

Brand Name: Evusheld

Generic: tixagevimab and cilgavimab

Type: monoclonal antibody

Year Accepted/Phase: 2021

Mechanism:

Tixagevimab and cilgavimab are monoclonal antibodies that bind to different, non-overlapping sites on the SARS-CoV-2 spike protein, preventing the virus from entering human cells and thereby providing protection against infection.

Chemical Structure: N/A

Indication:

Evusheld is indicated for the pre-exposure prophylaxis of COVID-19 in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) who are not currently infected with SARS-CoV-2 and who have not been recently exposed to an individual infected with SARS-CoV-2, and who have moderate to severe immune compromise or for whom vaccination is not recommended due to a history of severe adverse reactions.

Clinical trials:

PROVENT Trial (Phase III)

Pubmed: <https://pubmed.ncbi.nlm.nih.gov/35443106/>

Purpose: Evaluate the efficacy and safety of Evusheld for the prevention of COVID-19 in adults who are at increased risk of inadequate response to vaccination or have increased risk of exposure to SARS-CoV-2.

Dates: Conducted from November 2020 to April 2021.

Results: The PROVENT trial demonstrated that Evusheld significantly reduced the risk of developing symptomatic COVID-19 compared to placebo. The relative risk reduction was 77% at the primary analysis, with protection lasting at least six months. The trial also showed that the combination of tixagevimab and cilgavimab was well-tolerated with no serious safety concerns.

Impact: These results led to the emergency use authorization (EUA) by the FDA for Evusheld for pre-exposure prophylaxis of COVID-19 in December 2021.

STORM CHASER Trial (Phase III)

Pubmed: <https://pubmed.ncbi.nlm.nih.gov/36411267/>

Purpose: Evaluate the efficacy and safety of Evusheld for post-exposure prophylaxis of COVID-19 in adults who were recently exposed to SARS-CoV-2.

Dates: Conducted from December 2020 to April 2021.

Results: The STORM CHASER trial did not meet its primary endpoint of preventing symptomatic COVID-19 in people recently exposed to the virus. However, further analysis indicated that Evusheld might be beneficial in certain subpopulations, such as immunocompromised individuals.

Impact: Although the primary endpoint was not met, data from STORM CHASER contributed to understanding the potential role of Evusheld in specific high-risk populations.