HOOKIPA Pharma Announces FDA Clearance of its Investigational New Drug Application for HB-500 for the Treatment of Human Immunodeficiency Virus

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- Novel arenaviral therapeutic vaccine, developed in collaboration with Gilead Sciences, Inc. ('Gilead'), to be evaluated as a potential curative regimen for human immunodeficiency virus (HIV)
- Phase 1 trial to commence in the first half of 2024
- *Nature Partner Journals (NPJ) Vaccines* published peer-reviewed preclinical data that provides a preclinical proof of concept for the trial as the tested, representative vaccine design was safe, immunogenic, and efficacious

NEW YORK and VIENNA, Austria, Nov. 20, 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 Company has received clearance from the U.S. Food and Drug Administration (FDA) for its Investigational New Drug (IND) application for HB-500, a novel arenaviral therapeutic vaccine for the treatment of 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.

"This marks our fourth active IND program at HOOKIPA—a further testament to the broad potential of our arenavirus platform across multiple disease areas and indications," said Joern Aldag, Chief Executive Officer at HOOKIPA. "The ability to generate a potent and broad T cell response that can clear infected cells is critical for HIV control. Our novel arenaviral therapeutic vaccine offers promise in helping to address the unmet need for a functional HIV cure."

Nature Partner Journals (NPJ) Vaccines recently published the joint-preclinical research by HOOKIPA and Gilead, which served as the foundation for the IND submission. The analyses published were conducted with a simian immunodeficiency virus (SIV) model, commonly used in a preclinical setting as a surrogate to HIV. The data show that:

- Arenaviral therapeutic vaccination was well tolerated and generated robust, high-quality and durable immune responses (antigen-specific T cells and antibodies) in non-human primates; and,
- Arenaviral therapeutic vaccination significantly reduced SIV viral load and clinical illness in those animals compared to placebo.

HB-500 is an alternating, 2-vector arenaviral therapeutic vaccine for the treatment of HIV. One vector is based on lymphocytic choriomeningitis virus (LCMV) as its arenaviral backbone; another vector is based on Pichinde virus (PICV). Both encode the same HIV antigens. The alternating 2-vector approach is designed to further focus the immune response against the target antigen.

HB-500 is one of two separate development programs in HOOKIPA's collaboration and license agreement with Gilead.

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, 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.

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 public health crises, the impact of public health crises

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 September 30, 2023, which is available on the SEC'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.

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