HilleVax Announces Initiation of Phase 2b Clinical Trial of HIL-214 Vaccine Candidate for the Prevention of Norovirus-Related Acute Gastroenteritis in Infants

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BOSTON, May 02, 2022 (GLOBE NEWSWIRE) -- HilleVax, Inc. (Nasdaq: HLVX), a biopharmaceutical company focused on the development and commercialization of novel vaccine candidates, reported today dosing of the first subjects in its previously announced Phase 2b clinical trial of HIL-214, the company's virus-like particle (VLP) based vaccine candidate, for the prevention of moderate-to-severe acute gastroenteritis (AGE) caused by norovirus infection in infants.

"We're pleased to have dosed the first subjects in this Phase 2b study, the first ever field efficacy clinical trial of a norovirus vaccine candidate in infants," said Rob Hershberg, MD, PhD, Chairman and Chief Executive Officer of HilleVax. "We believe HIL-214 has the potential to address a vast unmet need which includes approximately 700 million cases, 200,000 deaths, and $60 billion of economic burden from norovirus-related AGE worldwide each year."

The clinical trial is a Phase 2b, randomized, double-blind, placebo-controlled study 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 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 GI.1 or GII.4 norovirus strains (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. A pre-specified safety and immunogenicity analysis is planned for the first 200 subjects.

About Norovirus
Norovirus is the most common cause of viral AGE worldwide and is characterized by symptoms including diarrhea, vomiting, abdominal pain, nausea, and, sometimes, fever that may lead to clinically significant dehydration. It is estimated that norovirus causes nearly 700 million cases of illness and more than 200,000 deaths with approximately $60 billion of economic burden worldwide each year. There are currently no approved vaccines or antiviral therapies for either the prevention or treatment of norovirus-related illness.

About HIL-214
HIL-214 is a bivalent vaccine candidate in development for the prevention of moderate-to-severe AGE caused by norovirus infection. HIL-214 consists of virus-like particles (VLPs) which are designed to mimic the structure of two major genotypes of norovirus, GI.1 and GII.4, and is co-formulated with an alum adjuvant. To date, HIL-214 has been studied in nine clinical trials which collectively generated safety data from more than 4,500 subjects and immunogenicity data from more than 2,200 subjects, including safety and immunogenicity data from more than 800 pediatric subjects. A randomized, placebo-controlled Phase 2b field efficacy trial enrolled 4,712 adult subjects, and HIL-214 was well tolerated and demonstrated clinical proof of concept in preventing moderate-to-severe cases of AGE from norovirus infection. We believe HIL-214 is the most advanced norovirus-related vaccine candidate in human clinical trials.

About HilleVax
HilleVax is a biopharmaceutical company focused on the development and commercialization of novel vaccine candidates. 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 caused by norovirus infection. For more information about HilleVax, visit the company's website at http://www.HilleVax.com.

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