Icosavax Announces Results from IVX-411 Drug Product Investigation and Outlines Additional Corporate Milestones

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- Antigen component of IVX-411 found to be unstable; issue specific to molecule, with no evidence of read-through to other Icosavax programs -

- Now focused on a bivalent strategy for COVID-19 candidate development displaying computationally engineered RBD antigens; provides optionality as a potential future component of combination vaccines –

- Additional corporate milestones across programs provided for 2H 2022 and 2023 -

SEATTLE, July 28, 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 results from an end-to-end drug product investigation of IVX-411, a VLP vaccine candidate displaying the SARS-CoV-2 receptor-binding domain (RBD). This investigation was initiated following the company's Phase 1/2 topline interim data results in which the immunologic response observed for IVX-411 was inconsistent with expectations based on known data for the company's platform and VLP technology.

The investigation involved a review of *in vitro* antigen stability and characterization (drug substance intermediate, drug substance, and drug product), and *in vivo* potency, as well as a review of data and protocols relating to the transport, storage, and administration of the vaccine. Icosavax tested a range of relevant samples, including a lab-scale VLP reference that was associated with robust and durable neutralizing titers in Non-Human Primate studies[i], and the Icosavax clinical VLP lot (GMP drug product) stored at 2-8 °C to assess its stability.

Investigation Results:

Results of the investigation confirmed the company's initial hypothesis that the reduced potency observed for IVX-411 was antigen-specific (i.e., related to the Receptor Binding Domain (RBD) antigen), and data to date indicate that this antigenic instability is not observed in other Icosavax vaccine candidates, including for RSV and hMPV.

Specifically:

- The RBD antigen component (Component A) of IVX-411 becomes unstable during manufacturing and subsequent storage at 2-8 °C
- An *in vivo* assessment in mice demonstrated that instability of the RBD antigen on the VLP surface translated to a loss of potency for IVX-411 consistent with that seen in the company's Phase 1/2 results
- No similar pattern of instability has been seen in data to date with the company's IVX-121 (RSV) and IVX-241 (hMPV) antigen components (Component A), or the fully assembled IVX-121 and IVX-241 VLPs, at 2-8 °C

"The results of our comprehensive IVX-411 investigation confirmed our original hypothesis that the lower-than-expected immunogenicity for IVX-411 was likely attributable to an antigen specific stability issue. These findings, combined with subsequent corroboration from the positive results of our Phase 1/1b study of IVX-121, reinforce the potential for potency of well-structured antigens displayed on Icosavax's two component VLP platform," said Adam Simpson, Chief Executive Officer of Icosavax. "Looking ahead, we plan to incorporate the learnings from this investigation into our current and future programs as well as our antigen design capability. In addition, consistent with the evolution of the field, we intend to focus on a bi-valent strategy for COVID-19 candidate development, providing us with optionality to include such a candidate as a potential future component of our VLP combination vaccines."

Adam Simpson continued, "Today we have also announced additions to our near-term milestones, which I believe highlight the expected continued progress and potential value-creating opportunities for Icosavax."

Near-Term Milestone Expectations:

- IND submission and initiation of a Phase 1 trial for IVX-A12 (RSV+hMPV) expected in 2H 2022
- IVX-121 (RSV) Phase 1b extension, 6-month immunogenicity data expected by early 2023
- IVX-121 (RSV) Phase 1b extension, 12-month immunogenicity data expected in mid-2023
- IVX-A12 (RSV+hMPV) Phase 1 topline interim data expected in mid-2023
- IVX-A12 (RSV+hMPV) Phase 2a initiation expected in 2H 2023
- COVID-19 bivalent candidate selection expected in 2023
- Flu program candidate selection expected in 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 interpretation of the results of its drug product investigation of IVX-411, the company's expectation regarding the prophylactic and commercial potential of its vaccine product candidates and its platform technology, and the company's milestone expectations. 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, which is a novel and unproven approach; 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 potential for challenges encountered in the manufacturing and scale up process, including without limitation challenges that reduce drug product stability or potency; the potential for delays in the development process including without limitation in candidate development, IND submission and the conduct of, and receipt of data from, clinical trials; and other risks described in the company's 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, 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] Although the sources referenced in this press release are believed to be reliable, the company makes no guarantees as to the accuracy or completeness of the sources and does not intend to incorporate into this press release the material contained in such sources.