Icosavax Announces Positive Topline Interim Phase 2 Results for Combination VLP Vaccine Candidate IVX-A12 Against RSV and hMPV in Older Adults

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– IVX-A12 induced robust immune responses at Day 28 to both RSV and hMPV, and was generally well tolerated, consistent with prior IVX-A12 Phase 1 data –

SEATTLE, Dec. 11, 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 announced positive topline interim results from its Phase 2 clinical trial of IVX-A12 against respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) in older adults.

"We're delighted to announce positive topline interim data from our Phase 2 trial of IVX-A12, our potential first-in-class combination vaccine candidate against RSV and hMPV," said Adam Simpson, Chief Executive Officer of Icosavax. "We believe that IVX-A12 has the potential to address a significant unmet need and, as the furthest advanced RSV and hMPV combination vaccine in the clinic, to build on an emerging, large market opportunity."

IVX-A12 Phase 2 Trial Design

The ongoing Phase 2 clinical trial of IVX-A12 is a randomized, observer-blinded, placebo-controlled, multi-center trial designed to evaluate the safety and immunogenicity of a single dose of RSV and hMPV combination VLP vaccine IVX-A12, with and without CSL Seqirus' proprietary adjuvant MF59 ® (MF59).

The trial enrolled 264 healthy older adults aged 60 to 85 years, of which 241 subjects were evaluable for immunogenicity. Subjects were administered a single dose of either IVX-A12 at the 300 µg combination dosage level (150 µg of RSV VLP (IVX-121) and 150 µg of hMPV VLP (IVX-241)), with or without MF59, or placebo.

Topline Interim Results

Topline interim safety and immunogenicity data from this trial were generally consistent with the previously reported Phase 1 data for IVX-A12.

Safety:

IVX-A12 was generally well-tolerated across both dosage groups.

- Solicited local and systemic adverse events (AEs) collected within seven days of vaccination were generally mild to moderate without severe events. No cases of fever were reported in any group.
    - For unadjuvanted IVX-A12, the proportion of subjects experiencing any systemic AE within seven days was 32%, and similar to placebo (36%).
- The most common local and systemic AEs were injection site tenderness, injection site pain, and myalgia.
- There were no vaccine related serious adverse events (SAEs), clinical events or AEs of special interest (AESIs), or AEs leading to discontinuation.

Immunogenicity:

IVX-A12 induced robust immune responses against both RSV and hMPV at Day 28 across both formulations with and without adjuvant. For unadjuvanted IVX-A12:

- IVX-A12 induced geometric mean titers (GMTs) in RSV-A neutralizing antibody titers (nAbs) of approximately 12,200 IU/mL compared to approximately 2,000 IU/mL for placebo at Day 28. IVX-A12 induced GMTs in RSV-B nAbs of approximately 5,500 IU/mL compared to approximately 1,300 IU/mL for placebo at Day 28.
- IVX-A12 induced GMTs in hMPV-A nAbs of approximately 1,600 assay units/mL compared to approximately 400 assay units/mL for placebo at Day 28. IVX-A12 induced GMTs in hMPV-B nAbs of approximately 15,300 assay units/mL compared to approximately 6,700 assay units/mL for placebo at Day 28. No standardized international units exist in the field for hMPV.

"The positive Phase 2 data announced today for IVX-A12 are very encouraging and mark another milestone in the field for RSV and hMPV vaccination in older adults, a vulnerable population with heightened risk of severe disease," said Niranjan Kanesa-thasan, M.D., Chief Medical Officer of Icosavax.

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 incorporates

antigen design capabilities and technology 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). Its pipeline includes additional candidates that provide optionality as potential components of future combination and pan-respiratory vaccines, including influenza and 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 and the potential for IVX-A12 to be a first-in-class combination vaccine candidate against RSV and hMPV. 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 company's approach to the development of vaccine candidates, including its development of a 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 commencement, enrollment, conduct of, and receipt of data from, clinical trials; unexpected adverse side effects or inadequate immunogenicity or efficacy of the company's vaccine candidates that may limit their development, regulatory approval, and/or commercialization; the company's dependence on third parties in connection with manufacturing, research, and clinical testing; the risk that third party marketed RSV vaccines may make conducting clinical trials more difficult and costly and otherwise adversely affect the ability to successfully develop, obtain regulatory approval of and commercialize its vaccine candidates; the potential for challenges encountered in the manufacturing and scale up process; competing approaches and approved vaccines limiting the commercial value of the company's vaccine candidates; regulatory developments in the United States and other countries; the company's ability to fund its operating plans with its current cash, cash equivalents and investments; 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, 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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