District 2 Public Health

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FDA AUTHORIZES COVID-19 PRE-EXPOSURE PREVENTION FOR CERTAIN INDIVIDUALS

GAINESVILLE – The Food and Drug Administration issued an emergency use authorization (EUA) for the first injectable monoclonal antibody medication for pre-exposure prevention of COVID-19 for certain adults and pediatric individuals (12 years and older).

The pre-exposure therapy, Evusheld by AstraZeneca, is 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. The authorization also requires that individuals either have:

- moderate to severely compromised immune systems due to a medical condition or due to taking immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination (examples of such medical conditions or treatments can be found in the fact sheet for health care providers) or;
- a history of severe adverse reactions to a COVID-19 vaccine and/or component(s) of those vaccines, therefore vaccination with an available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended.

“Vaccines have proven to be the best defense available against COVID-19. However, there are certain immune compromised individuals who may not mount an adequate immune response to COVID-19

vaccination, or those who have a history of severe adverse reactions to a COVID-19 vaccine and therefore cannot receive one and need an alternative prevention option," said Patrizia Cavazzoni, M.D., director of the FDA's Center for Drug Evaluation and Research. "Today's action authorizes the use of the combination of two monoclonal antibodies to reduce the risk of developing COVID-19 in these individuals."

To learn more about the pre-exposure monoclonal antibody therapy, speak with your physician or visit the District 2 Public Health website.