HilleVax Reports Topline Data from NEST-IN1 Phase 2b Clinical Study of HIL-214 in Infants

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The NEST-IN1 clinical study did not meet its primary or secondary efficacy endpoints, and the company will discontinue further development of HIL-214 in infants

The company is exploring the potential for continued development of HIL-214 and HIL-216 in adults

BOSTON, July 08, 2024 (GLOBE NEWSWIRE) -- HilleVax, Inc. (Nasdaq: HLVX), a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines, today announced topline data results from NEST-IN1. 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.

In the NEST-IN1 study there were 51 primary endpoint events with 25 in the vaccine arm (n=1,425) and 26 in the placebo arm (n=1,399) resulting in vaccine efficacy of 5% (95% confidence interval; -64%, 45%). The study did not meet its primary endpoint of efficacy against moderate or severe acute gastroenteritis (AGE) events due to GI.1 or GII.4 norovirus genotypes. No clinical benefit was observed across secondary endpoints. HIL-214 exhibited a safety and immunogenicity profile consistent with what was observed in the prespecified analysis of the first 200 subjects in NEST-IN1 and in previously reported studies.

“We are disappointed that the NEST-IN1 study did not meet its primary efficacy endpoint,” said Rob Hershberg, MD, PhD, Chairman and Chief Executive Officer of HilleVax. “While HIL-214 previously showed clinical benefit in adults, NEST-IN1 was the first efficacy study conducted in infants for a norovirus vaccine candidate. We believe the efficacy in the infant setting may have been impacted by the appearance of multiple emerging GII.4 strains in this trial.”

“We sincerely thank the trial investigators, clinical sites and the HilleVax team for conducting a highly rigorous study, and we are deeply appreciative to the infants and families that participated in this trial,” said Dr. Hershberg.

The NEST-IN1 study was conducted after a Phase 2b study in adults, NOR-211, demonstrated statistically significant efficacy against moderate or severe AGE due to norovirus. The company plans to discontinue further development of HIL-214 in infants and is exploring the potential for continued development of HIL-214 and HIL-216, HilleVax’s Phase 1 ready vaccine candidate, in adults.

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, our plans to focus our development efforts on, and advance the development of, HIL-214 and HIL-216 in adults and the potential opportunity for and benefits of HIL-214 and HIL-216. 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: to-date we have depended primarily on the success of HIL-214, and we may be unable to identify a viable development path forward for HIL-214; if we do identify a development path forward for HIL-214, we may require additional capital and other resources, including partnerships or other strategic collaborations, and we may be unable to secure partnerships, other strategic collaborations or other resources on acceptable terms or at all; topline results are based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the NEST-IN1 study and such topline data may not accurately reflect the complete results of a clinical trial; to the extent we pursue future studies, we may experience potential delays in the commencement, enrollment, data readouts and completion of clinical trials and preclinical studies; we depend 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, HIL-216 or any future vaccine candidates that may limit their development, regulatory approval, and/or commercialization; further unfavorable results from clinical trials; results from prior clinical trials and studies are not necessarily predictive of future results; we rely on intellectual property rights under our license agreements with Takeda Vaccines, Inc. and Kanghua Biological Products Co., Ltd.; we may be unable 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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