HOOKIPA announces clinical collaboration with Merck & Co., Inc., Kenilworth, NJ., USA to evaluate HB-200 in combination with KEYTRUDA® (pembrolizumab) in patients with advanced head and neck cancers

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- *Clinical collaboration to assess HB-200 in combination with KEYTRUDA®* (pembrolizumab) *as first-line treatment*
- *HOOKIPA poised to advance clinical development program with randomized Phase 2 study in 2022*

NEW YORK and VIENNA, Austria, Sept. 15, 2021 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today announced it has entered into a clinical collaboration and supply agreement with Merck & Co., Inc., Kenilworth, NJ., USA (known as MSD outside of the United States and Canada) to evaluate the combination of HB-200, a novel arenaviral immunotherapeutic, and Merck & Co., Inc., Kenilworth, NJ., USA's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) as first-line treatment for patients with advanced head and neck squamous cell carcinoma (HNSCC).

"Our collaboration with Merck & Co., Inc., Kenilworth, NJ., USA, a proven immuno-oncology leader, is an important step as we advance our HB-200 program for the treatment of Human Papillomavirus 16-positive (HPV16+) cancers and seek to introduce a new class of immunotherapeutics," said Joern Aldag, Chief Executive Officer at HOOKIPA. "There remains considerable unmet treatment need for people with metastatic head and neck cancers, and we believe the combination of HB-200 and KEYTRUDA may offer hope. We have seen encouraging early responses in heavily pre-treated patients with the addition of KEYTRUDA in our ongoing HB-200 trial. We are excited to explore the potential benefit of HB-200 as a first-line treatment in combination with KEYTRUDA, a leading anti-PD-1 inhibitor globally, and the possibility of making a meaningful impact on patients' lives."

The collaboration has been initiated based on promising data from the ongoing HB-200 Phase 1/2 clinical trial (NCT04180215) in advanced HPV16+ cancers. As reported at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, 15 patients with metastatic head and neck cancers were eligible for the efficacy analysis, as of data cut-off. HB-201 monotherapy showed an 18 percent overall response rate and median progression-free survival of 3.45 months in heavily pretreated head and neck cancer patients, better than current 2nd-line treatment. In addition, preliminary data on HB-201/HB-202 therapy showed a disease control rate of 100 percent (4/4 patients). Importantly, the Phase 1 data on 38 evaluable patients showed that HB-200 therapy has a favorable safety profile in heavily pre-treated patients with HPV16+ cancers, underlining its potential as a monotherapy and in possible combination with checkpoint inhibitors.

With a HB-200 program data read-out anticipated by Q4 2021, HOOKIPA anticipates initiating a Phase 2 trial with HB-200 in combination with KEYTRUDA in 2022. Additional Phase 2 expansion cohorts are also planned to start in Q1 2022.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

About HB-200
HB-201 and HB-202 are HOOKIPA's lead oncology candidates engineered with the company's proprietary replicating arenaviral vector platform. Each single-vector compound uses a different arenavirus backbone (Lymphocytic choriomeningitis virus for HB-201 and Pichinde virus for HB-202), while expressing the same antigen, an E7E6 fusion protein derived from HPV16. In pre-clinical studies, alternating administration of HB-201 and HB-202 resulted in a ten-fold increase in immune response and better disease control than either compound alone. HB-201 is being tested clinically as a single vector therapy and also in an alternating vector combination with HB-202.

About Human Papillomavirus
Human Papillomavirus, or HPV, is estimated to cause about 5 percent of the worldwide burden of cancers. This includes approximately 99 percent of cases in cervical, up to 60 percent of head and neck, 70 percent of vaginal and 88 percent 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 focused on developing novel immunotherapies that mobilize and amplify targeted T cells and antibodies, the body's natural infection killers, to fight or prevent serious disease.

HOOKIPA is developing a broad pipeline of potential first-in-class arenaviral immunotherapies in oncology and infectious disease. We are leveraging our proprietary, versatile platform to engineer arenaviral therapeutics that induce robust antigen-specific CD8+ T cells and pathogen-neutralizing antibodies to a broad range of self and non-self antigens, including viral antigens, tumor-associated antigens and neoantigens. Our immunotherapies are designed to use either non-replicating or replicating viral vectors based on the target disease, with the potential to induce CD8+ T cell response levels previously not achieved by other immunotherapy approaches.

HOOKIPA's pipeline include ongoing clinical trials in Human Papilloma Virus 16-positive cancers and Cytomegalovirus, as well as preclinical research in prostate cancer, HIV and Hepatitis B. The latter two are in collaboration with Gilead Sciences, Inc.

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 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 annual report on Form 10-Q for the financial year ended June 30, 2021 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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