

Perspective

Anti-SARS-CoV-2 Monoclonal Antibodies

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1. Description

The SARS-CoV-2 gene encodes 4 major structural proteins: spike (S), envelope (E), membrane (M), and nucleocapsid (N), as well as non-structural and associated proteins. Spike protein is divided into 2 subunits, S1 and S2, which mediate host cell attachment and invasion. Through its Receptor-Binding Domain (RBD), S1 attaches to the Angiotensin-Converting Enzyme 2 (ACE2) on the host cell. This initiates a configuration change in S2 leading to virus-host cell membrane fusion and viral entry. Anti-SARS-CoV-2 Monoclonal Antibodies (mAbs) targeting 1 spike protein has been shown to have clinical benefit in the treatment of SARS-CoV-2 Infection. After potential SARS-CoV-2 exposure at home, certain anti-SARS-CoV-2 mAbs have been demonstrated to be as effective as Post-Exposure Prophylaxis (PEP).

The Food and Drug Administration has granted Emergency Use Authorizations (EUAs) to four anti-SARS-CoV-2 mAb products (FDA) which includes Bamlanivimab Plus Etesevimab, Casirivimab Plus Imdevimab (REGEN-COV), and Sotrovimab, for moderate and moderate treatment of 19 non-hospitalized patients with laboratory-certified SARS-CoV-2 infection with high risk of progression to acute disease and or hospitalization. However, the distribution of Bamlanivimab Plus Etesevimab and Casirivimab Plus Imdevimab was paused due to reduced activity of the products against the B.1.1.529 (Omicron) Variant of Concern (VOC). Sotrovimab is expected to retain capability against the Omicron variant. The FDA has issued the EUA for tixagevimab plus cilgavimab (Evusheld), a long-acting anti-SARS-CoV-2 mAb combination. The EUA allows this combination to be used as SARS-CoV-2 PrEP for people who have not been infected with SARS-CoV-2 and who have not been exposed to a recent SARS-CoV-2 infection are in danger. Contains a documented history of adverse adverse reaction to the COVID-19 vaccine or of any severe adverse reaction to the available COVID-19 vaccine or any of its components.

2. The following are the approved anti-SARS-CoV-2 mAb products, listed sequentially:

Bamlanivimab plus Etesevimab

These are differentiated but overlapping, binding neutralizing mAbs of the spike protein RBD of SARS-CoV-2. The widespread distribution of Bamlanivimab plus Etesevimab in the United States has been paused as the Omicron variant has been significantly reduced *in vitro* susceptibility to Bamlanivimab and Etesevimab, therefore, does not provide clinical benefit to patients with omicron infection.

Casirivimab plus Imdevimab

These are recombinant human mAbs that bind to the non-overlapping epitopes of the spike protein RBD of SARS-CoV-2. The widespread distribution of Casirivimab Plus Imdevimab in the United States has been paused because the Omicron variant significantly reduced the *in vitro* susceptibility to Casirivimab and Imdevimab and, therefore, the clinical benefit to patients with Omicron infection.



Sotrovimab

This mAb was originally detected in 2003 by a person who had survived a SARS-CoV infection. It targets the epitope in the RBD of the spike protein preserved between SARS-CoV and SARS-CoV-2. Sotrovimab has *in vitro* activity against the Omicron variant.

Tixagevimab plus cilgavimab

These are recombinant human anti-SARS-CoV-2 mAbs that bind to the non-overlapping epitopes of the spike protein RBD of SARS-CoV-2. Although available *in vitro* data, it is suggested that the Omicron variant be suitable for this combination, but more data are needed to fully assess the functionality of this protocol when the Omicron variant rotates at a higher frequency.

The use of anti-SARS-CoV-2 mAbs may be considered for pregnant women with COVID-19, especially those with additional risk factors for acute illness. Like immunoglobulin (Ig) G mAbs, authorized SARS-CoV-2 mAbs are expected to cross the line. There are no specific data on the use of these mAbs however, other IgG products are safe to consume or apply when pregnant. Therefore, authorized SARS-CoV-2 mAbs should not be discontinued during pregnancy. Whenever possible, pregnant and lactating women should be included in clinical trials evaluating the use of anti-SARS-CoV-2 mAbs for the treatment and / or prevention of Covid-19.