Icosavax Announces Topline Interim Phase 1/2 Results for IVX-411 Against SARS-CoV-2

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- Immunologic response observed in both SARS-CoV-2 naive and previously vaccinated subjects, but lower than expected and inconsistent with known data on company's platform and VLP technology; end-to-end drug product investigation underway -

- Data indicate favorable preliminary reactogenicity profile -

- Company remains on track for Phase 1/1b topline, interim data for lead program IVX-121 against respiratory syncytial virus (RSV) in 2Q 2022 -

SEATTLE, March 25, 2022 (GLOBE NEWSWIRE) -- Icosavax, Inc. (Nasdaq: ICVX), a biopharmaceutical company leveraging its innovative virus-like particle (VLP) platform technology to develop vaccines against infectious diseases, today announced topline interim results from its ongoing Phase 1/2 clinical trial of IVX-411, a VLP vaccine candidate displaying the SARS-CoV-2 receptor-binding domain (RBD).

"While IVX-411 was immunogenic and well-tolerated in these initial topline data, the level of response was below our expectations given what we know about VLPs, including from clinical studies in COVID-19 and from our own preclinical data," said Niranjan Kanesa-thasan, M.D., Chief Medical Officer of Icosavax.

"Icosavax remains committed to its novel VLP platform and vision for combination and pan-respiratory vaccines," said Adam Simpson, Chief Executive Officer of Icosavax. "We plan to investigate the potential causes of these discordant clinical results, including manufacture, shipment, and administration of the product. As COVID-19 becomes endemic, it continues to be a strategic priority for Icosavax. With regard to our lead program in RSV, we look forward to sharing topline, interim data for IVX-121 in 2Q 2022, with the Phase 1 initiation of our first combination vaccine candidate, IVX-A12 against RSV and human metapneumovirus (hMPV), anticipated in 2H 2022."

The ongoing Phase 1/2 clinical trial (IVX-411-01) is a randomized, observer-blinded, placebo-controlled study to evaluate the safety and immunogenicity of IVX-411 in SARS-CoV-2 naïve (N=84) and previously vaccinated (N=84) adults 18 to 69 years of age. Naïve subjects received two doses, given 28 days apart, of IVX-411 at 5, 25 or 125 ug dosage levels or placebo, with or without adjuvant. Previously vaccinated subjects were boosted with a single dose of IVX-411 at 5, 25 or 125 ug or placebo, with or without adjuvant, at 3-6 months following completion of primary licensed vaccine regimen (mRNA or adenoviral). A supplemental analysis was also conducted to assess whether sera from subjects immunized with IVX-411 neutralize the SARS-CoV-2 Omicron variant.

Safety

In this topline interim data, IVX-411 was generally safe and well-tolerated. Solicited local and systemic adverse events (AEs) were all mild or moderate, without dose-limiting reactogenicity. The most common local and systemic AEs were injection site tenderness, and headache and fatigue, respectively. There were no serious AEs deemed to be related to vaccine, AE of special interest, or AEs leading to discontinuation.

- In the naïve setting, across the six dosage groups for IVX-411 with or without adjuvant, the proportion of subjects experiencing any systemic AE within seven days of any dose was 33-67%, versus 50% for placebo.
- In the booster setting, across the six dosage groups, 17-42% of subjects experienced any systemic AE within seven days of the booster dose, versus 25% for placebo.

Immunogenicity

In the naïve setting, a clear adjuvant effect on immunogenicity and a dose response were observed with IVX-411; however, the level of immune response in this initial data was comparable to or below the Human Convalescent Sera (HCS) control.

- At day 49 (or three weeks following the second dose), responses were up to 154 IU/mL across dosage groups in the live virus neutralization assay (HCS: 281 IU/mL), and up to 592 BAU/mL across groups in the spike IgG assay (HCS: 361 BAU/mL).

In previously vaccinated subjects, these initial data showed that IVX-411 boosted immunity following primary vaccination with an mRNA or adenovirus vaccine, and adjuvanted and unadjuvanted groups were generally similar.

- Pre- versus post-boost fold increases of up to 5x (599 IU/mL) for wild type virus were observed at day 28 post boost.
- For the Omicron variant, neutralizing antibody titers were up to 8-fold lower than observed for wild type virus in the same assay.

Icosavax anticipates providing an update on its end-to-end investigation after its completion.

About Icosavax

Icosavax is a biopharmaceutical company leveraging its innovative VLP platform technology to develop vaccines against infectious diseases, with an initial focus on life-threatening respiratory diseases and a vision for combination and pan-respiratory vaccines. Icosavax's VLP platform technology is designed to enable multivalent, particle-based display of complex viral antigens, which it believes will induce broad, robust, and durable protection

against the specific viruses targeted. Icosavax's pipeline includes vaccine candidates targeting respiratory syncytial virus (RSV), human metapneumovirus (hMPV) and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and an emerging program in influenza. Icosavax was formed in 2017 to advance the breakthrough VLP technology from the Institute for Protein Design at the University of Washington with the goal to discover, develop, and commercialize vaccines against infectious diseases. Icosavax is located in Seattle.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on the company's current beliefs and expectations and include but are not limited to: the possible safety and immunogenicity of IVX-411; the IVX-411-01, IVX-121 and IVX-A12 clinical trials (including projected timing of clinical trial milestones); IVX 411 development plans and the potential of the company's VLP technology. Actual results or developments may differ from those set forth in this press release due to the risks and uncertainties inherent in the company's business, including, without limitation: the company's dependence on third parties in connection with the manufacture and shipment of clinical supplies, and research and preclinical and clinical testing, including with respect to formulation, administration and other activities; the fact that topline results are based on preliminary analysis of key safety and immunogenicity data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial; the potential for the end-to-end drug product investigation to produce inconclusive results; the potential that, even if the investigation identifies a root cause or contributing factors for the discordant immunogenicity data, the company may be unable to resolve all ambiguity; the potential that any errors or other unknown factors that may have affected the interim immunogenicity data in the IVX-411-01 clinical trial may have impacted the safety data as well; the potential for the investigation into IVX-411 interim results to impact the results of the company's ongoing trial for IVX-121; the possibility of unexpected adverse side effects or inadequate immunogenicity or efficacy of IVX-411 that may limit its development, regulatory approval, and/or commercialization as a monovalent vaccine or in a combination or pan-respiratory vaccine; the possibility of disappointing results in later clinical trials despite promising results in earlier preclinical research or clinical trials; potential delays or difficulties in the commencement, enrollment, and completion of clinical trials; competing approaches limiting the commercial value of the company's vaccine candidate and VLP vaccine technology; regulatory developments in the United States and other countries; potential disruption to our operations and continued conduct of clinical trials from the COVID-19 pandemic or the conflict in Ukraine; and other risks described in the company's prior filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the company's quarterly report on Form 10-Q for the quarter ended September 30, 2021 and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and the company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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