HilleVax Announces Results from 5-Year Clinical Study Supporting Long-Term Immunogenicity of HIL-214 Norovirus Vaccine Candidate

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Pan-Ig and HBGA blocking antibody responses persisted to year 5

No adverse events deemed related to HIL-214

BOSTON, July 20, 2022 (GLOBE NEWSWIRE) -- HilleVax, Inc. (Nasdaq: HLVX), a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines, today announced results from NOR-213, a Phase 2 long-term immunogenicity follow-up clinical trial of adults and older adults who previously received HIL-214, the company's investigational virus-like particle (VLP) based vaccine for the prevention of moderate-to-severe acute gastroenteritis (AGE) caused by norovirus infection.

NOR-213 included 528 adult and older adult subjects that were enrolled following participation in prior clinical studies of HIL-214, including NOR-107, NOR-204, and NOR-210. The subjects received either one or two doses of HIL-214 (GI.1/GII.4 VLP combination with 500 µg alum) with or without the adjuvant monophosphoryl lipid A (MPL).

Among all dose regimens of HIL-214, GI.1-specific and GII.4-specific HBGA-blocking and pan-Ig responses to vaccination persisted to year 5 of the study and, at year 5, results were similar to those previously reported at year 3. These results further support a single dose of HIL-214 (15/50 µg GI.1/GII.4 VLP combination with 500 µg alum) without MPL as the intended regimen for future development in adults and older adults. No adverse events were deemed related to HIL-214, and no new safety risks were identified during the study.

The company anticipates presenting detailed data from the NOR-213 clinical trial at a future medical meeting.

"We believe the data from this 5-year clinical study are very encouraging for the long-term immunogenicity and safety profile of HIL-214," said Astrid Borkowski, MD, PhD, Chief Medical Officer of HilleVax. "We look forward to the continued development of HIL-214 across the age spectrum, including our ongoing Phase 2b study in infants and future clinical studies in adults and older adults."

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. A randomized, placebo-controlled Phase 2b field efficacy trial of 3,000 infant subjects is currently ongoing. We believe HIL-214 is the most advanced norovirus-related vaccine candidate in human clinical trials.

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. For more information about HilleVax, visit the company's website at http://www.HilleVax.com.

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