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AstraZeneca's Evusheld gets EUA nod in US for COVID-19 prevention

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Pivotal phase III data showed at least six months of protection with one dose in high-risk participant population

AstraZeneca's Evusheld (tixagevimab co-packaged with cilgavimab), a long-acting antibody (LAAB) combination, has received emergency use authorisation (EUA) in the US for the pre-exposure prophylaxis (prevention) of COVID-19, with first doses expected to become available very soon.

The Food and Drug Administration (FDA) granted the EUA for Evusheld for pre-exposure prophylaxis of COVID-19 in adults and adolescents (aged 12 and older who weigh 40kg or more) with moderate to severe immune-compromised due to a medical condition or immunosuppressive medications and who may not mount an adequate immune response to COVID-19 vaccination, as well as those individuals for whom COVID-19 vaccination is not recommended. Recipients should not be currently infected with or had recent known exposure to a person infected with SARS-CoV-2.

Gagandeep Singh Bedi, MD, AstraZeneca India Pharma added, "The US Food and Drug Administration's EUA approval of AZD7442 for the prevention of COVID-19 is an important milestone globally. We welcome this news and the opportunity it provides to support the unmet needs of high risk and immune-compromised patients and we have already initiated engagements with the relevant health authorities in India to provide them with the latest evidence. Recent data from the Phase III PROVENT trial showed a robust efficacy profile and AZD7442 has so far demonstrated protection of up to six months against COVID-19 in this population."