FACT SHEET FOR PATIENTS, PARENTS, AND CAREGIVERS
Emergency Use Authorization (EUA) 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 mild-to-moderate symptoms of COVID-19 in adults and children (12 years of age and older weighing at least 88 pounds [40 kg]) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk of progression to severe COVID-19, including hospitalization or death. Sotrovimab is investigational because it is still being studied. There is limited information about the safety and effectiveness of using sotrovimab to treat people with mild-to-moderate COVID-19.

The U.S. Food & Drug Administration (FDA) has authorized the emergency use of sotrovimab for the treatment of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the **"What is an Emergency Use Authorization (EUA)?"** section at the end of this Fact Sheet.

Who should not receive sotrovimab?

Do not take sotrovimab if you have had a serious allergic reaction to sotrovimab or to any of the ingredients in sotrovimab.

What are the ingredients in sotrovimab?

Active ingredient: sotrovimab

Inactive ingredients: L-histidine, L-histidine monohydrochloride, L-methionine, polysorbate 80, and sucrose

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
- Have had a serious allergic reaction to sotrovimab or to any of the ingredients in sotrovimab
- 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, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are not approved by FDA 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. For a mother and unborn baby, the benefit of receiving sotrovimab may be greater than the risk from the treatment. 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.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088, or call the GSK COVID Contact Center at 1-866-GSK-COVID (866-475-2684).

How can I learn more?

- Ask your healthcare provider
- Visit www.sotrovimabinfo.com
- Call the GSK COVID Contact Center at 1-866-GSK-COVID (866-475-2684)

- Visit https://www.covid19treatmentguidelines.nih.gov/
- Visit https://combatcovid.hhs.gov/i-have-covid-19-now/available-covid-19-treatment-options
- Contact your local or state public health department

What is an Emergency Use Authorization (EUA)?

The FDA has made sotrovimab available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

Sotrovimab has not undergone the same type of review as an FDA-approved medicine. In issuing an EUA under the COVID-19 public health emergency, the FDA 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 diagnosing, 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 diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives. All of these criteria must be met to allow for the medicine to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for sotrovimab is in effect for the duration of the COVID-19 declaration justifying emergency use of these medicines, unless terminated or revoked (after which the products may no longer be used).

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