Icosavax Launches COVID-19 Vaccine Program with Preclinical Data and $16.5 Million in New Funding

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Preclinical data published in Cell show the Icosavax's COVID-19 vaccine candidate induces high neutralizing antibody titers after a single administration.

Icosavax, Inc. announced the launch of the company's COVID-19 vaccine program with preclinical data on the company's VLP vaccine candidate, IVX-411, which comprises a virus-like particle (VLP) displaying the SARS-CoV-2 receptor-binding domain (RBD) in a highly immunogenic array.

Icosavax also announced that the Bill & Melinda Gates Foundation has provided a $10 million grant to support the company's COVID-19 vaccine program through the first in human Phase 1 clinical trial in young and older adults, expected to initiate in mid-2021. In addition, Icosavax received $6.5 million from Open Philanthropy to support development of the company's vaccine platform technology and COVID-19 vaccine candidate.

The company is currently advancing the necessary studies to support regulatory filings and has initiated GMP manufacturing. To enable rapid progress of the company's COVID-19 vaccine candidate to the clinic, Amgen has agreed to manufacture a key intermediate for initial clinical studies.

"This is truly a great example of the scientific community coming together in a time of exceptional need to fight this pandemic. We are grateful to the Bill & Melinda Gates Foundation and Open Philanthropy for their financial support and to Amgen for the supply of a key intermediate for manufacturing," said Adam Simpson, Chief Executive Officer of Icosavax.

"The team at Icosavax is dedicated to advancing vaccines against severe life-threatening respiratory diseases to protect our most at-risk populations. Because VLP vaccines have the

potential to induce high-neutralizing antibody titers, our COVID-19 VLP vaccine candidate could be especially important for older adults with age-related declines in immunity."

Developed by scientists at the University of Washington School of Medicine using structure-based vaccine design techniques invented at the Institute for Protein Design (IPD) at the UW Medicine, IVX-411, the lead vaccine candidate for COVID-19, is a self-assembling protein nanoparticle that displays 60 copies of the SARS-CoV-2 spike (S) glycoprotein receptor-binding domain in a highly immunogenic array. Preclinical data from UW researchers and their collaborators show IVX-411 induces high neutralizing antibody titers in mice after a single administration and further improvement after a second administration (Cell 2020).

Titers after the second administration were ten-fold higher than those seen with the soluble SARS-CoV-2 spike protein that forms the basis of many other vaccine candidates. The data also show a strong B-cell response after immunization, critical for immune memory and a durable vaccine effect, with antibodies that target multiple distinct epitopes on the RBD, suggesting potential protection from escape mutations.

"These data highlight that while our VLP-based SARS-CoV-2 vaccine may not be first to market, it has the potential to be a best-in-class vaccine that safely delivers potent and durable immune protection," said Icosavax co-founder Neil King, Ph.D. Dr. King is also inventor of the computationally designed VLP technology at the Institute for Protein Design, and assistant professor of biochemistry at the UW School of Medicine. "This technology is designed to drive higher neutralizing antibody titers than soluble protein approaches and to create safe, stable, and effective VLP vaccines with simple and scalable manufacturing."

"It's clear that we will need a variety of vaccine approaches to effectively fight this novel coronavirus," said Jean-Paul Prieels, Ph.D., former Senior Vice President of Research and Development at GSK Vaccines and member of the scientific advisory board of Icosavax. "That's why it's important to advance not just the fastest but the best vaccine technologies that can deliver safe, effective, and durable protection."

VLPs enable high-density, multivalent display of antigens in a manner that closely resembles viruses, with an important difference. VLPs contain no genetic material, so they are non-infectious and can provide a safer alternative to live-attenuated or inactivated vaccines. The high yield and stability of the protein components and assembled nanoparticles suggest that

manufacture of the nanoparticle vaccines will be highly scalable.

Icosavax has a worldwide license with an exclusive option for IVX-411 in North America and Europe from the University of Washington.

Read the original article on Icosavax.