

Preclinical Data on Novel Arenaviral HIV Therapeutic Vaccines Presented at Keystone Symposium

June 3, 2022

- Oral and poster presentations highlight robust and high-quality immune responses following administration of novel arenaviral therapeutic vaccines in preclinical setting
- Alternating 2-vector therapy induces greater immune response than single-vector therapy in preclinical setting and translates into significant reduction of viral load

NEW YORK and VIENNA, Austria, June 03, 2022 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, announced preclinical data, in collaboration with Gilead Sciences, Inc., on arenaviral therapeutic vaccines that are being studied as a component of a potential functional curative regimen for human immunodeficiency virus (HIV). These data presented at the Keystone Symposium: Progress in Vaccine Development for Infectious Disease in Breckenridge, Colorado highlight robust and high-quality immune responses following administration of replicating arenaviral therapeutic vaccines.

"These preclinical data highlight the potential of our novel arenaviral platform to deliver new options to treat HIV," said Joern Aldag, Chief Executive Officer at HOOKIPA. "As we've demonstrated in oncology, our arenaviral therapeutics induce robust and high-quality antigen-specific immune responses. The preclinical data highlight our 2-vector approach with intramuscular administration as optimal based on immune responses."

Together, the preclinical data on the HIV arenaviral program support clinical development as a component of a potential HIV therapeutic. The analyses were conducted with a simian immunodeficiency virus (SIV) model, commonly used in a preclinical setting as an analog to HIV. Data presented in an oral presentation (poster 2019) explored systemic immune response in the blood to help determine the ideal arenaviral technology (replicating or non-replicating), route of administration and dosing frequency. The study showed both single-vector and alternating 2-vector therapy induced robust antigen-specific T cell and antibody responses in nonhuman primates. The 2-vector approach elicited a significantly greater T cell response than single-vector therapy, and intramuscular administration showed a modest benefit over intravenous administration in both the magnitude of T cell response and the consistency and durability of antibody response.

Preclinical data in a separate poster presentation (poster 1019) showed the breadth and quality of the immune response with intramuscular administration of arenaviral therapeutic vaccines. Specifically, alternating 2-vector therapy generated robust antigen-specific immune responses throughout the body – in peripheral blood mononuclear cells (PBMCs), rectal mucosa and lymph nodes, all of which are important sites for HIV replication and/or transmission. The overall response was greater with the 2-vector approach compared to the single-vector approach.

About the HIV program

HOOKIPA, in collaboration with Gilead, is exploring the development of an arenaviral therapeutic vaccine as a component of a potential functional cure regimen for people with HIV. One single-vector compound uses Lymphocytic choriomeningitis virus (LCMV) as its arenaviral backbone; another single-vector compound uses Pichinde virus (PICV). Both contain the same antigen. The alternating 2-vector approach is designed to further focus the immune response against the target antigen.

Under the agreement with Gilead, HOOKIPA is responsible for advancing the HIV program through the completion of a Phase 1b clinical trial, with funding from Gilead via an upfront payment and equity purchases. Gilead has the exclusive right to assume further development of the program thereafter.

These compounds are investigational product candidates; they are not approved by any regulatory agency for any use and have not been proven safe or efficacious.

About HIV

HIV is one of the world's most formidable public health challenges. It is estimated there are more than 37 million people living with HIV worldwide. The virus infects and kills immune cells, and without effective ongoing treatment leaves the individual increasingly immunocompromised over time. While effective treatments have significantly extended the lives of people living with HIV and reduced the transmission of the virus, there is no cure for HIV or AIDS.

About HOOKIPA

HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical-stage biopharmaceutical company focused on developing novel immunotherapies, based on its proprietary arenavirus platform, which are designed to mobilize and amplify targeted T cells and thereby fight or prevent serious disease. HOOKIPAs replicating and non-replicating technologies are engineered to induce robust and durable antigen-specific CD8+ cell responses and pathogen-neutralizing antibodies. HOOKIPAs pipeline includes its wholly-owned investigational arenaviral immunotherapeutics targeting HPV16+ cancers, prostate cancer, KRAS-mutated cancers (including colorectal, pancreatic and lung), and other undisclosed programs. In addition, HOOKIPA aims to develop functional cures of HBV and HIV in collaboration with Gilead.

Find out more about HOOKIPA online at www.hookipapharma.com.

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Forward Looking Statements

Certain statements set forth in this press release constitute "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements can be identified by terms such as "believes," "expects," "plans," "potential," "would" or similar expressions and the negative of those terms. Such forward-looking statements involve substantial risks and uncertainties that could cause HOOKIPA's research and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including HOOKIPA's programs' early stage of development, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, HOOKIPA's ability to successfully establish, protect and defend its intellectual property, risks relating to business interruptions resulting from the coronavirus (COVID-19) disease outbreak or similar public health crises, the impact of COVID-19 on the enrollment of patients and timing of clinical results, and other matters that could affect the sufficiency of existing cash to fund operations. HOOKIPA undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the company in general, see HOOKIPA's quarterly report on Form 10-Q for the quarter ended March 31, 2022 which is available on the Security and Exchange Commission's website at www.bookipapharma.com.