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)	EUA
EUA Application Number	EUA 000100, SDN 74
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	December 22, 2021
Receipt Date	December 22, 2021
Review Completion Date	December 22, 2021
OND Division / Office	Division of Antivirals (DAV)/Office of Infectious Diseases (OID)
Reviewer Name(s)/Discipline(s)	Sarita Boyd, Clinical Reviewer Kimberly Struble, Clinical Team Lead Eric Donaldson, Clinical Virology Reviewer Julian O'Rear, Clinical Virology Team Lead Debra Birnkrant, Division Director, DAV John Farley, Office Director, 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. Review of Fact Sheet Revisions

The Microbiology/Resistance Information section (15) of the Fact Sheet (FS) for Healthcare Providers (HCP) was updated with information indicating that sotrovimab retains activity against the recently emerged SARS-CoV-2 variant of concern, Omicron (B.1.1.529/BA.1). The data are based on a pseudotyped virus-like particle (VLP) assessment showing < 5-fold reduction in susceptibility of sotrovimab against the SARS-CoV-2 spike protein containing all of the Omicron variant spike substitutions. The following changes from wild-type spike protein are found in the variant: A67V, del69-70, T95I, G142D/del143-145, del211/L212I, ins214EPE, G339D, S371L, S373P, S375F, K417N, N440K, G446S, S477N, T478K, E484A, Q493R, G496S, Q498R, N501Y, Y505H, T547K, D614G, H655Y, N679K, P681H, N764K, D796Y, N856K, Q954H, N969K, and L981F.

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.

II. Recommendations

The proposed revisions to the HCP FS are acceptable.

The agreed upon FS updates do 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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