FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Authorizes New Long-Acting Monoclonal Antibodies for Pre-exposure Prevention of COVID-19 in Certain Individuals

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Tixagevimab/Cilgavimab

- Adults and pediatric individuals ($\geq$ 12 years of age and $\geq$ 40 kilograms
- Only authorized for those individuals who are not currently infected with the SARS-CoV-2 virus and who have not recently been exposed to an individual infected with SARS-CoV-2.

Approval is for persons with:

- A moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** may not mount an adequate immune response to COVID-19 vaccination **or**
- 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 COVID- 19 vaccine component(s).

Dose/administration/side effects

- Tixagevimab150mg/1.5mL(100mg/mL)in a single-dose vial
- Cilgavimab 150mg/1.5mL (100mg/mL) in a single dose vial
- Given as 2 separate consecutive IM injections

- Most common adverse events (all grades, incidence ≥3%) are headache, fatigue, and cough

PROVENT Phase III pre-exposure prophylaxis trial (AZ)

- The trial included 5,197 participants in a 2:1 randomisation AZD7442 to placebo. The primary analysis was based on 5,172 participants who did not have SARS-CoV-2 infection at baseline.
- Risk reduction of developing symptomatic COVID-19 by 77% (95% confidence interval (CI): 46, 90), compared to placebo.
- The trial accrued 25 cases of symptomatic COVID-19 at the primary analysis.
- There were no cases of severe COVID-19 or COVID-19-related deaths in those treated with AZD7442. In the placebo arm, there were three cases of severe COVID-19, which included two deaths.
- More than 75% of participants had co-morbidities, which include conditions that have been reported to cause a reduced immune response to vaccination.
- The mAB was well tolerated and preliminary analyses show adverse events were balanced between the placebo and AZD7442 groups.

Warnings and precautions

- Hypersensitivity Including Anaphylaxis: Clinically monitor individuals after injections and observe for at least 1 hour. (5.1)
- Clinically Significant Bleeding Disorders: As with any other IM injection, EVUSHELD should be given with caution to individuals with thrombocytopenia or any coagulation disorder.
- Cardiovascular Events: A higher proportion of subjects who received EVUSHELD versus placebo reported myocardial infarction and cardiac failure serious adverse events. All of the subjects with events had cardiac risk factors and/or a prior history of cardiovascular disease, and there was no clear temporal pattern. A causal relationship between EVUSHELD and these events has not been established. Consider the risks and benefits prior to initiating EVUSHELD in individuals at high risk for cardiovascular events, and advise individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event.