Icosavax Granted FDA Fast Track Designation for IVX-A12

February 21, 2023

SEATTLE, Feb. 21, 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 U.S. Food and Drug Administration (FDA) has granted Fast Track designation for IVX-A12, a bivalent respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) VLP vaccine candidate, in older adults 60 years of age and above.

According to the FDA, Fast Track is a process designed to facilitate the development and expedite the review of investigational drugs to treat serious conditions and fulfill an unmet medical need. An investigational drug that receives Fast Track designation may be eligible for more frequent interactions with the FDA to discuss the candidate's development plan and, if relevant criteria are met, eligibility for Accelerated Approval and Priority Review.

"We are delighted to have received the Fast Track designation for IVX-A12, which we believe highlights the unmet medical need that could be addressed by developing a bivalent vaccine combination of RSV and hMPV," said Niranjan Kanesa-thasan, Chief Medical Officer of Icosavax. "IVX-A12 is differentiated as the most advanced vaccine candidate against these two leading causes of pneumonia in older adults. RSV is estimated to cause approximately 177,000 hospitalizations and 14,000 deaths each year in this population in the U.S. alone[i] and data support similar morbidity and mortality for hMPV. We will utilize the benefits of this important regulatory milestone to work to optimize the IVX-A12 development plan. In addition, we look forward to the upcoming topline results of our Phase 1 study, and thereafter to the planned initiation of our Phase 2 trial."

In October 2022, Icosavax announced the initiation of a Phase 1, randomized, observer-blinded, placebo-controlled, multi-center study of IVX-A12, with and without CSL Seqirus' proprietary adjuvant MF59®, in up to 120 healthy older adults aged 60 to 75 years. Icosavax anticipates announcing topline interim results from this Phase 1 trial in mid-2023, with subjects thereafter followed through 12 months after vaccination. The company currently plans to initiate a Phase 2 trial for IVX-A12 in 2H 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), 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.

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 September 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.

Icosavax's Contacts

Media Contact:
Jessica Yingling, Ph.D.,
Little Dog Communications Inc.
jessica@litldog.com
858.344.8091

Investor Contact:

Laurence Watts
Gilmartin Group, LLC
laurence@gilmartinir.com
619.916.7620

---

[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)