HOOKIPA Announces FDA Clearance of IND Application for HB-201 Clinical Trial to Treat HPV-Positive Cancers

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Phase 1/2 trial to be HOOKIPA's first clinical trial in immuno-oncology

New York and VIENNA, Austria, July 11, 2019 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK), a company developing a new class of immunotherapeutics targeting infectious diseases and cancers based on its proprietary arenavirus platform, today announced that its Investigational New Drug (IND) Application for a Phase 1/2 clinical trial of HB-201, a TheraT®*-based immunotherapy, for the treatment of Human Papilloma Virus (HPV)-positive cancers is now effective following the clearance by the U.S. Food and Drug Administration (FDA).

HB-201 (LCMV) is a TheraT®-based product candidate expressing a non-oncogenic but highly antigenic E6/E7 fusion protein derived from HPV16. In animal models, HB-201 was observed to induce strong immunogenicity, resulting in a robust E6 and E7 antigen specific CD8+ T cell response. HOOKIPA will now start a clinical trial with the goal to provide therapeutic benefit to patients with HPV16+ cancers. Based on the magnitude of response shown in pre-clinical models, HOOKIPA believes that HB-201 has the potential to induce levels of CD8+ T cells that were previously only attainable with adoptive cell therapies. However, HOOKIPA's approach is designed to directly reprogram the patient's immune system with an off the shelf systemic administration. This approach eliminates the need for any *ex vivo* logistics that burden adoptive cell therapy and any related *ex vivo* cellular approaches.

HOOKIPA intends to start the Phase 1/2 clinical trial in the second half of 2019 with preliminary safety and efficacy data expected in late 2020 or early 2021. It will be HOOKIPA's first clinical trial in immuno-oncology. In addition to obtaining both safety and efficacy of the targeted patient population, this program will also have a built-in translational component which will allow HOOKIPA to validate its mechanism of action within patients and further drive clinical development via a rigorous scientific method.

Joern Aldag, HOOKIPA's Chief Executive Officer, said: "With the FDA's clearance of our IND application we have achieved an important milestone advancing HB-201 into clinical development. We aim to prove that our technology platform can effectively super-charge the natural defense mechanisms in humans and deliver prevention or cure for the benefit of seriously ill patients."

About TheraT®

HOOKIPA's proprietary TheraT ® technology is a replication-attenuated arenavirus, designed to allow for repeat administration while maintaining an immune response. TheraT® has the potential to induce CD8+ T cell response levels previously not achieved by other published immuno-therapy approaches. Unlike naturally occurring arenaviruses, which have two genomic segments, our TheraT® constructs were engineered to have three segments in order to allow for the introduction of genomic space in which to insert additional target antigens of choice. As a result of the larger genome, the virus' ability to replicate is attenuated.

About Human Papilloma Virus (HPV) - associated head and neck cancers

Human papilloma virus (HPV) is estimated to cause about 5% of the worldwide burden of cancer including approximately 99% of cervical cancers, 25% to 60% of head and neck cancers, 70% of vaginal cancers and 88% of anal cancers. The majority of these cancers are caused by the HPV serotype 16. Most infections with HPV are cleared from the body with no lasting consequences. However, in some cases, HPV DNA becomes integrated into chromosomal DNA. When host cells take up this DNA, they express the HPV E6 and E7 proteins. This can potentially lead to cancer**,** since expression of these proteins leads to alterations in cell cycle control, which in turn predisposes these cells to becoming cancerous.

About HOOKIPA

HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical stage biopharmaceutical company developing a new class of immunotherapeutics, targeting infectious diseases and cancers based on its proprietary arenavirus platform that is designed to reprogram the body's immune system.

HOOKIPA's proprietary arenavirus-based technologies, VaxWave ®*, a replication-deficient viral vector, and TheraT®*, a replication-attenuated viral vector, are designed to induce robust antigen specific CD8+ T cells and pathogen-neutralizing antibodies. Both, VaxWave® and TheraT®, are designed to allow for repeat administration while maintaining an immune response. TheraT® has the potential to induce CD8+ T cell response levels previously not achieved by other published immuno-therapy approaches. HOOKIPA's "off-the-shelf" viral vectors target dendritic cells in vivo to activate the immune system.

HOOKIPA has successfully completed a Phase 1 trial of a VaxWave®-based prophylactic vaccine to protect against cytomegalovirus infection and has started dosing patients in a Phase 2 trial in cytomegalovirus-negative patients awaiting kidney transplantation from cytomegalovirus-positive donors. To expand its infectious disease portfolio, HOOKIPA has entered into a collaboration and licensing agreement with Gilead Sciences, Inc. to jointly research and develop functional cures for HIV and Hepatitis B infections. HOOKIPA is building a proprietary immuno-oncology pipeline by targeting virally mediated cancer antigens, self-antigens and next-generation antigens.

TheraT® and VaxWave® are not approved anywhere globally and their safety and efficacy have not been established.

Find out more about HOOKIPA online at www.hookipapharma.com.

*Registered in Europe; Pending in the US.

HOOKIPA 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 and other matters that could affect the sufficiency of existing cash to fund operations and HOOKIPA’s ability to achieve the milestones under the agreement with Gilead. 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, 2019 which is available on the Security and Exchange Commission’s website at www.sec.gov and HOOKIPA’s website at www.hookipapharma.com.

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