

Compound ID: VAC31518 (JNJ-78436735, Ad26COVS1 Vaccine, Ad26.COVS Vaccine)

JNJ-78436735 is a monovalent vaccine composed of a recombinant, replication-incompetent adenovirus serotype 26 (Ad26) vector, constructed to encode the Severe Acute Respiratory Syndrome coronavirus-2 (SARS-CoV-2) virus spike (S) protein.

WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS OF PARTICIPATING?**Potential Discomforts, Side Effects, and Risks Associated with Ad26.COVS**

Ad26.COVS has been studied in the test tube and in animals. In studies where animals were vaccinated with Ad26.COVS or similar Ad26-based vaccines, no vaccine-related adverse effects have been observed.

Vaccines similar to Ad26.COVS (that is, Ad26-based vaccines) have been given to participants in studies designed to prevent RSV (respiratory syncytial virus), HIV (human immunodeficiency virus), Ebola/filovirus, Zika virus, HPV (human papillomavirus) and malaria. As of 04 September 2020, Ad26-based vaccines have been administered to approximately 114,000 participants in ongoing and completed studies, including more than 99,000 participants in an ongoing Ebola vaccine study in the Democratic Republic of the Congo and in an ongoing immunization campaign in Rwanda. Pain, tenderness and redness at the injection site, headache, chills, joint pain, muscle pain, tiredness, generally not feeling well, nausea and fever have been seen with these study vaccines. These reactions usually start within 1 to 2 days after the injection and most of the reactions get better within 1 to 3 days.

As of 10 September 2020, a single injection of Ad26.COVS has been administered to 805 human participants, aged 18 and older. Following administration of Ad26.COVS, fever, muscle aches and headache appear to be more common in younger adults and can be severe. For this reason, we recommend you take a fever reducer or pain reliever if symptoms appear after receiving the vaccination, or upon your study doctor's recommendation. Please tell the study staff if you take anything.

Some vaccines may cause a more severe course of disease when you are vaccinated against a disease and then become infected by that disease germ. This is called vaccine-enhanced disease and it has been described during animal testing for some vaccines against other coronavirus infections such as SARS (Severe Acute Respiratory Syndrome) and MERS (Middle East Respiratory Syndrome). However, studies in human volunteers with vaccines using similar technology to Ad26.COVS have produced responses that are not associated with vaccine-enhanced disease. Nevertheless, the risk of a more severe course of SARS-CoV-2 infection cannot be absolutely ruled out with the vaccine tested in this study. Because of this, all participants in this study will be monitored for vaccine-enhanced disease throughout the study. We will do this by taking nasal swabs in participants suspected of having SARS-CoV-2 infection. Study participants with a positive test result will be followed until the signs and symptoms resolve. These procedures will allow us to

recognize and intervene early in the course of disease. Early recognition and intervention will reduce the risk of a bad outcome if enhanced disease should occur.

All vaccines can cause side effects. Problems that are not expected may happen and these may be life-threatening. If you have any side effects or problems during this study, please tell your study doctor right away.

There may be risks associated with Ad26.COVS that we don't know about yet. If we learn new information about the study vaccine and risks associated with it, we will tell you.

Risks and possible side effects of vaccines in general

All types of injections can cause:

- Stinging, itching, arm discomfort, pain, soreness, redness, hardness, bruising and swelling where you receive the injection
- Fever
- Chills
- Rash
- Itching in other areas of your body
- Aches and pains
- Muscle and joint pain
- Throwing up and nausea
- Headache
- Dizziness
- Feeling very tired
- Fainting

These side effects usually last 2 to 3 days.

Rarely, people may have more severe side effects that limit their normal activities or make them go to the doctor.

Allergic reactions

<In First in Human study and Phase 2 study, use the following:>

You could have an allergic reaction to a vaccine, including a rash, hives, or difficulty breathing. Some allergic reactions can be life-threatening. The study staff will watch you for at least 60 minutes after each injection.

<For Phase 3 studies, use the following>

You could have an allergic reaction to a vaccine, including a rash, hives, or difficulty breathing. Some allergic reactions can be life-threatening. The study staff will watch you for at least 15 minutes after each injection.

