

## **169th Meeting of the Vaccines and Related Biologic Products Advisory Committee Meeting Overview**

On October 14 -15, 2021, the Vaccines and Related Biologic Products Advisory Committee (VRBPAC) will meet to hear presentations on a total of four issues that are related to the use of booster vaccine doses following the primary vaccine series of the authorized or approved COVID-19 vaccines.

### **Day 1**

Issue 1: Update on the use of booster doses of vaccine in Israel

Issue 2: Data supporting the use of a booster dose of the Moderna COVID-19 vaccine following the Moderna COVID-19 primary series

### **Day 2**

Issue 3: Data supporting the use of a booster dose of the Janssen COVID-19 vaccine following primary vaccination with the Janssen COVID-19 Vaccine

Issue 4: Data on heterologous (mix-and-match) boosting using the currently available vaccine

The authorized or approved COVID-19 vaccines provide protection against a variety of non-serious and serious outcomes resulting from infection with SARS-CoV-2, including hospitalization and death. Emerging data over the past months suggest that the protection of the currently authorized or approved COVID-19 vaccines wanes over time for the provision of protection against infection with SARS-CoV-2. Such waning of protection may leave previously vaccinated individuals susceptible to both non-serious and serious outcomes from COVID-19, including the occurrence of long COVID-19 following symptomatic breakthrough infections. In considering direct benefits of vaccination that could support emergency use authorization of booster doses, the administration of booster vaccinations following the primary series may reduce these adverse outcomes and may be indicated, provided they are associated with a favorable benefit-risk profile.

First, an update to the data presented at the September 17, 2021 VRBPAC meeting on the waning of protection against COVID-19 in the Israeli population will be presented. At the time of the September 17 presentation, myocarditis data in the younger population were not mature, and the data were considered to have most compellingly indicated the potential benefit of a booster dose following a primary vaccination series of the Pfizer-BioNTech COVID-19 vaccine in individuals at least 65 years of age.

Next, Moderna's data supporting the use of a booster dose at least six months following the Moderna COVID-19 Vaccine primary series will be presented. Moderna conducted a study evaluating immunogenicity of a booster dose of 50 µg that represents half the dose that is being administered for each dose of the primary series (100 µg).

On the second day of the meeting, Janssen's (Johnson and Johnson's) data supporting the use of a booster dose given at least two months following a single dose of their vaccine will be presented. Rather than providing a single immunogenicity and safety study supporting the request, Janssen has provided several studies that have evaluated safety and immunogenicity or efficacy of the vaccine as a second dose administered 2-3 months after the first dose or as a booster dose administered approximately 6 months after a single dose primary vaccination.

Finally, a study sponsored by the National Institute of Allergy and Infectious Diseases evaluating the immunogenicity of each of the vaccines following immunization with the same or a different primary series will be presented. Such heterologous boosting data may be of interest to various stakeholders.