HOOKIPA Pharma Announces First Person Dosed in Phase 1b Clinical Trial of HB-500 for the Treatment of HIV

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- Novel arenaviral therapeutic vaccine, developed in collaboration with Gilead Sciences, Inc. (Gilead), to be evaluated as a potential component of a curative regimen for human immunodeficiency virus (HIV)
- HOOKIPA achieves a $5 million non-dilutive milestone payment under its collaboration and license agreement with Gilead
- Under the collaboration agreement, HOOKIPA is responsible for advancing the HIV program through the completion of a Phase 1b clinical trial

NEW YORK and VIENNA, July 01, 2024 (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 Phase 1b clinical trial of HB-500, an investigational therapeutic vaccine for the treatment of HIV. As a result, HOOKIPA achieves a $5 million non-dilutive milestone payment under its collaboration and license agreement with Gilead.

The Phase 1b clinical trial (NCT06430905) will evaluate the safety and tolerability, reactogenicity, and immunogenicity to repeated doses of HB-500 in participants with HIV on suppressive antiretroviral treatment. The Phase 1b design comprises two dose escalation cohorts that will be randomized to receive HB-500 or placebo. The first participant was dosed on July 1, 2024, and enrollment is ongoing.

“HIV impacts the daily lives of millions globally, with no known curative treatment. While current treatments effectively block viral replication and can prevent progression to AIDS, they have not been shown to clear the virus from people living with HIV, requiring lifelong treatment,” said Joern Aldag, Chief Executive Officer of HOOKIPA. “We have previously published impressive findings in our preclinical studies of HB-500, and we are happy to have begun the Phase 1b trial. Our team has worked tirelessly, alongside our great collaboration partners at Gilead, to reach this point, and we are excited to take an important step toward finding a curative treatment for HIV.”

HOOKIPA is responsible for advancing the HIV program through the completion of a Phase 1b clinical trial. Gilead has the exclusive right to assume further development of the program thereafter. HB-500 is one of two separate developmental programs in HOOKIPA’s collaboration and license agreement with Gilead.

About HB-500
HB-500 comprises two genetically engineered replicating vectors based on the arenaviruses Pichinde virus and lymphocytic choriomeningitis virus, respectively. The HB-500 vectors have been engineered to deliver HIV antigens derived from parts of key, immunogenic regions of HIV type 1 (HIV-1) proteins that are highly conserved within HIV-1 clade B variants. The designed immunogens differ from each other by their amino acid sequence allowing for coverage of >80% of circulating HIV-1 viral variants.

About HIV
HIV is one of the world’s most formidable public health challenges. It is estimated there are more than 38 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. 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, KRAS-mutated cancers, 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.

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 “anticipates”, “believes,” “expects,” “plans,” “potential,” “will,” “would” or similar expressions and the negative of those terms. Forward-looking statements in this press release include HOOKIPA’s statements regarding the potential of its product candidates to positively impact quality of life and alter the course of disease in the patients it seeks to treat, HOOKIPA’s plans, strategies, expectations and anticipated milestones for its preclinical and clinical programs, including the timing of initiating clinical trials and patient enrollment, the availability and timing of results from preclinical studies and clinical trials, the timing of regulatory filings, the expected safety profile of HOOKIPA’s product candidates, and the probability of successfully developing and receiving regulatory approval for its product candidates. 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, plans and timelines for the preclinical and clinical development of its product candidates, including the therapeutic potential, clinical benefits and safety thereof, expectations regarding timing, success and data announcements of current ongoing preclinical and clinical trials, the ability to initiate new clinical programs, the risk that the results of current preclinical studies and clinical trials may not be predictive of future results in connection with current or future preclinical and clinical trials, including those for HB-200, HB-700, HB-400 and HB-500, 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 public health crises, the impact of public health crises on the enrollment of patients and timing of clinical results, HOOKIPA's ability to achieve the expected benefits of its strategic reprioritization 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, 2023, as well as discussions of potential risks, uncertainties, and other important factors in HOOKIPA's subsequent filings with the Securities and Exchange Commission, which are available on the SEC's website at https://sec.gov and HOOKIPA's website at www.hookipapharma.com. All information in this press release is as of the date of the release, and HOOKIPA undertakes no duty to update this information unless required by law.

Availability of Other Information About HOOKIPA

Investors and others should note that we announce material financial information to our investors using our investor relations website, www.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 investors 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 social media channels listed on our investor relations website.

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