HOOKIPA Announces First Person Dosed in Phase 1a/b Clinical Trial of HB-400, in Collaboration with Gilead, for Treatment of Hepatitis B

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NEW YORK and VIENNA, Austria, May 09, 2023 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today announced that the first person has been dosed in a Gilead-led Phase 1 clinical trial of HB-400, an investigational therapeutic vaccine for chronic hepatitis B. HB-400 is one of two novel compounds being developed in collaboration with Gilead.

"Dosing of the first person in the Phase 1 clinical trial of HB-400 is an important milestone for HOOKIPA, as another program with our novel arenaviral technology progresses to the clinic," said Joern Aldag, Chief Executive Officer at HOOKIPA. "More importantly, the start of the HB-400 trial is an important milestone for the hepatitis B community as hepatitis B remains an area of critical unmet need. We look forward to working with Gilead to assess the potential impact of our novel arenaviral technology as part of a combination regimen for people living with the disease."

HB-400 is an alternating, 2-vector non-replicating arenaviral therapeutic vaccine for the treatment of chronic hepatitis B. It uses the lymphocytic choriomeningitis virus and pichinde virus as arenaviral backbones, with each expressing three highly conserved hepatitis B virus antigens. HOOKIPA's alternating 2-vector approach is designed to optimize and focus the immune response against the target antigens.

The Phase 1 clinical trial (NCT05770895) aims to evaluate the safety and tolerability of repeated doses of HB-400 in healthy participants and participants with chronic hepatitis B. Gilead is solely responsible for further development and commercialization of HB-400, referenced as GS-2829 and GS-6779.

HOOKIPA earned a $5 million non-dilutive payment under its collaboration agreement in January 2023, following the submission of the clinical trial application (IND equivalent) and the completion of the regulatory support package for the Phase 1 clinical trial.

The hepatitis B program is one of two independent development programs in HOOKIPA's collaboration and license agreement with Gilead. The other program aims to develop a novel arenaviral vaccine as a component of a potential functional curative regimen for human immunodeficiency virus (HIV). HOOKIPA is responsible for advancing the investigational HIV therapeutic vaccine through completion of a Phase 1b clinical trial.

About Hepatitis B
Hepatitis B virus is the leading cause of liver cancer, as well as a major cause of cirrhosis, liver failure and death globally. It is estimated that nearly 300 million people live with chronic hepatitis B infection, and there are 1.5 million new infections annually.

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. HOOKIPA's replicating and non-replicating technologies are engineered to induce robust and durable antigen-specific CD8+ T cell responses and pathogen-neutralizing antibodies. HOOKIPA's pipeline includes its wholly owned investigational arenaviral immunotherapies targeting Human Papillomavirus 16-positive cancers, prostate cancers, and other undisclosed programs. HOOKIPA is collaborating with Roche on an arenaviral immunotherapeutic for KRAS-mutated cancers. 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 annual report on Form 10-K for the year ended December 31, 2022, which is available on the Security and Exchange Commission's website at www.sec.gov and HOOKIPA's website at www.hookipapharma.com.

Investors and others should note that we announce material financial information to our investors using our investor relations website

(https://ir.hookipapharma.com/), SEC filings, press releases, public conference calls and webcasts. We use these channels, as well as social media, to communicate with our members and the public about our company, our services and other issues. It is possible that the information we post on social media could be deemed to be material information. Therefore, we encourage investors, the media, and others interested in our company to review the information we post on the U.S. social media channels listed on our investor relations website.