FDA accepts HOOKIPA's Investigational New Drug Application for HB-300 for the treatment of metastatic castration-resistant prostate cancer

July 25, 2022

- Novel arenaviral immunotherapy is directed against the prostate cancer targets PAP and PSA; Phase 1/2 trial to commence by early 2023
- Drug Master File (DMF) accepted to support future FDA submissions

NEW YORK and VIENNA, Austria, July 25, 2022 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapies based on its proprietary arenavirus platform, has received U.S. Food and Drug Administration (FDA) acceptance of its Investigational New Drug (IND) application for HB-300, a novel arenaviral immunotherapy for the treatment of metastatic castration-resistant prostate cancer.

"*FDA acceptance of our IND application for HB-300 is a key milestone as we expand and diversify our oncology pipeline and arenavirus platform from viral antigens to self-antigens,*" said Joern Aldag, Chief Executive Officer at HOOKIPA. " *With the concurrent acceptance of the Drug Master File, we have reduced cycle time between completion of preclinical studies and clinical entry of our pipeline projects."*

About HB-300
HB-300 is an alternating, 2-vector replicating arenaviral immunotherapy for metastatic castration-resistant prostate cancer. It uses the Lymphocytic Choriomeningitis Virus and Pichinde Virus as arenaviral backbones, with each expressing two well-defined antigens of prostate cancer, PAP and PSA. Subsequent clinical development may include addition of arenaviral therapeutics expressing a third antigen, PSMA. HOOKIPA's approach is designed to focus the immune response against the target antigens. The technology has demonstrated the ability to induce potent antigen-specific T cell responses and anti-tumor activity in preclinical tumor models.

About the Drug Master File
A Drug Master File (DMF) is a voluntary submission to the FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. The information contained in the DMF may be used to support additional INDs and other submissions. The FDA accepted HOOKIPA's submission of a Type II Master File to the FDA's Center for Biologics Evaluation and Research to present data specific to HOOKIPA's proprietary replicating arenavirus platform.

About prostate cancer
Prostate cancer is the most diagnosed cancer and fifth leading cause of death from cancer in men. There are several stages of prostate cancer, and prostate cancer cells usually need androgen hormones, such as testosterone, to grow. Treatment for early-stage prostate cancer often aims to lower testosterone levels to stop or slow growth. Metastatic castration-resistant prostate cancer is when the cancer has spread, or metastasized, to other parts of the body including the lymph nodes, bones, rectum, liver and lungs. Metastatic castration-resistant prostate cancer does not respond to hormone therapy. Currently, there are limited treatment options for people with metastatic castration-resistant prostate cancer and only 30 percent will survive beyond five years.

About HOOKIPA
HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical-stage biopharmaceutical company focused on developing novel immunotherapies, based on its proprietary arenavirus platform, that 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+ cell responses and pathogen-neutralizing antibodies. HOOKIPA's pipeline includes its wholly owned investigational arenaviral immunotherapies 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 for 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.sec.gov and HOOKIPA's website at www.hookipapharma.com.