sotrovimab – Emergency use authorization approval

- On May 26, 2021, the FDA announced the emergency use authorization (EUA) approval of GlaxoSmithKline (GSK)/Vir Biotechnology's sotrovimab, for the 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 kilograms [about 88 pounds]) with positive results of direct severe acute respiratory symptom coronavirus 2 (SARS-CoV-2) viral testing and who are at high risk for progression to severe COVID-19, including hospitalization or death.
    - Sotrovimab is not authorized for use in patients who are hospitalized due to COVID-19, or who require oxygen therapy due to COVID-19, or who require an increase in baseline oxygen flow rate due to COVID-19.
    - GSK does not yet have a government contract for sotrovimab. For other COVID-19 monoclonal antibodies (eg, bamlanivimab/etesevimab and casirivimab/imdevimab), the drug is supplied by the federal government and payers cover the administration costs. GSK is having conversations with the U.S. government but is also considering commercial channels.
- Sotrovimab is a monoclonal antibody that is specifically directed against the spike protein of SARS-CoV-2 and is designed to block the virus' attachment and entry into human cells.
    - Laboratory testing showed that sotrovimab retains activity against the current circulating variants first reported in the United Kingdom, South Africa, Brazil, California, New York and India.
- The EUA was approved based on data from an interim analysis from a double-blind, placebo-controlled trial (COMET-ICE) in 583 non-hospitalized adults with mild-to-moderate COVID-19 symptoms and a positive SARS-CoV-2 test result. The primary endpoint was progression of COVID-19 (defined as hospitalization for greater than 24 hours for acute management of any illness or death from any cause) through day 29.
    - Hospitalization or death occurred in 21 (7%) patients who received placebo vs. 3 (1%) patients treated with sotrovimab (adjusted relative risk reduction 85% [97.24% CI: 44, 96]; p = 0.002).
- Warnings and precautions for sotrovimab include hypersensitivity including anaphylaxis and infusion-related reactions; clinical worsening after SARS-CoV-2 monoclonal antibody administration; and limitations of benefit and potential for risk in patients with severe COVID-19.
- The most common treatment-emergent adverse events observed in the sotrovimab treatment group in COMET-ICE were rash (2%) and diarrhea (1%), all of which were grade 1 (mild) or grade 2 (moderate).
- The recommended dose of sotrovimab in adults and pediatric patients (12 years of age and older weighing at least 40 kg) is a single intravenous infusion of 500 mg. Sotrovimab should be given as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 10 days of symptom onset.
- GlaxoSmithKline plans to launch sotrovimab in the coming weeks. Sotrovimab will be available as a 500 mg solution in a single-dose vial.

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- The issuance of an EUA is different than FDA approval. In determining whether to issue an EUA, the FDA evaluates the totality of available evidence and carefully balances any known or potential risks with any known or potential benefits of the product for use during an emergency.
- GlaxoSmithKline plans to submit a full biologics license application (BLA) for sotrovimab in the second half of 2021.

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