Icosavax Initiates Phase 2 Trial of IVX-A12 Against RSV and hMPV in Older Adults

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- Phase 2 topline interim results expected in 1Q 2024 -

- 6-month durability data for Phase 1 trial of IVX-A12 also expected in 1Q 2024 -

SEATTLE, June 20, 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 the initiation of a Phase 2 clinical trial of IVX-A12, a combination bivalent respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) virus like particle (VLP) vaccine candidate, in older adults.

IVX-A12 is a liquid, refrigerator-stable formulation comprised of IVX-121, Icosavax's RSV prefusion F protein VLP vaccine candidate, and IVX-241, Icosavax's hMPV prefusion F protein VLP vaccine candidate. The company previously announced positive topline interim Phase 1 results for IVX-A12 in May 2023.

"The initiation of this Phase 2 trial for IVX-A12 marks another important milestone for Icosavax, as we advance this potential first-in-class combination vaccine candidate into mid-stage development," said Adam Simpson, Chief Executive Officer of Icosavax. "We are highly encouraged by the recent findings from the Phase 1 study of IVX-A12 and believe that it has the potential to address an unmet need as the first bivalent vaccine candidate against both RSV and hMPV, two of the leading causes of pneumonia in adults."

IVX-A12 Phase 2 Trial Design

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

The company anticipates enrolling approximately 250 healthy older adults aged 60 years or older. Subjects will be administered a single dose of IVX-A12, at one of the two combination dosage levels below, or placebo:

- 300 µg total VLP content (150 µg of IVX-121 (RSV) and 150 µg of IVX-241 (hMPV)), without MF59®
- 300 µg total VLP content (150 µg of IVX-121 (RSV) and 150 µg of IVX-241 (hMPV)), with MF59®
- Note: 150 µg of IVX-121 VLP and 150 µg of IVX-241 VLP correspond to 84 µg RSV antigen content and 82 µg hMPV antigen content, respectively

The objective of the Phase 2 study of IVX-A12 is to evaluate safety and immunogenicity against both RSV and hMPV, to inform selection of the formulation for a subsequent Phase 2b proof-of-concept trial for efficacy (hMPV human challenge), as well as assess longer-term safety and durability of immune response. Icosavax anticipates announcing topline interim results from this Phase 2 trial in 1Q 2024.

IVX-A12 recently demonstrated robust immunogenicity and favorable tolerability in a Phase 1 study, and these Phase 1 older adult subjects continue to be followed, with six-month immunogenicity data expected in Q1 2024. Clinical samples from this trial will also be used to explore the potential to protect against hMPV infection in a nonclinical passive transfer model.

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; 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 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; difficulties in developing an hMPV challenge model; 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 recent and expected regulatory approval of 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; 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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