HilleVax Announces Positive Immunogenicity Results for Run-In Cohort of NEST-IN1 Phase 2b Clinical Trial of HIL-214 Norovirus Vaccine Candidate

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BOSTON, Dec. 05, 2022 (GLOBE NEWSWIRE) -- HilleVax, Inc. (Nasdaq: HLVX), a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines, today reported results from a prespecified immunogenicity analysis of the 203 subjects enrolled in the run-in cohort of NEST-IN1 (**N**orovirus **E**fficacy and **S**afety **T**rial for **IN**fants), the company's ongoing Phase 2b trial for HIL-214, its investigational virus-like particle (VLP) based vaccine candidate for the prevention of moderate-to-severe norovirus-related acute gastroenteritis (AGE) in infants. These results follow the previously announced positive recommendation from an independent safety data monitoring committee based on this same cohort.

Immunogenicity Results:

- Geometric Mean Titers (GMTs) of pan-IG antibodies 28 days following the second dose were 11,102.0 IU/mL and 2,185.5 IU/mL for GI.1 and GII.4, respectively, for HIL-214 compared to 59.6 IU/mL and 73.5 IU/mL for GI.1 and GII.4, respectively, for placebo. These titers corresponded to a Geometric Mean Fold Rise (GMFR) versus baseline of more than 18-fold for HIL-214.

- Seroresponse rates (SRRs) for HIL-214, defined in NOR-212 as the percentage of subjects with at least a 4-fold increase in pan-Ig (immunoglobulin) antibody titers 28 days following the second dose compared to pre-vaccination baseline, were 99.0% for GI.1 and 86.9% for GII.4. SRRs for placebo were 4.1% and 3.1% for GI.1 and GII.4, respectively.

"We are very pleased with the immunogenicity results from the NEST-IN1 run-in cohort which were consistent with our expectations based on previous studies of HIL-214 given to infants," said Rob Hershberg, MD, PhD, Chairman and Chief Executive Officer of HilleVax. "We now look forward to the full NEST-IN1 topline safety and efficacy data which remain on-track for the second half of 2023."

NEST-IN1 is a Phase 2b, randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy, safety, and immunogenicity of HIL-214 in infants of approximately 5 months of age at time of initial vaccination at sites in the United States and Latin America. The study is planned to enroll 3,000 subjects who will be randomized 1:1 to receive a two-dose regimen of either HIL-214 or placebo. The clinical trial protocol includes the now completed prespecified 200 subject run-in to assess safety and immunogenicity. The primary objective of the trial is to evaluate the protective efficacy of HIL-214 against the first confirmed moderate or severe AGE event due to a HIL-214 vaccine strain, GI.1 or GII.4, (excluding certain co-infections) that occurs prior to each subject reaching 12 months of age. A key secondary endpoint is to evaluate the protective efficacy of HIL-214 against any GI or GII norovirus strain.

Forward-Looking Statements

HilleVax cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on our current beliefs and expectations and include, but are not limited to, the expected continuation of enrollment in the NEST-IN1 trial and the expected timing of data readouts from this trial. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: we currently depend entirely on the success of HIL-214, and we have not yet completed any clinical trials of HIL-214; potential delays in the commencement, enrollment, and completion of clinical trials and preclinical studies; our dependence on third parties in connection with manufacturing, research and clinical and preclinical testing; unexpected adverse side effects or inadequate immunogenicity or efficacy of HIL-214 or any future vaccine candidates that may limit their development, regulatory approval, and/or commercialization; unfavorable results from clinical trials; results from prior clinical trials and studies not necessarily being predictive of future results; our ability to maintain undisrupted business operations due to the COVID-19 pandemic, including delaying or disrupting our clinical trials, manufacturing and supply chain; regulatory developments in the United States and foreign countries; any future impacts to our business resulting from the conflict between Russia and Ukraine or other geopolitical developments outside our control; our reliance on intellectual property rights under our license agreement with Takeda Vaccines, Inc.; our ability to obtain, maintain and enforce intellectual property protection for our vaccine candidates; we may use our capital resources sooner than we expect; and other risks described in our prior press releases and our filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our quarterly report on Form 10-Q 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 we undertake 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.

About HilleVax

HilleVax is a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines. Its initial program, HIL-214, is a VLP based vaccine candidate in development for the prevention of moderate-to-severe acute gastroenteritis (AGE) caused by norovirus infection. Globally, norovirus is estimated to result in over approximately 700 million cases of AGE and 200,000 deaths per year, resulting in over $4 billion in direct health system costs and $60 billion in societal costs per year. The burden of norovirus falls disproportionately on young children and older adults. For more information about HilleVax, visit the company's website at http://www.HilleVax.com.

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