Communication of the President of the Office of 30.03.2023 on the recommendation of the CHMP to authorise a booster vaccine Bimervax (formely COVID-19 Vaccine HIPRA) for 16 years of age and older previously vaccinated with mRNA vaccine against COVID-19.

Wysłane przez m.koszewski w Czw, 30/03/2023 - 18:16

PREZES
Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych

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EMA’s human medicines committee (CHMP) has recommended authorising the COVID-19 vaccine Bimervax (previously COVID-19 Vaccine HIPRA) as a booster in people aged 16 years and above who have been vaccinated with an mRNA COVID-19 vaccine.

Bimervax, developed by HIPRA Human Health S.L.U., contains a protein produced in the laboratory that consists of part of the SARS-CoV-2 spike protein from the alpha and beta virus variants.

The CHMP concluded that sufficiently robust data on the quality, safety and immunogenicity of the vaccine are now available to recommend its marketing authorisation in the EU.

The main study carried out with Bimervax is an immunobridging trial, which compared the immune response triggered by this new vaccine with that triggered by the authorised mRNA vaccine Comirnaty that targets the original (Wuhan) SARS-CoV-2 spike protein.

The study involved 765 adults who had previously completed primary vaccination with 2 doses of Comirnaty and who were subsequently given a booster dose of either Bimervax or Comirnaty. Although Bimervax triggered the production of lower levels of antibodies against the original strain of SARS CoV 2 than Comirnaty, it led to higher levels of antibodies against the Beta and Omicron variants and comparable levels against the Delta variant.

Supportive data were provided from another ongoing study that included 36 adolescents aged 16 to 17 years old, with immune response data available for 11 of them. The study found that Bimervax given as a booster produced an adequate immune response in these adolescents, with antibody production comparable to that seen in adults who received Bimervax.

The CHMP therefore concluded that a booster dose of Bimervax is expected to be at least as effective as Comirnaty at restoring protection against COVID-19 in people aged 16 years and older.

The safety profile of Bimervax is comparable to that of other COVID-19 vaccines. The most common side effects seen with Bimervax were pain at the injection site, headache, tiredness and muscle pain. These were usually mild to moderate and cleared within a few of days after vaccination.

The safety and effectiveness of the vaccine will continue to be monitored as it is used across the

EU, through the EU pharmacovigilance system and additional studies by the company and European authorities.

Based on the available evidence, the CHMP concluded that the benefits of Bimervax outweigh its risks and recommended granting a standard marketing authorisation in the EU.

The product information for Bimervax contains information for healthcare professionals, a package leaflet for members of the public and details of the vaccine's authorisation.

The full risk management plan provides more information on the safety of Bimervax and describes studies that will be carried out to gain more knowledge about its safety and effectiveness.

An assessment report with details of EMA's evaluation of Bimervax will be published shortly and clinical trial data submitted by the company in the application for marketing authorisation will be published on the Agency's clinical data website in due course.

More information is available in an overview of the vaccine in lay language, including a description of the vaccine's benefits and risks and why EMA recommended its authorisation in the EU.

Bimervax works by preparing the body to defend itself against COVID-19. It contains part of the SARS-CoV-2 spike protein from the alpha and beta virus variants, which have been combined into a single protein in the laboratory. The spike protein is found on the surface of SARS-CoV-2 (the virus that causes COVID-19) and is used by the virus to enter the body's cells. The vaccine also contains an 'adjuvant', a substance to help strengthen the immune responses to the vaccine.

When a person is given the vaccine, their immune system will identify the combined protein in the vaccine as foreign and produce natural defences — antibodies and T cells — against it. If, later on, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the spike protein on the virus and be prepared to attack it. The antibodies and immune cells can protect against COVID-19 by working together to kill the virus, prevent its entry into the body's cells and destroy infected cells.

A booster injection of Bimervax is given into the muscle, usually of the upper arm, at least 6 months after the last dose of an mRNA COVID-19 vaccine.

In line with the EU's safety monitoring plan for COVID-19 vaccines, Bimervax will be closely monitored and subject to several activities that apply specifically to COVID-19 vaccines.

The company is required to provide regular safety updates. In addition, independent studies of COVID-19 vaccines coordinated by EU authorities will give more information on the vaccines' long-term safety and benefits in the general population.

These measures will allow regulators to swiftly assess data emerging from a range of different sources and take any necessary regulatory action to protect public health.

During the assessment of Bimervax, the CHMP had the support of EMA's safety committee, the PRAC, who assessed the risk management plan of the vaccine, and the COVID-19 EMA pandemic task force (COVID-ETF), a group that brings together experts from across the European medicines regulatory network to facilitate rapid and coordinated regulatory action on medicines and vaccines for COVID-19.

Bimervax was evaluated as part of 'OPEN', an initiative started in December 2020 with the aim of increasing international collaboration in the EU review of COVID-19 vaccines and therapeutics. More information can be found on the EMA's governance during COVID-19 pandemic webpage.

More information available on the website: https://www.ema.europa.eu/en/news/ema-recommends-approval-bimervax-covid-19-booster-vaccine [1]

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President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Odnośniki
[1] https://www.ema.europa.eu/en/news/ema-recommends-approval-bimervax-covid-19-booster-vaccine