Capsule Summary

EVUSHELD: Unleashing the power of monoclonal antibodies against COVID-19

The US Food and Drug Administration (FDA) recently granted emergency use authorization (EUA) of EVUSHELD, a monoclonal antibody combination, for the pre-exposure prophylaxis of COVID-19 disease. This EUA represents a paradigm shift in the prevention of a life-threatening disease that has upended our lives for over two years.

EVUSHELD is Authorized for use:

In certain adults and pediatric individuals (12 years of age and older weighing at least 40 kilograms): Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2. Who have moderate to severe immune-compromised due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination. For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID19 vaccine component(s).

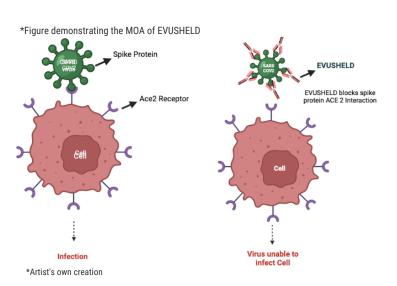
Composition: A combination of MAB's (Tixagevimab and Cilgavimab)

Manufacturer: Astra Zeneca

Country of Origin: United States of America

Mechanism of Action

Administered as 150 mg of Tixagevimab and 150 mg of Cilgavimab as two separate consecutive intramuscular injections. Harnesses the power of monoclonal antibodies directed against the spike protein of SARS-CoV-2. The two antibodies bind to distinct non-overlapping regions of the receptor-binding domain of SARS-CoV2 spike protein. This blocks the interaction of the SARS-CoV2 virus with the human ACE2 receptor, the SARS-CoV2 receptor, which is critical for virus attachment and entry into the cells, thereby ultimately blocking infection. First of its kind monoclonal antibody therapy to prevent COVID-19, potentially providing long-lasting durable protection of up to six months after a single injection.



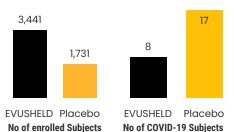
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Clinical Trials

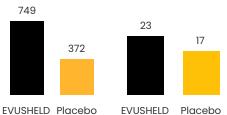
Efficacy data from **PROVENT Phase III trial** – Pre-exposure prophylaxis (Median follow-up time – 83 days, range 3 to 166 days)



Relative Risk reduction % @ 95% CI = 77% (46, 90)

EVUSHELD reduced the incidence of COVID-19 illness when given as a pre-exposure prophylaxis

Efficacy data from **STORM CHASER Phase III trial** – Post-exposure prophylaxis (Median follow-up time – 49 days, range 5 to 115 days)



Relative Risk reduction % @ 95% CI = 33% (-26, 65)

EVUSHELD does not reduce the incidence of COVID-19 illness when given as a post-exposure prophylaxis

Conclusion

No of enrolled Subjects

Based on these clinical trials, it was concluded that EVUSHELD is effective in reducing the incidence of COVID-19 illness when administered in a Preexposure prophylaxis manner, but not as post-exposure prophylaxis.

No of COVID-19 Subjects

Information Source:

Information presented in this article was extracted from a specific EVUSHELD related Factsheet published by the US FDA which can be found at - https://www.fda.gov/media/154701/download