HOOKIPA Pharma Announces Enrollment Completion of Phase 1b Clinical Trial Evaluating HB-500 for the Treatment of HIV

January 30, 2025 at 7:00 AM EST

HB-500 is a next-generation therapeutic vaccine being developed in collaboration with Gilead Sciences, Inc. (Gilead) as a potential component of a curative regimen for human immunodeficiency virus (HIV)

Under the collaboration agreement, HOOKIPA is responsible for advancing the HIV program through the completion of a Phase 1b clinical trial

Primary completion expected H2 2025

NEW YORK and VIENNA, Jan. 30, 2025 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, "HOOKIPA", the "Company"), a clinical-stage biopharmaceutical company developing next-generation immunotherapeutics for the treatment of cancer and serious infectious diseases, today announced that enrollment is complete in the Phase 1b clinical trial evaluating HB-500 for the treatment of HIV, with 30 participants enrolled across five sites in the United States.

"Completing enrollment in our Phase 1b trial marks an important milestone for the HB-500 program and our strategic collaboration with Gilead and speaks to the focus on operational excellence at Hookipa," said **Mark Winderlich, PhD, Chief Research & Development Officer** of HOOKIPA.

The Phase 1b clinical trial (NCT06430905) is evaluating 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 with participants randomized to receive HB-500 or placebo. The first participant was dosed on July 1, 2024, and primary completion is expected in the second half of 2025.

"HB-500 is designed to induce robust and durable immunity and is a key component of a combination strategy for a potential functional cure of HIV using novel mechanisms aimed at driving viral suppression, durable immunity and eradication of the pro-viral reservoir," commented **Dan H. Barouch, M.D., Ph.D., Director of the Center of Vaccine and Virology Research, Beth Israel Deaconess Medical Center and Professor of Medicine, Harvard Medical School.**

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 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 next generation immunotherapeutics based on its proprietary arenavirus platform. The company's product candidates are designed to induce specific, robust and durable CD8+ T cells and antibodies to eliminate cancers and serious infectious diseases. HOOKIPA's pipeline includes biological therapies for oncology, targeting human papillomavirus type 16-positive (HPV16+) cancers, KRAS mutated cancers, and other targets. In addition, HOOKIPA has partnered with Gilead Sciences, Inc. to develop therapies that are intended to provide functional cures for hepatitis B virus (HBV) and human immunodeficiency virus-1 (HIV-1). 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 improve the care of the patients it seeks to treat and the timing of primary completion of the Phase 1b trial evaluating HB-500. 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 eseba-vec (also known as HB200), 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, and HOOKIPA's ability to continue as a going concern and other matters that could affect the sufficiency of existing cash to fund operations, as well risks and uncertainties related to the proposed combination of HOOKIPA with Poolbeg Pharma plc and the proposed concurrent private placement, including whether a firm offer will be made or the parties are otherwise able to reach binding agreement for the proposed combination, whether the proposed combination and private placement will be consummated, and whether the expected benefits of the proposed combination and private placement will ultimately be realized. 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 U.S. Securities and Exchange Commission (SEC), 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, 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.

For further information, please contact:

Investors
Chuck Padala
Chuck@LifeSciAdvisors.com