# 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 60</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: | (6) |
| Phone: | (6) |

| Manufacturer | GlaxoSmithKline, Parma. |
| Submission Date | October 1, 2021 |
| Receipt Date | October 1, 2021 |
| Review Completion Date | October 29, 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 |
I. Review of Fact Sheet Revisions

The following proposed updates to the long version of the Fact Sheet (FS) for Healthcare Providers (HCP) were reviewed. Corresponding changes, where applicable, were made to the short version of the FS for HCP and to the FS for Patients, Parents, and Caregivers.

A. Contraindications (4)

The Applicant is proposing a contraindication in patients who have a history of anaphylaxis to sotrovimab or any of the excipients in the formulation. The FS for patients was in turn updated to include the list of excipients.

Although sotrovimab is authorized for use as a single dose, patients previously treated with sotrovimab may experience reinfection with SARS-CoV-2 and become eligible for a separate treatment course of single-dose sotrovimab. The proposal is acceptable.

B. Overall Safety Summary: Post-Authorization Experience (6.2)

The Applicant is proposing the addition of anaphylaxis specifically as an adverse reaction reported during post-authorization use of sotrovimab. A 26-year-old male in the United Arab Emirates with mild to moderate COVID-19, a positive SARS-CoV-2 test result, and risk factors of diabetes and being overweight received a single IV infusion of sotrovimab 500 mg. Soon after, he experienced generalized rash and facial swelling, which were treated with corticosteroids. Two hours later, he progressed to anaphylactic shock leading to hospitalization and treatment with epinephrine. The outcome of the event was not reported.

The current FS includes anaphylaxis as an adverse reaction reported after sotrovimab infusion in a study in hospitalized patients, a population for whom sotrovimab is not authorized. The proposed addition of Section 6.2 accurately conveys that anaphylaxis has also been observed with sotrovimab in the post-authorization outpatient setting and specifically in a patient representing the population for whom sotrovimab is authorized. Importantly, the Warning and Precaution (5.1) for Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions is unchanged and remains adequate. Overall, the proposal is acceptable.

C. Microbiology/Resistance Information (15)

The Applicant is proposing to update the Section 15: Microbiology/Resistance Information of the Fact Sheet for Healthcare Providers to include additional information regarding SARS-CoV-2 variants of concern/variants of interest. The revision provided summary data of cell culture pseudotype virus like particle assessments of sotrovimab antiviral
activity against the SARS-CoV-2 Lambda (C.37, Peru origin) and Mu (B.1.621, Brazil origin) variants, which resulted in no change in susceptibility (<5-fold reduction).

Clinical Virology reviewed the revisions and identified minor edits in the footnotes describing the Lambda (C.37, Peru origin) and Mu (B.1.621, Brazil origin) variants that were communicated to the Applicant. In addition, the Applicant identified minor inaccuracies pertaining to the fold-shifts in susceptibility of the Delta (B.1.617.2, India origin) and Kappa (B.1.617.1, India origin) variants that were corrected. The proposed revisions to the Fact Sheet for Healthcare Providers and are acceptable with edits.

II. Recommendations

The proposed revisions to the Fact Sheet for Healthcare Providers and Fact Sheet for Patients, Parents, and Caregivers are acceptable with edits.

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  
11/01/2021 09:57:28 AM

ERIC F DONALDSON  
11/01/2021 10:07:17 AM

JULIAN J O REAR  
11/01/2021 10:16:10 AM

KIMBERLY A STRUBLE  
11/01/2021 10:18:22 AM