Icosavax Announces Positive Topline Interim Phase 1/1b Results for VLP Vaccine Candidate IVX-121 Against RSV

June 28, 2022

- IVX-121 demonstrated robust immunologic response to RSV, with comparable Geometric Mean Titer (GMT) levels achieved at Day 28 in both young and older adult groups -

- IVX-121 was generally well tolerated with no vaccine-related SAEs -

- Provides initial indication of a differentiated VLP platform technology -

- Icosavax plans to file an IND submission and initiate a Phase 1 trial for IVX-A12, a combination bivalent RSV + hMPV VLP candidate, in 2H 2022 –

- Company to host conference call/webcast today at 4:30 p.m. ET / 1:30 p.m. PT -

SEATTLE, June 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 positive topline interim results from its Phase 1/1b clinical trial of IVX-121, a VLP displaying a prefusion stabilized Respiratory Syncytial Virus (RSV) F antigen, in young and older adults.

“I’m delighted to share these topline, interim data from our Phase 1/1b trial in RSV, in which IVX-121 demonstrated a robust immunologic response in both young and older adult groups. Importantly, we believe these Phase 1/1b data provide initial validation of our underlying VLP technology. They also reaffirm our strategy to combine multiple pathogen targets in one vaccine,” said Adam Simpson, Chief Executive Officer of Icosavax. “As planned, Icosavax will now progress development of IVX-121 combined with a human metapneumovirus (hMPV) VLP, as our IVX-A12 bivalent vaccine candidate. We believe IVX-A12 could be unique in providing protection against these two leading causes of pneumonia, each of which currently lack an approved vaccine.”

IVX-121 Phase 1/1b Trial Design

The Phase 1/1b clinical trial of IVX-121 is a randomized, observer-blinded, placebo-controlled, multi-center study designed to evaluate the safety and immunogenicity of three dose levels of IVX-121, with and without aluminum hydroxide adjuvant, in healthy young and older adults.

The Phase 1 part of the trial enrolled 90 healthy young adults aged 18-45 years. The Phase 1b part of the trial enrolled 130 healthy older adults aged 60-75 years. Subjects were administered a single dose of IVX-121 at one of three dose levels (25, 75, 250 µg), with or without aluminum hydroxide adjuvant, or placebo.

The primary outcomes of the study were safety and immunogenicity up to 28 days post-vaccination; neutralizing antibodies to RSV-A and RSV-B were measured in international units (IU/mL) using the WHO international reference standard. The trial was intended to inform the dose of IVX-121 to be evaluated in combination with Icosavax’s hMPV VLP in an upcoming Phase 1 clinical trial of the company’s RSV/hMPV bivalent vaccine candidate IVX-A12.

Topline Results

Safety:

In this Phase 1/1b study, IVX-121 was generally well-tolerated across all dosage groups.

- Solicited local and systemic adverse events (AEs) were generally mild or moderate, without dose-limiting reactogenicity.
  - In the older adult target population, across the six dosage groups for IVX-121 with or without adjuvant, the proportion of subjects experiencing any systemic AE within seven days was 11-33%, and similar to 21% for placebo.
- The most common local and systemic AEs were injection site tenderness, headache and fatigue.
- There were no serious AEs related to vaccine, AEs of special interest, or AEs leading to discontinuation.

Immunogenicity:

In this Phase 1/1b study, IVX-121 induced a robust immune response in both young and older adult groups.

- The data indicated a dose-independent response, including at the lowest non-adjuvanted dose (25 µg).
- No additional benefit from the aluminum hydroxide adjuvant was observed at any dosage level in either portion of the study.
- Geometric mean titers for RSV-A and RSV-B were in comparable ranges for both groups.

Young Adults (Phase 1):

- In young adults, across dosage groups, IVX-121 induced Geometric Mean Titers (GMTs) in RSV-A neutralizing antibodies (nAbs) of up to 7,687 IU/mL compared to 1,100 IU/mL for placebo at Day 28.
    - These titers corresponded to a Geometric Mean Fold Rise (GMFR) versus baseline up to 10-fold for IVX-121 at Day 28.

Older Adults (Phase 1b):

- GMT responses in IU/mL for older adults were comparable with those for young adults.
    - Across dosage groups, IVX-121 induced GMTs in RSV-A nAbs of up to 7,561 IU/mL compared to 1,692 IU/mL for placebo at Day 28.
    - GMFR at Day 28 was up to 6-fold, reflecting higher baseline titers in the older adults group.

“These topline interim data from our Phase 1/1b trial indicate that IVX-121 was generally well tolerated and elicited a strong and consistent response against RSV in healthy young and older adults. These data are particularly encouraging for the vulnerable older adult population with co-morbidities and increased risk for severe disease and hospitalization,” said Niranjan Kanesa-thasan, M.D., Chief Medical Officer of Icosavax. “The immunogenicity of IVX-121, even at very low microgram dosage levels, and its favorable tolerability to the highest dose level, makes it well suited to a combination vaccine approach.”

Icosavax plans to submit an IND for IVX-A12 to the U.S. Food and Drug Administration (FDA) and thereafter initiate a Phase 1 clinical trial in 2H 2022. This study will examine safety and immunogenicity of bivalent (RSV/hMPV) formulations, incorporating a single RSV dosage level and multiple hMPV dosage levels.

Interim data from the Phase 1/1b IVX-121 trial will also support a Phase 1b extension study, in which eligible older adults from the Phase 1b cohort will be followed out to 12 months to assess durability of response.

Conference Call and Webcast

Icosavax will host a conference call and a live webcast at 4:30 p.m. ET / 1:30 p.m. PT on June 28, 2022 to discuss the topline interim Phase 1/1b results for IVX-121. Individuals interested in listening to the conference call may do so by dialing (844) 467-8978 for domestic callers, or (929) 517-0913 for international callers and reference conference ID: 6829745; or from the webcast link in the investor relations section of the company's website at www.icosavax.com. The webcast will be available in the investor relations section on the company's website for 30 days following the completion of the call.

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.

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 potential for the company’s VLP platform to result in safe and effective vaccines against infectious diseases; the potential for IVX-A12 to serve as a safe and effective combination vaccine and provide protection against RSV and hMPV; and the company’s specific plans and anticipated timing to file an IND submission and initiate a Phase 1 trial for IVX-A12. Actual results or developments 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 fact that topline results are based on preliminary analysis of key safety and immunogenicity data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of the clinical trial; the risk that interim results of a clinical trial do not predict final results and that one or more of the outcomes may materially change as follow-up on the outcome of any particular subject continues, as more subject data become available and following more comprehensive reviews of the data; the possibility of unexpected adverse side effects or inadequate immunogenicity or efficacy of IVX-121 or IVX-A12 that may limit development, regulatory approval, and/or commercialization; the possibility of disappointing results in later clinical trials despite promising results in earlier preclinical research or clinical trials; the possibility that cross study comparisons may not prove accurate as clinical data accrue or due to the inherent limitations of cross study comparisons; potential delays or difficulties in submission of an IND and the commencement, enrollment, and completion of the Phase 1b extension study for IVX-121, the planned Phase 1 trial for IVX-A12 and other clinical trials; the company’s approach to the discovery and development of vaccine candidates, which is novel and unproven; competing approaches limiting the commercial value of the company’s vaccine candidates and VLP vaccine technology; regulatory developments in the United States and other countries; potential disruption to the company’s operations and continued conduct of clinical trials from the COVID-19 pandemic or the conflict in Ukraine; 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, 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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