (EMA) began rolling review of the HIPRA vaccine. The EMA has been evaluating the compliance of the vaccine with the usual EU standards for effectiveness, safety and quality. This rolling review precedes the marketing authorisation of the vaccine.

For the company, “the HIPRA vaccine meets the current needs of the European Region. With close to 50% of the population still without a booster dose and with the autumn vaccination campaigns in mind, it can only be a good thing that vaccines based on technologies other than mRNA are available to European citizens. The broad spectrum of protection against the variants that have emerged and its good safety

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profile make the HIPRA vaccine an appealing solution for people who need to be vaccinated in accordance with the recommendations of health authorities."

The data mentioned in this press release have been shared with the regulatory authorities. Some have already been published on the MedRxiv server.

About the HIPRA COVID-19 vaccine

The COVID-19 vaccine developed by HIPRA is an adjuvanted recombinant protein vaccine (bivalent) 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. The HIPRA vaccine **is stored at refrigerated temperature between 2 and 8ºC**, facilitating storage and distribution. In addition, it is **ready-to-use**, meaning that unlike other vaccines, it does not need to be reconstituted or thawed before use.

More than 50 years' experience in vaccine production

HIPRA, headquartered in Amer (Girona, Spain), is a biotech pharmaceutical company focused on prevention in animal and human health care, with a wide range of highly innovative vaccines and an advanced diagnostic service. In line with its mission statement "Building immunity for a healthier world", HIPRA affirms its commitment to providing solutions that improve global health.

The company has a strong international presence with 40 wholly owned subsidiaries (of which 21 are located in European countries), 3 R&D centres and 6 production sites strategically located in Europe (Spain) and America (Brazil). In addition, its extensive international distribution network keeps marketing channels open with nearly 100 more countries, thus covering all 5 continents.

Research and development are at the core of its expertise. The company dedicates 10% of its annual turnover to R&D activities that focus on the creation and application of the latest scientific advances for the development of innovative vaccines of the highest quality. To add value to its vaccination expertise, the company also develops medical devices and traceability services. It performs and monitors all stages of production of its services and biological products in its state-of-the-art facilities. HIPRA has launched a total of 22 vaccines in the last 10 years, more than any other biotech company.

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