EUA 000100

GRANTING LETTER-
REVISED FACT SHEET

GlaxoSmithKline, LLC
Attention: Debra H. Lake, MS
Senior Director, Global Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Durham, NC 27709

Dear Ms. Lake:

Please refer to your Emergency Use Authorization (EUA) authorizing sotrovimab for treatment of mild-to-moderate coronavirus disease (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, issued on May 26, 2021, under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3).

We refer to your submission dated December 22, 2021, to EUA 000100, wherein you submitted proposed revisions to the authorized Fact Sheet for Health Care Providers.

We have completed our review and concur with the following revisions to the Fact Sheet for Health Care Providers:

- Microbiology/Resistance Information (Section 15): Updated with information on susceptibility of the SARS-CoV-2 Omicron (B.1.1.529/BA.1) variant to sotrovimab.
- The box was updated to include a reference to the FDA website for additional information on all products authorized for treatment and prevention of COVID-19.

The updated Fact Sheet for Health Care Providers is attached to this correspondence for your reference. This document must be made available consistent with the terms and conditions of this authorization.

By submitting this amendment for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the Letter of Authorization for EUA 000100, dated May 26, 2021, authorizing the emergency use of REGEN-COV for treatment of mild-to-moderate COVID-19.

Sincerely,

--/S/--

John Farley, MD, MPH
Director
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Fact Sheet for Healthcare Providers