Icosavax Reports Positive 12-Month Durability Data for VLP Vaccine Candidate IVX-121 Against RSV and Initial Evidence for Revaccination Potential

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- In new data from Icosavax's IVX-121 Phase 1b extension trial in older adults, GMTs against RSV through day 365 persisted at ~45-70% of the GMTs at day 28 (for 75 and 250 µg unadjuvanted dosages) -

- Data provide additional clinical evidence of potential differentiation on durability with company's VLP platform technology -

- Robust immune response against RSV-A observed in Phase 1b extension trial participants who were revaccinated with IVX-121 twelve months following initial dose -

- IVX-121 continues to be generally well tolerated with no additional safety concerns observed with longer-term follow up or revaccination -

- IVX-A12 (a potential-first-in-class bivalent combination of IVX-121 for RSV and IVX-241 for hMPV) currently in a Phase 2 trial; Phase 2 topline interim data now expected by end 2023 -

SEATTLE, Aug. 08, 2023 (GLOBE NEWSWIRE) -- Icosavax, Inc. (Nasdaq: ICVX), a biopharmaceutical company leveraging its innovative virus-like particle (VLP) platform technology to develop vaccines against infectious diseases, with an initial focus on life-threatening respiratory diseases and a vision of creating pan-respiratory vaccines for older adults, today provided a 12-month immunogenicity update from its Phase 1b extension trial of IVX-121 against Respiratory Syncytial Virus (RSV) in older adults. These data demonstrate substantial durability of neutralizing antibody (NAb) response against RSV at twelve months after a single administration of IVX-121. The company also reported initial evidence for revaccination potential with its VLP-based vaccines, including robust immune responses against RSV-A in Phase 1b extension trial participants who received 75 µg unadjuvanted IVX-121 at one year after their first dose.

"We continue to believe that there is a need for long-lasting, well-tolerated vaccines, particularly in combinations. These 12-month immunogenicity data from our Phase 1b extension trial of IVX-121 provide additional clinical evidence of a potentially differentiated durability profile for our VLP-based technology, as well as initial data supporting the potential for revaccination to boost immune responses in the second year," said Adam Simpson, Chief Executive Officer of Icosavax.

IVX-121 (RSV) Phase 1b extension 12-month immunogenicity update

Icosavax has previously reported day 28 and day 180 data from the IVX-121 Ph 1/1b trial, which followed young and older adult subjects through six months after administration of either IVX-121 or placebo. Older adult subjects had the opportunity to participate in a Phase 1b extension trial that allowed continued evaluation through 12 months following their initial dose of vaccine.

IVX-121 continued to be generally well-tolerated with no safety concerns observed in this 12-month follow up. No vaccine related serious adverse events (SAEs) were observed.

Data described below refer to RSV neutralizing antibody (NAb) responses to a single administration of IVX-121 at the 75 and 250 µg unadjuvanted dosage levels or placebo in older adults at the designated timepoints. Geometric mean neutralizing antibody titers (GMTs) were measured in international units (IU/mL) using the WHO international reference standard.

GMTs for RSV-A at day 365 were maintained within a range of ~45-50% relative to the GMTs at day 28 for the same group of subjects. RSV-B titers were also durable, persisting at ~65-70% of the GMTs at day 28 for the same dosage groups.

IVX-121 (RSV) Phase 1b extension trial revaccination data

The Phase 1b extension trial also evaluated immune responses one month after revaccination, in older adult participants who received IVX-121 (75 µg without adjuvant) approximately 12 months after their initial dose of vaccine or placebo in the Phase 1b trial. Revaccination with IVX-121 was generally well tolerated.

At one month after revaccination (month 13 overall), IVX-121 induced robust RSV-A immune responses with GMTs for RSV-A NAbs increased to a range of ~70-115% of the GMTs observed one month after the initial dose for the same subset of participants. RSV-B titers did not increase following revaccination but remained at ~40-60% of the GMTs observed 28 days after the initial dose.

"Recent data and the initial ACIP recommendation for RSV vaccines highlight potential opportunities for improvements in durability and revaccination," said Niranjan Kanesa-thasan, M.D., Chief Medical Officer of Icosavax. "I am pleased with these data for IVX-121 and their support of potential differentiation of our VLP technology."

Update on IVX-A12 (RSV/hMPV) Phase 2 topline interim data milestone timing

IVX-121 is a component of Icosavax's lead vaccine candidate IVX-A12, a potential first-in-class bivalent combination in Phase 2 for RSV and hMPV in older adults.

Icosavax is pleased to report that dosing has been completed in its Phase 2 trial of IVX-A12, and the company now expects to announce topline interim data by the end of 2023 versus the prior guidance of 1Q 2024.

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 lead program is a combination vaccine candidate targeting respiratory syncytial virus (RSV) and human metapneumovirus (hMPV), and its pipeline includes additional programs in influenza and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). 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.

For more information, visit www.icosavax.com.

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 company's expectation regarding the opportunities for, and the prophylactic and commercial potential of, its vaccine candidates and technology platform, including the potential for IVX-A12 to be a first-in-class vaccine; and the company's planned development activities, including clinical trials and data readouts, and the timing thereof. Actual results 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 early stage of the company's development efforts; the risk that results of a clinical trial at a particular time point may not predict final results and that an outcome may materially change as follow-up of subjects continues and following more comprehensive reviews of the data; the possibility of disappointing results in later clinical trials despite promising results in earlier preclinical research or clinical trials; potential unexpected adverse side effects or inadequate immunogenicity or efficacy of IVX-121 or IVX-A12 that may limit their development, regulatory approval, and/or commercialization; the company's approach to the development of vaccine candidates, including its IVX-A12 combination bivalent RSV/hMPV VLP vaccine candidate, which is a novel and unproven approach; potential delays in the development process including without limitation in the enrollment, conduct of, and receipt of data from, clinical trials; the company's dependence on third parties in connection with manufacturing, research, and clinical testing; the risk that approved third party RSV vaccines may make conducting clinical trials more difficult and costly and otherwise adversely affect the company's ability to successfully develop, obtain regulatory approval of and commercialize its vaccine candidates; approved vaccines and competing approaches limiting the commercial value of the company's vaccine candidates; regulatory developments in the United States and other countries; 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 March 31, 2023 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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