HilleVax and Kangh Announce Exclusive License Agreement for Hexavalent VLP Norovirus Vaccine Candidate Outside of China

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Collaboration leverages HilleVax's leading norovirus vaccine development expertise and adds a Phase 1-ready next-generation program to HilleVax's pipeline

BOSTON and CHENGDU, China, Jan. 08, 2024 (GLOBE NEWSWIRE) -- HilleVax, Inc. (Nasdaq: HLVX), a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines, and Chengdu Kanghua Biological Products Co., Ltd. (Kangh) (SHE: 300841), a biopharmaceutical company engaged in the research, development, production, and sale of bioproducts, today announced the entry into an exclusive license agreement for rights to Kangh's hexavalent virus-like particle (VLP) vaccine candidate for norovirus, referred to by HilleVax as HIL-216, outside of Greater China.

HIL-216 includes VLPs for six of the most common norovirus genotypes, including GI.1, GII.2, GII.3, GII.4, GII.6, and GII.17. The Investigational New Drug (IND) application for HIL-216 was cleared by the U.S. FDA in September 2023. As part of the exclusive license agreement, Kangh will supply HIL-216 for use in HilleVax's near-term clinical trials, including a Phase 1 trial that HilleVax expects to initiate in 2024.

"We are extremely pleased to enter this collaboration with Kangh as we seek to build out a long-term norovirus vaccine leadership position," said Rob Hershberg, MD, PhD, Chairman and Chief Executive Officer at Hillevax. "Our bivalent norovirus VLP vaccine candidate, HIL-214, remains the most advanced norovirus vaccine candidate in clinical development, and we are on-track to report topline safety and efficacy data in mid-2024 from our ongoing Phase 2b NEST-IN1 trial. We believe that HIL-214 will be the first norovirus vaccine submitted for registration and, if approved, would address the significant unmet medical need in infants and other at-risk populations. We further believe that HIL-216 is an exciting addition to the HilleVax portfolio as a next generation, higher valency VLP-based vaccine and is an ideal fit with the expertise, capabilities and long-term aspirations of HilleVax."

"We are delighted to partner with HilleVax, a company with world-class expertise in norovirus vaccine development and a deep commitment to making an impact on the considerable morbidity, mortality, and economic burden associated with norovirus," said Mr. Wang Zhentao, Chairman of Kangh. "This agreement represents a significant milestone for Kangh in our aim to bring our novel pipeline of vaccine products to global markets and is representative of our significant vaccine discovery, development, and manufacturing capabilities."

HilleVax will pay Kangh an upfront payment of $15 million with the potential for additional payments of up to $255.5 million upon achieving certain development and sales milestones. Kangh is also eligible to receive a single-digit tiered royalty on net sales outside of Greater China.

BFC Group, Ltd. acted as advisors to HilleVax.

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.

About Kangh

Chengdu Kanghua Biological Products Co., Ltd. (SHE: 300841) is a biopharmaceutical company engaged in the research, development, production, and sale of bioproducts. Established in 2004, Kangh is equipped with an animal testing center and high-tech GMP production workshops for bacterial and viral vaccines. The current product portfolio includes "ACYW135 Meningococcal Polysaccharide Vaccine" (trade name: Micin®) and "Freeze-dried Human Rabies Vaccine (Human Diploid Cells)" (trade name: HDCV®). Since its establishment, Kanghua Biological has been honored with titles such as "Postdoctoral Innovation Practice Base" and "Innovative Enterprise Cultivation in Sichuan Province" by the Ministry of Personnel and the Ministry of Science and Technology, and recognized as an "Outstanding and Honest Demonstration Unit in Sichuan Province." The company has also obtained GMP certification from the National Medical Products Administration. In recent years, Kanghua Biological has undertaken several scientific and technological projects and applied for over a hundred patents. For more information about Kangh, please visit the website at www.kangh.com.

HilleVax 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 potential opportunity for and benefits of HIL-216 and HIL-214, the planned initiation of a Phase 1 clinical trial of HIL-216 and the timing thereof, the expected timing of a data readout from the NEST-IN1 clinical trial, the advancement of HIL-214 to registration as the first norovirus vaccine, and longer-term market leadership plans. 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, data readouts 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, HIL-216 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; and unstable market and economic conditions 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 military conflicts or other geopolitical developments

outside our control; our reliance on intellectual property rights under our license agreements with Takeda Vaccines, Inc. and Kangh; 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.

Kangh Forward-Looking Statements

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