HOOKIPA Announces First Patient Dosed in Phase 1/2 Clinical Trial for HB-202/HB-201 Alternating Vector Therapy to Treat Human Papillomavirus 16-Positive Cancers

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- HB-202/HB-201 alternating two-vector therapy is added as an additional arm that expands the ongoing HB-201 clinical trial

- Pre-clinical data show that adding an additional arenaviral vector to achieve alternating two-vector therapy enhances immune response

NEW YORK and VIENNA, Austria, Oct. 29, 2020 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today announced the first patient dosed with HB-202, a replicating arenavirus therapy based on the Pichinde Virus (PICV). HB-202 is part of a sequential alternating regimen of HB-202/HB-201 for the treatment of Human Papillomavirus 16-positive ($HPV16^+$) cancers in the ongoing HB-201 Phase 1/2 trial (NCT04180215).

"We are excited to expand our ongoing Phase 1/2 trial in HPV to explore the potential of combining HB-202 and HB-201 as an alternating two-vector therapy to enhance and focus the immune response against $HPV16^+$ cancers," said Joern Aldag, Chief Executive Officer of HOOKIPA. "HPV-associated cancers remain an area of unmet need and a key focus for our oncology efforts. The start of this HB-202/HB-201 arm of our trial is an important achievement in our clinical development of improved therapeutics for people with $HPV16^+$ cancers."

HB-202 and HB-201 are engineered using HOOKIPA's replicating arenaviral vector platform. They are designed to use different arenavirus backbones (PICV for HB-202 and LCMV for HB- 201), while expressing the same antigen, an E7/E6 fusion protein derived from HPV16. In pre-clinical studies, alternating administration of HB-202 and HB-201 resulted in a ten-fold increase in immune response and better disease control than either compound alone.

The alternating, sequential HB-202/HB-201 two-vector therapy has been incorporated into the ongoing Phase 1/2 trial (NCT04180215). As such, the first patient dosed in the alternating HB-202/HB-201 arm received Dose Level 1 of HB-202 and is scheduled to receive Dose Level 2 of HB-201. This Phase 1/2 clinical trial is an open-label dose-escalation and dose-expansion trial in patients with treatment-refractory $HPV16^+$ cancers. In addition to the newly added HB-202/HB-201 therapy option, patients will continue to be enrolled into the HB-201 dose groups.

The primary endpoint of the Phase 1 is a recommended Phase 2 dose based on safety and tolerability. Secondary endpoints include anti-tumor activity as defined by RECIST 1.1 and immunogenicity. Patients will receive HB-202/HB-201 via intravenous dosing or, for patients with an accessible lesion, the first dose of HB-201 will be delivered via intratumoral injection and the remaining doses of HB-202 and HB-201 will be administered intravenously.

The Phase 2 portion of the trial will investigate the efficacy of our arenaviral regimens alone and also in combination with a PD-1 inhibitor. While HOOKIPA intends to release preliminary data for the HB-201 arm of the trial in late 2020 or early 2021, the Company expects to provide interim safety, dose escalation, and efficacy data on the HB-202/HB-201 arm in mid-2021.

About Human Papillomavirus
Human Papillomavirus, or HPV, is estimated to cause about 5% of the worldwide burden of cancers. This includes approximately 99% of cases in cervical, up to 60% of head and neck, 70% of vaginal, 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 uptake can potentially lead to cancer since expression of these proteins leads to alterations in cell cycle control, which in turn predisposes these cells to become 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 reprograms the body's immune system.

HOOKIPA's proprietary arenavirus-based technologies, non-replicating (VaxWave ®) and replicating (TheraT®), induce robust antigen-specific $CD8^+$ T cells and pathogen-neutralizing antibodies. HOOKIPA's viral vectors target antigen presenting cells in vivo to activate the immune system. Both technologies enable repeat administration to augment and refresh immune responses. As a monotherapy, our replicating arenavirus technology has the potential to induce $CD8^+$ T cell response levels previously not achieved by other immuno-therapy approaches.

HOOKIPA's non-replicating prophylactic Cytomegalovirus (CMV) vaccine candidate is currently in a Phase 2 clinical trial for patients awaiting kidney transplantation. To expand its infectious disease portfolio, HOOKIPA entered into a collaboration and licensing agreement with Gilead Sciences, Inc. to research arenavirus-based functional cures for HIV and chronic 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 lead replicating arenavirus oncology product candidates, HB-201 and HB-202, are in development for the treatment of Human Papilloma Virus 16-positive cancers in a Phase 1/2 clinical trial.

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

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, 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 for HB-101 and other programs, 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 June 30, 2020 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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