Antibodies for prevention of COVID-19 granted FDA emergency use authorization

December 13 2021, by Bill Snyder

Credit: Erin O. Smith

On Wednesday, the U.S. Food and Drug Administration granted emergency use authorization (EUA) to the global biopharmaceutical company AstraZeneca for a long-acting antibody combination which protects against COVID-19, discovered last year at Vanderbilt University Medical Center (VUMC). A number of medical conditions result in immune compromise, from treatments for many cancers to organ transplantation.

The combination of two monoclonal antibodies, called Evusheld, was authorized as a pre-exposure prophylaxis to prevent COVID-19 in adults

and children 12 years and older who have compromised immune systems or a history of severe adverse reactions to a COVID-19 vaccine.

The antibody combination was discovered in the Vanderbilt Vaccine Center directed by James Crowe, MD.

"We are proud of Vanderbilt's contributions in the battle against COVID-19. The antibodies discovered by Dr. Crowe's team offer additional protection for millions of immunocompromised people who are not fully protected by the vaccines and have been at risk for severe infection throughout the pandemic," said Jeff Balser, MD, Ph.D., President and Chief Executive Officer of VUMC and Dean of Vanderbilt University School of Medicine.

Studies have found that Evusheld effectively prevents infection from the COVID-19 virus in those not currently infected or known to be recently exposed. In the primary trial supporting the FDA's EUA, over 5,000 people received Evusheld or a placebo.

Evusheld recipients saw a 77% reduced risk of developing COVID-19 compared to those treated with a placebo, and the reduction in risk was maintained through six months. According to the FDA, there are no adequate, approved and available alternatives to Evusheld to preventCOVID-19 infection in immunocompromised patients or in patients with a history of severe adverse reactions (e.g., severe allergic reactions) to COVID-19 vaccines.

"We are so excited to see these antibodies gain emergency use approval, since they will be the only antibodies authorized in the U.S. for pre-exposure prophylaxis," said Crowe, who led the research at VUMC.

"This prevention shot will give millions of high-risk and immunocompromised people who don't respond well to vaccines access

to immunity for COVID," Crowe said.

Other monoclonal antibodies granted emergency use authorization (EUA) by the FDA are delivered by intravenous infusion to people already infected by the COVID-19 virus to prevent severe illness or hospitalization.

According to AstraZeneca, Evusheld may benefit an estimated 7 million people in the United States who may not respond adequately to COVID-19 vaccines because of medications they take to prevent rejection of transplanted organs or treat diseases including cancer, multiple sclerosis and rheumatoid arthritis suppress their immune responses.

Preliminary laboratory findings suggest that Evusheld can neutralize recent emergent variants of the virus, including the delta variant, AstraZeneca officials said. Studies are underway to determine how effective the combination may be against the recently emerged omicron variant.

"We are all checking on omicron right now," said Crowe, the Ann Scott Carell Professor and professor of Pediatrics and Pathology, Microbiology & Immunology at VUMC. "I predict this general approach will change the way we think about the overall role of monoclonal antibodies in the prevention of many other infectious diseases."

Crowe and his colleagues have developed ultra-fast methods to discover highly potent antiviral human monoclonal antibodies and validate their effectiveness.

In June 2020, six of the COVID-19 antibodies isolated at VUMC were licensed to AstraZeneca for optimization and advancement into clinical development. In January 2021, the company announced it was advancing

a combination of two long-acting antibodies into phase 3 clinical trials.

Provided by Vanderbilt University