HilleVax Announces Completion of Enrollment of NEST-IN1 Phase 2b Clinical Study of HIL-214 Norovirus Vaccine Candidate

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Topline safety and clinical efficacy data from NEST-IN1 expected in the first quarter of 2024

HIL-214 is the most advanced vaccine candidate for norovirus infection

There are currently no approved vaccines for norovirus

BOSTON, April 25, 2023 (GLOBE NEWSWIRE) -- HilleVax, Inc. (Nasdaq: HLVX), a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines, today announced completion of enrollment of NEST-IN1 (**N**orovirus **E**fficacy and **S**afety **T**rial for **IN**fants), with over 3,000 subjects enrolled in six countries. NEST-IN1 is 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. Topline safety and clinical efficacy data from NEST-IN1 are expected in the first quarter of 2024.

"I am excited to announce the completion of enrollment of our NEST-IN1 study which brings us one step closer to topline results in the first quarter of 2024," said Rob Hershberg, MD, PhD, Chairman and Chief Executive Officer of HilleVax. "There are no approved vaccines for norovirus, a disease that results in approximately 700 million cases of acute gastroenteritis and 200,000 deaths per year."

About NEST-IN1

NEST-IN1 is a Phase 2b clinical trial to evaluate the efficacy, safety and immunogenicity of HIL-214 in over 3,000 infants. This clinical trial is a randomized, double-blind, placebo-controlled trial in infants of approximately 5 months of age at time of initial vaccination at sites in the United States and Latin America. Subjects were randomized 1:1 to receive either HIL-214 or placebo. In the vaccine arm, subjects received HIL-214 (50/150 µg GI.1/GII.4 VLP combination with 500 µg alum) in a two-dose regimen delivered 28 to 56 days apart. In the control arm, subjects received saline placebo at the corresponding timepoints. The primary objective of NEST-IN1 is to evaluate the protective efficacy of HIL-214 against moderate or severe AGE events associated with GI.1 or GII.4 norovirus strains (excluding certain co-infections) during a pre-determined surveillance period that begins one month after the administration of the second dose of HIL-214. A key secondary endpoint is the evaluation of the protective efficacy of HIL-214 against any GI or GII norovirus strain. Other secondary endpoints include the evaluation of safety and immunogenicity of HIL-214.

About HilleVax

HilleVax is a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines. Its initial program, HIL-214, is a virus-like particle (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.

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 timing of data readouts from the NEST-IN1 clinical 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 or other epidemic diseases, including delaying or disrupting our clinical trials, manufacturing and supply chain; unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may adversely affect our business and financial condition and the broader economy and biotechnology industry; 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 annual report on Form 10-K 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.

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