# GSK EMERGENCY USE ADVISORY

**Date:** December 13th, 2024

Dear Health Care Provider:

**Title:** Notification of the revocation of the Emergency Use Authorization of sotrovimab for the treatment of mild-to-moderate COVID-19 in high-risk patients

## Key Messages

GSK is writing to inform you as of December 13th, 2024, the Emergency Use Authorization (EUA) for sotrovimab will be officially revoked by the United States (US) Food and Drug Administration (FDA).

- All commercially available stock of sotrovimab, including any supply distributed by the Administration for Strategic Preparedness and Response (ASPR), has expired. Any remaining supply of sotrovimab should be discarded or returned to GSK.
- On May 26, 2021, the FDA issued an EUA to permit the emergency use of the unapproved product sotrovimab (VIR-7831) for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.[1]
- On April 05, 2022, the FDA announced a revision to the EUA of sotrovimab. Data showed that the authorized dose of sotrovimab was unlikely to be effective against the dominant circulating SARS-CoV2 variants in the US. Due to these data, sotrovimab was deauthorized to treat COVID-19 in all US states and territories and made no longer available for administration, until further notice.[2]
- GSK is dedicated to upholding the highest standards of patient safety and care. We encourage health care providers to utilize decision aids, such as the Infectious Disease Society of America (IDSA) Guidelines on the Treatment and Management of Patients with COVID-19[3], along with resources from the Center for Disease Control (CDC)[4] and ASPR[5] to guide the selection of appropriate treatment options for patients.

## Action Being Taken by GSK

GSK is providing notification to Health Care Providers about the official revocation of the EUA for sotrovimab by the FDA.

## Action Required by Health Care Professionals

Health Care Providers who have remaining supply of sotrovimab are advised to discard or return product to GSK Return Goods at www.gsk-ecs.com.

## Reporting Adverse Events

Health Care Providers and patients are encouraged to report adverse events in patients taking sotrovimab to GSK at 1-888-825-5249. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

## Contact for Further Information or Questions

You may contact our medical information department at 1-877-GSK-MI4U (475-6448) if you have any questions about the information contained in this letter.

Sincerely,

Herson I. Quiñones, PhD
Vice President, US Medical Affairs &
Therapeutic Area Head - Specialty, COVID and Pipeline

References:
1. Coronavirus (COVID-19) Update: FDA Authorizes Additional Monoclonal Antibody for Treatment of COVID-19 | FDA. Accessed Nov 18, 2024
2. FDA updates Sotrovimab emergency use authorization | FDA. Accessed Nov 18, 2024
3. Infectious Disease Society of America (IDSA) Guidelines on the Treatment and Management of Patients with COVID-19. Accessed Nov 19, 2024
4. CDC: COVID-19 Treatment Clinical Care for Outpatients. Accessed Nov 19, 2024
5. ASPR: What are the Possible Treatment Options for COVID-19. Accessed Nov 19, 2024