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

Identifying Information

<table>
<thead>
<tr>
<th>Application Type (EUA or Pre-EUA)</th>
<th>EUA</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUA Application Number</td>
<td>EUA 000100, SDN 74</td>
</tr>
</tbody>
</table>
| 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: [redacted]
Phone: [redacted] |
| 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 IgG1k 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.
This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

SARITA D BOYD  
12/22/2021 05:18:12 PM

ERIC F DONALDSON  
12/22/2021 05:20:13 PM

JULIAN J O REAR  
12/22/2021 05:43:01 PM

KIMBERLY A STRUBLE  
12/22/2021 05:43:45 PM