

COVID-19 vaccine candidate, tested at UAB, will start Phase 1 clinical trial

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Preclinical testing of the vaccine candidate at UAB in 2020. Credit: UAB

The Altimmune Inc. vaccine candidate that was tested preclinically at the University of Alabama at Birmingham last year is expected to start patient enrollment for its Phase 1 clinical trial next week.

Maryland-based biopharmaceutical company Altimmune announced that the United States Food and Drug Administration has cleared the company's Investigational New Drug application for its Phase 1 clinical trial of AdCOVID, a novel, single-dose, intranasal COVID-19 vaccine candidate.

The UAB preclinical testing of AdCOVID last spring and summer was led by Fran Lund, Ph.D., chair of the UAB Department of Microbiology, and it included 23 other researchers from six UAB labs in the UAB School of Medicine—all working under strict COVID-19 safety protocols that required masking and social distancing. The UAB researchers found potent serum neutralizing [antibody responses](#), T cell responses and a robust induction in mucosal immunity in mice following a single intranasal dose of AdCOVID.

The [vaccine candidate](#) has tantalizing promises, according to Altimmune. No need of refrigeration. Simple one-dose administration by a spray into the nose. The power to elicit mucosal immunity at the linings of the nose and lungs would protect not only against infection but also against transmission. Existing intramuscular COVID-19 vaccines are not known to elicit this kind of immunity.

Altimmune says it expects that these simple and convenient handling requirements, together with the potential ability to block SARS-CoV-2 transmission, could position AdCOVID as a leading intranasal COVID-19 vaccine.

"We believe deployment of intranasal vaccines like AdCOVID will be essential to a successful global response to the pandemic," said Vipin K. Garg, Ph.D., president and chief executive officer of Altimmune. "Developing vaccines that can effectively prevent transmission is a growing imperative to block the spread of disease and combat the emergence of new variants."

Altimmune's Phase 1 clinical trial will evaluate safety and immunogenicity of AdCOVID in up to 180 healthy volunteers between the ages of 18 and 55. AdCOVID will be administered as a nasal spray at one of three dose levels. Altimmune will look primarily for safety and tolerability, but it will also measure immunogenicity of AdCOVID by serum IgG binding and neutralizing antibody titers, mucosal IgA antibody from nasal samples and T cell responses.

Lund said of last year's preclinical testing, "In animals, intranasal vaccination initiated immune responses to the SARS-CoV-2 virus in the nose and lungs, which are the sites that are first infected by the virus.

"If the [vaccine](#) works similarly in humans, then we hope that vaccination via the intranasal route might not only protect the vaccinated person from serious

illness but also help minimize virus transmission within the community. We look forward to seeing the first data from the human studies."

Provided by University of Alabama at Birmingham

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