SISONKE 4 – FREQUENTLY ASKED QUESTIONS

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of the study is to evaluate the effectiveness of the heterologous mRNA-1273 (Moderna) boost against any COVID-19 and against severe COVID-19 (including hospitalizations and deaths) among health care workers who participated in the Sisonke trial and who received either a single dose or two doses of Ad26.COV2.S (Janssen, Johnson and Johnson) COVID-19 vaccine as their primary vaccination. Furthermore, the study aims to collect additional safety and immunogenicity data on the heterologous mRNA-1273 boost among a sub-group of SHERPA study participants.

WHY IS THIS PHASE 3 OPEN-LABEL STUDY BEING CONDUCTED?

Immunogenicity studies have indicated that a heterologous mRNA vaccine boost strategy may elicit stronger neutralizing antibody responses among people who received the Ad26.COV2.S and other vector-based vaccines. Considering the good safety and immunogenicity data from heterologous mRNA boost studies, the Sisonke 4 (SHERPA) study provides a good opportunity to test mRNA boosting with the Moderna mRNA-1273 vaccine after a single or two doses of Ad26.COV2.S among health care workers in South Africa. The data will also provide SAHPRA, the South African regulator, with local data on the safety and effectiveness of the heterologous boost using the mRNA-1273 (Moderna) to support potential licensure of this vaccine in South Africa.

WHAT IS THE DIFFERENCE BETWEEN A HETEROLOGOUS AND A HOMOLOGOUS VACCINATION?

Several COVID-19 vaccines were rapidly developed over the past 2 years, for example the Johnson and Johnson Ad26.COV2.S vector-based vaccine and the mRNA-1273 Moderna vaccine. In the initial studies the same vaccine was given to one person, for example 2 Pfizer vaccines, or 2 AstraZeneca vaccines. This is called homologous vaccination. However, once more vaccines became available, some countries started offering so-called heterologous vaccination schedules, for example in Europe and Canada some people first received the AstraZeneca vaccine followed by a Moderna or a Pfizer vaccine. Surveillance of these vaccination schedules have shown that heterologous vaccination strategies are safe and can be as effective as homologous vaccination schedules.

WHAT IS THE BOOSTER DOSE AND HOW IS THE VACCINE GIVEN?

The mRNA-1273 vaccine will be administered as a single 50 mcg booster dose of 0.25 ml suspension. This is the internationally recommended booster dose for the mRNA-1273 Moderna vaccine. It has been evaluated in studies and is currently being given as a booster vaccine to many people across the world. The study vaccine is given by injection, in your upper arm. You will remain at the study site for observation for about 15 minutes after receiving the vaccine. There is no placebo in this study, which means that everyone will receive the booster.

WHO CAN PARTICIPATE IN SISONKE 4?

Healthcare workers who received either a single dose or two doses of the Johnson & Johnson Ad26.COV2.S vaccine and are willing to receive a mRNA-1273 booster.

WHO CANNOT PARTICIPATE?

If you are not a Sisonke participant or if you have received any COVID-19 vaccines other than one or two doses of Ad26.CoV2.S (for example, another mRNA booster dose such as the Pfizer vaccine).

HOW MANY HEALTHCARE WORKERS WILL PARTICIPATE IN THIS STUDY?

The study aims to enrol up to 15 000 participants. These participants have already participated in the Sisonke study.

IS THE MODERNA MRNA-1273 BOOSTER VACCINE SAFE?

Several studies have investigated the safety of the Moderna mRNA-1273 vaccine and have confirmed that it is safe to be administered as a homologous (Moderna vaccine followed by Moderna vaccine) and heterologous (Vector-based vaccine followed by the Moderna mRNA-1273 vaccine) vaccination schedule. In addition, studies have shown that the Moderna mRNA-1273 vaccine given as a 50mcg booster dose has been safe in populations in the United States, Canada and Europe and in other parts of the world. Overall, more than 150 million doses have been administered to people across the world. Apart from the common vaccine related symptoms such as fever, headache and muscle aches, very rare cases of myocarditis (inflammation of the heart muscle) has been described particularly among young men (18 – 24 years old). However, the majority of these rare cases (up to 40 cases per 1 million vaccinees) have been self-limiting, that means that they recovered with supportive care.

WHAT WILL BE DONE ON THE DAY OF MY VISIT?

We will ask you questions about your general health, your vaccination history, and whether you are taking any medications. We will also briefly examine you. If you are female of reproductive age, we may also ask you to do a pregnancy test. However, in case you are pregnant, that would not exclude you from the study. We will next take a blood sample (up to 1 teaspoon) from you to check for previous COVID-19 infection and a nasal swab to check whether you carry the virus at the time of your visit. Once that is done you will have the mRNA-1273 Moderna vaccine booster administered, and study staff will observe you for approximately 15 minutes. After the observation period you are good to go. You will only have to return to the site if you have any concerns. We will monitor you through the study safety desk and will send you a text message with a link where you can report any reactogenicity or adverse events. No additional visits are required, except if you join the sub-study. Sub-study participants will need to return to a designated research site for 2 more visits to monitor immunogenicity.