<For other studies, use the following>

You could have an allergic reaction to a vaccine, including a rash, hives, or difficulty breathing. Some allergic reactions can be life-threatening. The study staff will watch you for at least 30

minutes after each injection.

Always tell the study staff if you have ever had a bad reaction to any injection or vaccine. They can give you medicines in the clinic to treat serious allergic reactions. If you think you're having a severe allergic reaction after you leave the study site, contact the emergency number and get medical help right away.

<For Phase 3 studies, use the following>

RISK OF TESTING POSITIVE FOR SARS-CoV-2 ANTIBODIES

If you receive the Ad26.COV2.S vaccine (instead of placebo), your body may have an immune response to the specific coronavirus proteins that are part of the vaccine. This immune response will not affect any results of COVID-19 tests, whether taken as part of the study or outside of the study, that are obtained from a swab of your nose (or from your throat) as these tests tell you if you currently have COVID-19 virus in your body. Some tests, however, are done to check if you have previously been infected with COVID-19—these tests check for antibodies. These antibody test results might be positive if you received Ad26.COV2.S vaccine, even if you were never truly infected with the virus. For this reason, we recommend that you not seek testing outside of the study, but rather speak with study staff if you need to get tested. The study staff will provide you with additional information and help you get the right test.

If you become pregnant during or after the study and have antibodies in response to the vaccine, we don't know if the antibodies can be passed to your baby. We do know that antibodies from other vaccines, like tetanus vaccine, do get passed to the baby. For most babies, antibodies passed from the mother last for about six months.

BIRTH CONTROL AND PREGNANCY DURING THE STUDY

Animal studies have shown that Janssen's licensed Ad26-based vaccine against Ebola did not raise concerns in preclinical reproductive toxicity studies. These are studies in pregnant animals that received the vaccine, and then delivered animal babies. Therefore, ongoing studies with the Ebola vaccine allow pregnant women and women planning to become pregnant to receive that vaccine. However, the results of such studies in animals are not yet available for Ad26.COV2.S. For this reason, in this study, we will not enroll pregnant women, or those who aim to get pregnant within 3 months of receiving the study vaccine. The appropriate animal studies are currently underway.

Female Participants Who Cannot Get Pregnant

If you are postmenopausal for at least two years or have had a total hysterectomy (surgical removal of the womb) or bilateral tubal ligation/clip (surgical sterilization) or surgical removal of both ovaries, you cannot get pregnant. Therefore, the section below does not apply to you.

Female Participants Who Can Get Pregnant

If you are female and can get pregnant (meaning that you are neither post-menopausal for two years nor surgically sterile) and sexually active, you must avoid getting pregnant in order to take part in this study. You will be required to agree to use an approved method of birth control (as described below) prior to the study vaccination and continuing for 3 months after the administration of study vaccine. In addition, you will need to have a negative pregnancy test before vaccination.

Birth control methods that can be used while in this study include:

- Hormonal contraception
- Intrauterine devices (IUD)
- Intrauterine hormone-releasing systems
- Vasectomized partner (the vasectomized partner should be your sole partner)
- Abstinence (defined as refraining from heterosexual intercourse from signing the informed consent until at least 3 months following the study vaccination)

Please talk to the study staff about specific questions concerning acceptable birth control methods and he/she must approve the method you use before you can enter the study.

If you are a female who can get pregnant, you must agree to have a urine β -hCG pregnancy test at screening and immediately prior to study vaccine administration to demonstrate that you are not pregnant.

If you suspect that you have become pregnant during the study, you must notify your study doctor immediately. If you become pregnant during the study, you may continue in other study procedures (you may have blood drawn for safety and immune response testing), if the investigator decides it is safe for you and your unborn child. The study doctor will collect information about your pregnancy and the health of your baby. If you do not wish to be followed, you can withdraw your consent at any time by informing your doctor.

Male Participants

If your partner becomes pregnant during the study, you should tell the study doctor immediately. Your partner will be asked for permission to allow the study doctor to follow up and collect information about her pregnancy and the health of the baby. It is entirely voluntary. Your partner does not have to provide any information.