10 November 2022
EMA/653900/2021

EMA recommends approval of VidPrevtyn Beta as a COVID-19 booster vaccine

EMA's human medicines committee (CHMP) has recommended authorising the COVID-19 vaccine VidPrevtyn Beta as a booster in adults previously vaccinated with an mRNA or adenoviral vector COVID-19 vaccine.

VidPrevtyn Beta, developed by Sanofi Pasteur, contains a version of the spike protein found on the surface of the Beta variant of the SARS-CoV-2 virus. It also contains an 'adjuvant', a substance to help strengthen the immune responses to the vaccine.

EMA's human medicines committee (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 studies conducted with VidPrevtyn Beta are two immunobridging trials, which compare the immune response induced by this new vaccine with that induced by an authorised comparator vaccine effective against the disease.

The first trial involved 162 people aged 18 years and older, who were given a booster of VidPrevtyn Beta or the comparator vaccine (the originally authorised Comirnaty vaccine targeting the wild-type SARS-CoV-2 spike protein). The study showed that a booster dose of VidPrevtyn Beta triggers a higher production of antibodies against the SARS-CoV-2 Omicron BA.1 subvariant than Comirnaty.

In a second main study, a booster injection with VidPrevtyn Beta restored immunity against different SARS-CoV-2 virus variants in 627 people aged 18 and older who had previously completed a primary vaccination course with an mRNA vaccine (Comirnaty or Spikevax) or an adenoviral vector vaccine (Vaxzevria or Jcovden).

The CHMP therefore concluded that a booster dose of VidPrevtyn Beta is expected to be at least as effective as Comirnaty at restoring protection against COVID-19.

The most common side effects observed with VidPrevtyn Beta in studies were pain at the injection site, headache, muscle or joint pain, feeling generally unwell and chills. These were usually mild and cleared within a couple of days after vaccination.

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The safety and effectiveness of the vaccine will continue to be monitored as the vaccine 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 VidPrevtyn Beta outweigh its risks and recommended granting a standard marketing authorisation in the EU.

Standard marketing authorisation

The dossier for the vaccine includes the results from two immunobridging trials. Although efficacy placebo-controlled trials have been the standard for authorising previous COVID-19 vaccines, EMA considers that well-justified and appropriately designed immunobridging studies are adequate for authorising future COVID-19 vaccines at this point in the pandemic. This is because there are now a number of COVID-19 vaccines authorised in the EU that are proven to be safe and effective and that can be used as comparators in studies. Additionally, at present, it would be difficult to recruit enough individuals who have not been vaccinated nor previously exposed to the virus to conduct large efficacy clinical trials.

The European Commission will now fast-track the decision-making process to grant a decision on the standard marketing authorisation for VidPrevtyn Beta, allowing this vaccine to be included in vaccination programmes rolled out across the EU. A standard marketing authorisation is considered appropriate for this vaccine since the immunobridging studies met their objectives and data provided are considered sufficient.

Where to find more information

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

An assessment report with details of EMA's evaluation VidPrevtyn Beta and the full risk management plan will be published shortly. 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.

How VidPrevtyn Beta works

VidPrevtyn Beta works by preparing the body to defend itself against COVID-19. The vaccine contains a laboratory-produced version of the spike protein found on the surface of SARS-CoV-2 Beta variant. It 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 protein 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 VidPrevtyn Beta is given into the muscle, usually of the upper arm.

Monitoring the safety of VidPrevtyn Beta

In line with the EU's safety monitoring plan for COVID-19 vaccines, VidPrevtyn Beta will be closely monitored and subject to several activities that apply specifically to COVID-19 vaccines. Although large numbers of people have received COVID-19 vaccines in clinical trials, certain side effects may only emerge when millions of people are vaccinated.

The company is required to provide monthly safety reports in addition to the regular updates required by legislation. In addition, independent studies of COVID-19 vaccines coordinated by EU authorities will give more information on the vaccine's 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.

Assessment of VidPrevtyn Beta

During the assessment of VidPrevtyn Beta, 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.

VidPrevtyn Beta 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.