FACT SHEET FOR PATIENTS AND CAREGIVERS
Interim Authorization of Sotrovimab for the Treatment of Coronavirus Disease 2019 (COVID-19)

You are being given a medicine called **sotrovimab** for the treatment of coronavirus disease 2019 (COVID-19). This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking sotrovimab, which you may receive.

Receiving sotrovimab may benefit certain people with COVID-19.

Read this Fact Sheet for information about sotrovimab. Talk to your healthcare provider if you have any questions. It is your choice to receive sotrovimab or stop it at any time.

What is COVID-19?

COVID-19 is caused by a virus called a coronavirus. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, diabetes, for example, and other conditions including obesity, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people at higher risk of being hospitalized for COVID-19.

What are the symptoms of COVID-19?

The symptoms of COVID-19 are fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness, including breathing problems, can occur and may cause your other medical conditions to become worse.

What is sotrovimab?

Sotrovimab is an investigational medicine used to treat adult patients 18 years of age and above with coronavirus disease (COVID-19) who do not require oxygen supplementation and who are at risk of progressing to severe COVID-19. Sotrovimab is investigational because it is still being studied. There is limited information about the safety and effectiveness of using sotrovimab to treat at-risk people with COVID-19 who do not require oxygen supplementation.

The Health Sciences Authority (HSA) has granted an Interim Authorization to permit the emergency use of sotrovimab for the treatment of adult patients 18 years of age and above with COVID-19. For more information on Interim Authorization, see the **"What is an Interim Authorization?"** section at the end of this Fact Sheet.

What should I tell my healthcare provider before I receive sotrovimab?
Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

How will I receive sotrovimab?

- You will receive 1 dose of sotrovimab.
- Sotrovimab will be given to you through a vein (intravenous or IV infusion) over 30 minutes.
- You will be observed by your healthcare provider for at least 1 hour after you receive sotrovimab.

What are the important possible side effects of sotrovimab?

Possible side effects of sotrovimab are:

- **Allergic reactions.** Allergic reactions can happen during and after infusion with sotrovimab. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever; difficulty breathing; low oxygen level in your blood; chills; tiredness; fast or slow heart rate; chest discomfort or pain; weakness; confusion; nausea; headache; shortness of breath; low or high blood pressure; wheezing; swelling of your lips, face, or throat; rash including hives; itching; muscle aches; dizziness; feeling faint; and sweating.

The side effects of getting any medicine through a vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

These are not all the possible side effects of sotrovimab. Not many people have been given sotrovimab. Serious and unexpected side effects may happen. Sotrovimab is still being studied, so it is possible that all of the risks are not known at this time.

It is possible that sotrovimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, sotrovimab may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

What other treatment choices are there?

Like sotrovimab, HSA may allow for the emergency use of other medicines to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials for which you may be eligible.

It is your choice to be treated or not to be treated with sotrovimab. Should you decide not to receive sotrovimab, or stop it at any time, it will not change your standard medical care.

What if I am pregnant or breastfeeding?

There is no experience treating pregnant women or breastfeeding mothers with sotrovimab. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects with sotrovimab?

Tell your healthcare provider right away if you have any side effects that bother you or do not go away.

How can I learn more?

- Ask your healthcare provider
- Visit www.sotrovimabinfo.com

What is an Interim Authorization?

The HSA has made sotrovimab available under an emergency access mechanism called the Interim Authorization. The Interim Authorization enables regulatory agilities in responding to an emergency that may pose serious threats to public such as in the situation of a pandemic. Given the urgent public health need, HSA will prioritize the review of emergency therapeutic products to facilitate timely access while ensuring the scientific rigor of the assessment of their quality, safety and efficacy.

Sotrovimab has not undergone the same type of review as an HSA-approved medicine. In issuing an Interim Authorization, the HSA must determine, among other things, that based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective for treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there is on-going quality, safety and efficacy data generated to support the eventual transition of the Interim Authorization to product registration.

What sotrovimab contains:

- The active substance is sotrovimab. Each vial contains 500mg of sotrovimab in 8 mL solution.
- The other ingredients are L-histidine, L-histidine monohydrochloride, L-methionine, polysorbate 80 and sucrose.

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