Emergency Use Authorization (EUA) for Sotrovimab 500 mg
Center for Drug Evaluation and Research (CDER) Memorandum on Fact Sheet Update

Identifying Information

Application Type (EUA or Pre-EUA) If EUA, designate whether pre-event or intra-event EUA request.	EUA
EUA Application Number(s)	EUA 000100
Sponsor (entity requesting EUA or pre-EUA consideration), point of contact, address, phone number, fax number, email address	EUA Sponsor GlaxoSmithKline Research & Development Limited 980 Great West Road Brentford Middlesex, TW8 9GS UK GSK US Point of Contact Debra H. Lake, M.S. Sr. Director Global Regulatory Affairs GlaxoSmithKline 5 Moore Drive PO Box 13398 Research Triangle Park, NC 27709-3398 Email: (b) (6) Phone: (b) (6)
Manufacturer	GlaxoSmithKline, Parma.
Submission Date	June 22, 2021
Receipt Date	June 22, 2021
Review Completion Date	June 24, 2021
OND Division / Office	Division of Antivirals (DAV) / Office of Infectious Diseases (OID)
Proprietary Name	None
Established Name/Other names used during development	Sotrovimab (VIR-7831)
Dosage Forms/Strengths	Sterile solution for injection, 500mg/8 mL vial
Therapeutic Class	SARS-CoV-2 spike protein directed human IgG1κ monoclonal antibody (mAb)

Intended Population	Treatment of mild-to-moderate coronavirus disease 2019 (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

I. Summary of Fact Sheet Revision

In the Fact Sheet for Healthcare Providers the Sponsor proposes to remove the requirement to prime the infusion set with a separate 0.9% sodium chloride injection. The rationale for this change is to simplify the administration process and maintain consistency with standard clinical practice.

II. Recommendations

The proposed revision to the Fact Sheet for Healthcare Providers is acceptable and does not alter the benefit-risk analysis or conclusion in the initial review to support authorization of EUA 100.

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/s/

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07/09/2021 11:05:46 AM