HilleVax Announces Positive Recommendation from Safety Data Monitoring Committee for NEST-IN1 Phase 2b Clinical Trial of HIL-214 Norovirus Vaccine Candidate

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Enrollment of remaining subjects in NEST-IN1 has resumed

Immunogenicity results from the first 200 subjects expected in Q4 2022

BOSTON, Aug. 31, 2022 (GLOBE NEWSWIRE) -- HilleVax, Inc. (Nasdaq: HLVX), a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines, today reported that an independent safety data monitoring committee (DMC) completed a prespecified review of safety data from the 203 subjects enrolled in the run-in portion of NEST-IN1 (**N**orovirus **E**fficacy and **S**afety **T**rial for **IN**fants, or NOR-212), the company's 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. Based on this review, the DMC recommended continuation of NEST-IN1 without modification and enrollment has subsequently resumed.

"The positive DMC recommendation and continuation of enrollment for the remaining 2,800 subjects in our Phase 2b NEST-IN1 study is an important milestone for HIL-214 and HilleVax," said Rob Hershberg, MD, PhD, Chairman and Chief Executive Officer of HilleVax. "We now anticipate immunogenicity results from the first 200 subjects earlier than expected in the fourth quarter of this year and remain on-track for topline safety and efficacy data from the full study in 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 the 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 a 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; 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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