HOOKIPA Announces First Patient Dosed in Phase 1/2 Clinical Trial for HB-201 for the Treatment of Human Papillomavirus 16-Positive Cancers

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NEW YORK and VIENNA, Austria, Dec. 30, 2019 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics targeting infectious diseases and cancers based on its proprietary arenavirus platform, today announced that the first patient has been dosed in a Phase 1/2 clinical trial (NCT04180215) of HB-201, an immunotherapy for the treatment of Human Papillomavirus 16-positive ($HPV16^+$) cancers. This trial is HOOKIPA's first clinical trial in immuno-oncology.

HB-201 is a TheraT® platform-based vector (replication attenuated) from the arenavirus family expressing a non-oncogenic but highly antigenic E6/E7 fusion protein from HPV16. In preclinical studies, HB-201 was observed to be highly immunogenic, resulting in a robust $CD8^+$ T cell response as compared to the levels induced by other approaches including adoptive cell therapies. In addition to strong immunogenicity, HOOKIPA observed robust anti-tumor activity in mouse models. HOOKIPA believes that HB-201 has the potential to provide therapeutic benefit to patients across the $HPV16^+$ cancer setting.

Joern Aldag, Chief Executive Officer at HOOKIPA, commented: "We are excited to begin first-in-human testing with HB-201, our first clinical trial in immuno-oncology. Translating our promising preclinical data to cancer patients is an important milestone. We believe HOOKIPA's approach can supercharge the natural defence mechanisms by inducing strong T cell responses to the benefit of patients affected by cancer and infectious diseases."

About the HB-201 Clinical Trial

The HB-201 Phase 1/2 trial is an open-label dose-escalation and dose-expansion trial in 100 patients with treatment-refractory $HPV16^+$ cancers. It is designed to evaluate the safety and tolerability and preliminary efficacy of HB-201 as monotherapy and in combination with an immune checkpoint inhibitor.

For Phase 1 dose escalation, the patient population will be divided into two groups of 20 patients, each: the first group will include patients with progressing $HPV16^+$ tumors who will receive monthly intravenous (IV) administration of HB-201; the second group will include patients with progressing $HPV16^+$ tumors and an accessible tumor site who will receive one intratumoral (IT) administration of HB-201 followed by monthly IV administration of HB-201.

The primary endpoint of the Phase 1 portion of this trial will be to evaluate safety and tolerability to determine the recommended dose for the Phase 2 portion. Secondary endpoints will evaluate anti-tumor activity, as defined by RECIST (Response Evaluation Criteria In Solid Tumors) 1.1, and immunogenicity. The Phase 2 portion of the trial will also investigate the efficacy of HB-201 alone and in combination with a PD-1 inhibitor. HOOKIPA expects to provide interim safety, dose escalation, and efficacy data from HB-201 in late 2020 or early 2021. These data will be supplemented by a series of translational data sets designed to demonstrate the mechanism of action.

About Human Papillomavirus

Human Papillomavirus (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[1]. 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.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5520228/

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 technologies are designed to allow for repeat administration to augment and refresh immune responses. TheraT® has the potential to induce $CD8^+$ T cell response levels previously not achieved by other immuno-therapy approaches. HOOKIPA's "off-the-shelf" viral vectors target dendritic cells in vivo to activate the immune system.

HOOKIPA's VaxWave ®-based prophylactic Cytomegalovirus vaccine candidate is currently in a Phase 2 clinical trial in patients awaiting kidney transplantation from living 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.

In addition, HOOKIPA is building a proprietary immuno-oncology pipeline by targeting virally mediated cancer antigens, self-antigens and next-generation antigens. The TheraT® based lead oncology product candidates, HB-201 and HB-202, are in development for the treatment of Human Papilloma Virus16-positive cancers. The Phase 1/2 clinical trial for HB-201 was initiated in December 2019. The HB-202 IND filing is intended for the

first half of 2020.

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 September 30, 2019 which is available on the Security and Exchange Commission’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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