Icosavax Initiates Phase 1/2 Trial of COVID-19 VLP Vaccine Candidate

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- *First participants dosed in a Phase 1 clinical trial to assess safety and efficacy of IVX-411 with or without Seqirus Inc.'s proprietary adjuvant MF59® in subjects naïve to COVID-19*
- *Phase 2 will evaluate safety and efficacy of adjuvanted or unadjuvanted IVX-411 as a booster in adults who have been previously vaccinated with an approved vaccine against COVID-19*

SEATTLE, June 8, 2021 – Icosavax, Inc. today announced the first subjects have been dosed with IVX-411, a virus-like particle (VLP) displaying the SARS-CoV-2 receptor-binding domain (RBD), in a Phase 1/2 clinical trial. As previously announced, the Phase 1/2 trial is being funded by the Bill & Melinda Gates Foundation. Amgen is manufacturing a key intermediate, and Seqirus is providing its proprietary MF59® adjuvant for this trial.

"We believe a variety of vaccine approaches, including boosters, will be needed to continue the fight against COVID-19," said Adam Simpson, Chief Executive Officer of Icosavax. "We are pleased to be working with Seqirus to evaluate MF59 in combination with IVX-411, our COVID-19 VLP vaccine candidate. Subject to successful clinical development, we believe that IVX-411 could become a leading next generation vaccine against SARS-CoV-2, particularly for older adults who have a diminished immune response."

The Phase 1/2 clinical trial is a randomized, observer-blinded, placebo-controlled trial designed to evaluate the safety and immunogenicity of adjuvanted and unadjuvanted IVX-411. The trial is enrolling up to 168 healthy volunteers (18 to 69 years of age) in Australia. The Phase 1 part of the trial will enroll SARS-CoV-2 seronegative adults who have not had COVID-19 and have not been vaccinated with a licensed COVID-19 vaccine. The Phase 2 part of the trial will enroll SARS-CoV-2 seropositive adults who have completed a vaccine regimen using a licensed COVID-19 vaccine.

The trial will evaluate different dose levels of adjuvanted and unadjuvanted IVX-411 to help determine if an adjuvant may boost the immune response and potentially reduce the amount of antigen required for protection against SARS-CoV-2.

"We are delighted that Seqirus' proprietary adjuvant MF59 will be evaluated in combination with Icosavax's virus-like particles," said Russell Basser, M.D., Senior Vice President of Research and Development at Seqirus. "As a company dedicated to protecting millions of people around the world each year from influenza, Seqirus is happy to partner with Icosavax to advance a next generation vaccine solution in the global fight against COVID-19."

About Virus-Like Particles (VLP) Vaccines

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. Because VLP vaccines have the potential to induce high-neutralizing antibody titers, they could be especially important for older adults where the gradual deterioration of the immune system as adults age can make vaccines less effective. The high yield and stability of the protein components and assembled nanoparticles suggest that manufacture of the nanoparticle vaccines will be highly scalable.

About IVX-411, COVID-19 VLP Vaccine Candidate

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 Icosavax 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 (RBD) in a highly immunogenic array.

Preclinical data on IVX-411 and precursor candidates in mice and non-human primates show induction of robust neutralizing antibody titers and protection from viral challenge (Cell 2020, Nature 2021). The data also showed a strong B-cell response after immunization, critical for immune memory and a durable vaccine effect.

About Icosavax

Icosavax is focused on developing safe and effective vaccines against infectious diseases that cause severe, life-threatening respiratory illnesses. Icosavax is advancing VLP vaccine candidates against respiratory syncytial virus (RSV), human metapneumovirus (hMPV), and SARS-CoV-2 (COVID-19). These vaccine candidates have shown induction of high and durable neutralizing antibody titers in preclinical studies and could protect the most vulnerable populations, including older adults. Icosavax was founded on breakthrough computationally designed VLP technology developed at the Institute for Protein Design. Icosavax exclusively licensed the technology for use in several vaccine fields from the University of Washington. For SARS-CoV-2, Icosavax has a worldwide license with an exclusive option for IVX-411 in North America and Europe from the University of Washington. Icosavax is located in Seattle.

For Media Only: Jessica Yingling, Ph.D., Little Dog Communications Inc., jessica@litldog.com, +1.858.344.8091

Icosavax Investor Contact: Laurence Watts, Gilmartin Group, LLC, laurence@gilmartinir.com, +1.619.916.7620