HOOKIPA announces strategic collaboration and license agreement with Roche to develop novel arenaviral immunotherapy for KRAS-mutated cancers

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- Roche to receive license for HOOKIPA's HB-700 program and option to license a second undisclosed novel arenaviral immunotherapy
- HOOKIPA to receive $25 million in upfront cash as well as potential future success-based milestone payments up to approximately $930 million for both programs, plus tiered royalties

NEW YORK and VIENNA, Oct. 20, 2022 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapies based on its proprietary arenavirus platform, announced today a strategic collaboration and license agreement with Roche to develop HB-700 for KRAS-mutated cancers and a second undisclosed novel arenaviral immunotherapy. This represents HOOKIPA's first oncology licensing collaboration.

Through the collaboration, HOOKIPA will conduct research and early clinical development through Phase 1b for HB-700, a novel investigational arenaviral immunotherapy for the treatment of KRAS-mutated cancers. Upon the completion of the Phase 1b trial, Roche has the right to assume development responsibility and to commercialize licensed products across multiple indications upon approval. The agreement also includes an option for Roche to license a second arenaviral cancer immunotherapy.

"*Roche is an ideal partner, both in terms of development and reaching patients with novel cancer therapeutics. We look forward to working with them to benefit people with KRAS-mutated cancers*," said Joern Aldag, Chief Executive Officer at HOOKIPA. " *This collaboration validates the potential of our arenavirus platform and accelerates the development pathway to bring new treatments to people with cancer*."

"*We are excited to collaborate with HOOKIPA in leveraging their arenaviral technology, which has clinically demonstrated the ability to induce potent antigen specific CD8+ T cell responses and represents a promising approach for new cancer immunotherapies*," said James Sabry, Global Head of Pharma Partnering at Roche. "*This collaboration further strengthens our leadership in oncology, and we are optimistic about advancing this innovative platform to potentially provide more options for people with KRAS-mutated cancers, as well as other potential cancer types*."

Under the terms of the agreement, HOOKIPA will receive an upfront payment of $25 million. Roche will have the option to expand the initial collaboration by adding an additional product candidate, whereafter HOOKIPA will receive an additional $15 million payment at option exercise. Including this option payment, HOOKIPA is eligible for research, development and commercialization milestone-based payments for HB-700 and the additional product candidate totaling up to approximately $930 million. Upon commercialization, HOOKIPA is eligible to receive tiered royalties of a high single-digit to mid-teens percentage on the worldwide net sales of HB-700 and the additional product candidate.

About KRAS-mutated cancers
KRAS is a gene that acts as an on/off switch for cell growth. When there is a mutation, or error, in the gene, cells can grow out of control. KRAS mutations are among the most common mutations that cause cancer. While KRAS-mutated, tumor-specific treatments exist, there remains an opportunity to target a broader range of KRAS-mutations simultaneously to potentially help more people impacted by these cancers.

About HOOKIPA's Arenaviral Technology
HOOKIPA's novel, replicating arenaviral technology has demonstrated the ability to induce potent antigen-specific T cell responses and promising anti-tumor activity in a Phase 1 clinical trial which treated patients with advanced Human Papillomavirus 16-positive head and neck cancers. Preclinical studies have also demonstrated the ability of arenaviral immunotherapies to break self-tolerance and induce potent T cell responses to tumor self-antigens and mutated epitopes, or target parts of a mutated, cancer-causing gene. These findings provide scientific rationale for the HB-700 program.

About HB-700
HB-700 is an investigational arenaviral immunotherapy designed to treat KRAS-mutated lung, colorectal, pancreatic and other cancers. HB-700 is a replicating 2-vector therapy that targets the most common KRAS mutations: (G12D, G12V, G12R, G12C and G13D) and thereby benefits more patients than single mutation inhibitors.

About HOOKIPA

HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical-stage biopharmaceutical company focused on developing novel immunotherapies, based on its proprietary arenavirus platform, which 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+ T cell responses and pathogen-neutralizing antibodies. HOOKIPA's pipeline includes its wholly owned investigational arenaviral immunotherapies targeting Human Papillomavirus 16-positive cancers, prostate cancers, and other undisclosed programs. HOOKIPA is collaborating with Roche on an arenaviral immunotherapeutic for KRAS-mutated cancers. In addition, HOOKIPA aims to develop functional cures of 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 June 30, 2022, which is available on the Security and Exchange Commission’s website at www.sec.gov and HOOKIPA’s website at www.hookipapharma.com.