Icosavax Initiates Phase 1 Trial of IVX-A12 Against RSV and hMPV in Older Adults

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- IVX-A12 is the first combination bivalent vaccine candidate against both respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) to reach clinical stage -

- Phase 1 topline interim results expected in mid-2023 -

- Phase 2 initiation planned to follow in 2H 2023 -

SEATTLE, Oct. 04, 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, 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 1 clinical trial of IVX-A12, a combination bivalent RSV and hMPV VLP vaccine candidate, in older adults.

IVX-A12 is 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 1/1b results for IVX-121 in June 2022.

With this trial initiation, IVX-A12 becomes the first combination bivalent vaccine candidate against both respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) to enter the clinic, and the first candidate from Icosavax's novel VLP platform to receive IND authorization in the U.S.

"The initiation of a Phase 1 trial for IVX-A12 is an important step towards our vision for creating pan-respiratory vaccines, and I am pleased with the execution by our team. Not only is IVX-A12 Icosavax's first combination bivalent VLP vaccine candidate, it is also the most advanced vaccine candidate against both RSV and hMPV in older adults, and the only clinical stage VLP in this space," said Adam Simpson, Chief Executive Officer of Icosavax. "The inclusion of a proprietary prefusion hMPV-F component in a combination RSV/hMPV vaccine candidate is differentiating from the current RSV candidates in Phase 3 development, and is intended to address two leading causes of pneumonia in one shot."

Simpson continued, "In older adults, RSV is estimated to cause approximately 177,000 hospitalizations and 14,000 deaths each year in the U.S. alone[i], and data support similar morbidity and mortality for hMPV. As such, we look forward to sharing topline results from this first trial of a combined RSV and hMPV vaccine candidate in mid-2023, and thereafter plan to initiate a Phase 2 trial of IVX-A12 in 2H 2023."

IVX-A12 Phase 1 Trial Design

The Phase 1 clinical trial of IVX-A12 is a randomized, observer-blinded, placebo-controlled, multi-center study designed to evaluate the safety and immunogenicity of multiple dosage levels of IVX-A12, with and without CSL Seqirus' proprietary adjuvant MF59 ®.

The company anticipates enrolling up to 120 healthy older adults aged 60 to 75 years. Subjects will be administered a single shot of IVX-A12, at one of three combination dosage levels below, or placebo:

- 75 µg of IVX-121 and 75 µg of IVX-241, with or without MF59®
- 75 µg of IVX-121 and 150 µg of IVX-241, with or without MF59®
- 75 µg of IVX-121 and 225 µg of IVX-241, without MF59®

The objective of the Phase 1 study of IVX-A12 is to evaluate safety, and immunogenicity against both RSV and hMPV, as well as to assess immunologic non-interference. Icosavax anticipates announcing topline interim results from this Phase 1 trial in mid-2023, with subjects thereafter followed through 12 months after vaccination. Contingent upon a positive outcome from this trial, the company then expects to initiate a Phase 2 trial for IVX-A12 in 2H 2023.

The IVX-121 (RSV) component of IVX-A12 (RSV/hMPV) demonstrated robust immunogenicity and favorable tolerability in a prior Phase 1/1b study, and a subset of these Phase 1b older adult subjects continue to be followed, with six-month immunogenicity data expected by early-2023 and 12-month immunogenicity data in mid-2023.

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) and human metapneumovirus (hMPV), as well as programs in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and 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.

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 ability to advance its IVX-A12 development program and achieve the noted development milestones in 2023. 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 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; potential 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; results from preclinical studies or early clinical trials not necessarily being predictive of future results; the company's dependence on third parties in connection with manufacturing, research, and clinical testing; the potential for challenges encountered in the manufacturing and scale up process; competing approaches limiting the commercial value of the company's vaccine candidates; 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 June 30, 2022 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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[i] Havers F, June 2022 ACIP presentation: Epidemiology and Burden of Respiratory Syncytial Virus in Older Adults in the U.S. (https://www.cdc.gov/vaccines/acip/meetings/slides-2022-06-22-23.html)