

# **FACT SHEET FOR PATIENTS AND PARENTS/CAREGIVERS EMERGENCY USE AUTHORIZATION (EUA) OF SOTROVIMAB FOR THE TREATMENT OF CORONAVIRUS DISEASE 2019 (COVID-19)**

You are being given this fact sheet because your healthcare provider believes it is necessary to provide you or your child with sotrovimab for the treatment of adults and children (12 years of age and older weighing at least 88 pounds [40 kg]) with positive results of direct SARS-Co-V-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. This fact sheet contains information to help you understand the potential risks and potential benefits of receiving sotrovimab, which you or your child have received or may receive.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make sotrovimab available during the COVID-19 pandemic (for more details about an EUA please see **“What is an Emergency Use Authorization?”** at the end of this document). Sotrovimab is not an FDA-approved medicine in the United States. Read this Fact Sheet for information about sotrovimab. Talk to your healthcare provider about your options or if you have any questions. It is your choice for you or your child 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 close 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 some of your or your child’s other medical conditions to become worse. Older people and people of all ages with severe, long lasting (chronic) medical conditions like heart disease, lung disease, and diabetes for example, seem to be at higher risk of being hospitalized for COVID-19.

## **WHAT IS SOTROVIMAB?**

Sotrovimab is an investigational medicine used for the treatment of adults and children (12 years of age and older weighing at least 88 pounds [40 kg]) with positive results of direct SARS-Co-V-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 FDA has authorized the emergency use of sotrovimab for the treatment of adults and children (12 years of age and older weighing at least 88 pounds [40 kg]) with positive results of direct SARS-Co-V-2 viral testing, and who are at high risk of progression to severe COVID-19, including hospitalization or death, under an EUA. For more information on EUA, see the **“What is an Emergency Use Authorization (EUA)?”** section at the end of this Fact Sheet.

Sotrovimab is not authorized for use in people who:

- are hospitalized due to COVID-19, **or**
- require oxygen therapy or breathing support due to COVID-19, **or**
- are on chronic oxygen therapy or breathing support at home before their COVID-19 diagnosis, and who require an increase in the amount of oxygen they need or breathing support due to COVID-19.

## **WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE I OR MY CHILD RECEIVE SOTROVIMAB?**

**Tell your healthcare provider if you or your child:**

- have any allergies
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed
- have any serious illnesses
- take any medicines including prescription, over-the-counter medicines, vitamins, and herbal products

## **HOW WILL I OR MY CHILD RECEIVE SOTROVIMAB?**

- You or your child will receive 1 dose of sotrovimab.
- Sotrovimab will be given through a vein (intravenous or IV infusion) by a healthcare provider over 15 or 30 minutes.

- You or your child will be monitored by your healthcare provider for at least 1 hour after receiving sotrovimab.

## **WHO SHOULD GENERALLY NOT RECEIVE SOTROVIMAB?**

Do not receive sotrovimab if you or your child have had a serious allergic reaction to sotrovimab or to any of the ingredients in sotrovimab. See the end of the Fact Sheet for a complete list of ingredients in 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 receiving sotrovimab. Tell your healthcare provider right away if you or your child develop 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.

Side effects of receiving sotrovimab intravenously may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

Other possible side effects of sotrovimab include rash and diarrhea.

These are not all the possible side effects of 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.

## **WHAT OTHER TREATMENT CHOICES ARE THERE?**

Veklury (remdesivir) is FDA-approved for the treatment of mild-to-moderate COVID-19 in certain adults and children. Talk with your healthcare provider to see if Veklury is appropriate for you.

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 authorized 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 for you or your child to be treated or not to be treated with sotrovimab. Should you decide not to receive it or your child not to receive it, it will not change your or your child's 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.

### Pregnancy Exposure Registry

There is a pregnancy exposure registry for individuals who receive sotrovimab during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how to take part in this registry. For more information visit <https://covid-pr.registry.com> or call 1-800-616-3791.

## **HOW DO I REPORT SIDE EFFECTS WITH SOTROVIMAB?**

Contact your healthcare provider if you or your child have any side effects that bother you or your child or do not go away. Report side effects to **FDA MedWatch** at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088, or call GSK at 1-866-475-2684.

## **How can I learn more about COVID-19?**

- Ask your healthcare provider
- Visit <https://www.cdc.gov/COVID19>
- Contact your local or state public health department

## **What is an Emergency Use Authorization?**

The United States FDA has made sotrovimab available under an emergency access mechanism called an Emergency Use Authorization (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 for the treatment of adults and children (12 years of age and older) weighing at least 88 pounds [40 kg] with positive results of direct SARS-Co-V-2 viral testing, and who are at high risk of progression to severe COVID-19, including hospitalization and death, has not undergone the same type of review as an FDA-approved product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In

addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic.

All of these criteria must be met to allow for the product 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 sotrovimab, unless terminated or revoked (after which sotrovimab may no longer be used under the EUA).



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