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

AEMPS authorizes Phase IIb second clinical trial of the HIPRA's vaccine against Covid-19

The objective is to confirm the safety and the immunogenicity when it is used as a booster with people vaccinated with two doses of AstraZeneca's vaccine and without having passed the Covid-19

The biotechnological pharmaceutical company HIPRA has received the authorization of the Spanish Agency of Medicines and Health Products (AEMPS) to start Phase IIb second clinical trial of the HIPRA's vaccine against Covid-19. This trial will complete the results that HIPRA's vaccine has obtain until the moment.

The objective of this Phase IIb second clinical trial is to evaluate safety and immunogenicity when it is used as a booster. It will involve 270 volunteers over the age of 18, who have not passed Covid-19 and have received two doses of AstraZeneca. The new trial will take place in five Spanish hospitals: HM Sanchinarro (Madrid), Hospital Gregorio Marañón (Madrid), HM Puerta del Sur (Móstoles), HM Modelo (A Coruña) and HM Rosaleda (Santiago de Compostela).

This Phase IIb second trial will be randomized, controlled and double-blind (HIPRA's vaccine or a masked approved vaccine is administered to prevent identification by both the patient and the research team). Hospitals have set up channels for volunteers that want to sign up:

- HM Sanchinarro (Madrid), HM Puerta del Sur (Móstoles), HM Modelo (A Coruña) y HM Rosaleda (Santiago de Compostela): https://ecv.microsoft.com/L0vyXXcytA
- Hospital Gregorio Marañón (Madrid): investigacionmicrobiologia@iisgm.com

In the first Phase IIb clinical trial, authorized on November 15, the study was carried out with volunteers who had been vaccinated with Pfizer. In order to authorize this Phase IIb second clinical trial, it has been positively assessed that in the three already approved trials of the HIPRA's vaccine against the Covid-19, no safety concerns have been noted and only the expected reactions of any vaccine have been encountered.

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

In parallel to this Phase IIb, HIPRA's clinical trial of the vaccine continues to advance with Phase III authorized on February 1. It focuses on evaluating the safety and tolerability of this vaccine as a booster dose of any of the then-authorized vaccines: Janssen, AstraZeneca, Moderna and Pfizer.

HIPRA's vaccine

The vaccine against Covid-19 that HIPRA is developing is an adjuvant recombinant protein vaccine, based on a receptor-binding domain fusion heterodimer (RBD) containing the B.1.1.7 (alpha) and B.1.351 (beta) variants of SARS-CoV-2.

The HIPRA's vaccine is stored between 2 and 8 ºC, facilitating its logistics and distribution. The technology used allows great versatility to adapt it to new variants of the virus, if necessary, in the future. The results obtained, show that the vaccine produces neutralizing antibodies against the current VOC (variants of "concern") and efficacy in disease prevention too.

March 11, 2022