HOOKIPA to Present Complete HB-200 Phase 1 Results and Recommended Phase 2 Dose for HB-202/HB-201 for the Treatment of Advanced HPV16+ Cancers at ASCO

May 26, 2022

- Phase 1 data show single-vector HB-201 and 2-vector HB-202/HB-201 were generally well tolerated, rapidly induced tumor-specific T cells and showed anti-tumor activity in heavily pre-treated head and neck cancer patients
- Poster presentation to include data supporting recommended Phase 2 dose for alternating 2-vector HB-202/HB-201 and Phase 2 development plans in head and neck cancers

NEW YORK and VIENNA, Austria, May 26, 2022 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today announced that complete HB-200 Phase 1 results (NCT04180215) for single-vector HB-201 and alternating 2-vector HB-202/HB-201 in patients with advanced Human Papillomavirus 16-positive (HPV16+) cancers, including the recommended Phase 2 dose for HB-202/HB-201, will be shared in a poster presentation at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place June 3-7, 2022. Data as of March 31, 2022 will be presented on 68 patients, 54 of whom had head and neck squamous cell carcinoma (HNSCC).

"*We look forward to sharing the full Phase 1 data results on our HB-200 program at ASCO. The final analysis shows that HB-201 and 2-vector HB-202/HB-201 were generally well tolerated and showed anti-tumor activity in these difficult-to-treat patients. We also will share additional translational data that continue to show robust tumor-specific T cell responses from use of our HB-200 therapies*," said Joern Aldag, Chief Executive Officer at HOOKIPA. "*We are continuing to advance this truly novel science through the clinic, and the learnings from this phase help deepen our understanding of the potential of our technology. These insights inform our path as we advance the 2-vector HB-202/HB-201 immunotherapy into the ongoing Phase 2 HNSCC portion of the study, as well as our approach to our HB-300 program in prostate cancer*."

The abstract is available on the ASCO website with key details noted below:

- Recommended Phase 2 dose (RP2D) of HB-200 arenavirus-based cancer immunotherapies in patients with HPV16+ cancers
    - Abstract # 2517, *Developmental Therapeutics – Immunotherapy*
        - Poster session: Sunday, June 5, 8:00 a.m. – 11:00 a.m. CDT
        - Poster discussion session: Sunday, June 5, 11:30 a.m. – 1:00 p.m. CDT in Hall D2
    - Presenter: Siqing Fu, M.D., Ph.D., Professor of Investigational Cancer Therapeutics and principal investigator at The University of Texas MD Anderson Cancer Center
    - Key findings:
        - Single-vector HB-201 and 2-vector HB-202/HB-201 immunotherapies were generally well tolerated and showed anti-tumor activity in heavily pre-treated patients with HPV16+ head and neck cancer
        - HB-201 was evaluated at three dose levels, with two dosing schedules and two administration routes for safety, efficacy and immunogenicity
        - HB-202/HB-201 was evaluated at four dose levels and two administration routes for safety, efficacy, and the recommended Phase 2 dose
        - Anti-tumor activity in this heavily pre-treated patient population was observed with HB-201 and HB-202/HB-201 treatments alone, including sustained tumor control and partial responses.

About HB-202/HB-201
HB-201 and HB-202/HB-201 are HOOKIPA's lead oncology candidates engineered with the company's proprietary replicating arenaviral vector platform. HB-201 is a single-vector compound that uses Lymphocytic Choriomeningitis Virus as its arenaviral backbone. HB-202 is a single-vector compound that uses Pichinde Virus as its arenaviral backbone. Both express the same antigen, an E7E6 fusion protein derived from HPV16. HB-202/HB-201 is an alternating 2-vector immunotherapy designed to further focus the immune response against the target antigen. 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. Both novel immunotherapy candidates, in combination with pembrolizumab, received Fast Track Designation from the U.S. Food and Drug Administration for the treatment of 1st-line advanced/metastatic HPV16+ head and neck cancers.

About the HB-200 trial (NCT04180215)
This Phase 1/2 clinical trial is an open-label trial exploring different dose levels and dosing schedules in individuals with treatment-refractory HPV16+ head and neck cancers who progressed on standard of care, including checkpoint inhibitors. The HB-200 trial is evaluating two HOOKIPA compounds: HB-201 as single-vector therapy, HB-202/HB-201 as an alternating 2-vector therapy, and both in combination with a PD-1 inhibitor. The primary endpoint of Phase 1 is a recommended Phase 2 dose. Secondary endpoints include safety and tolerability, as well as preliminary efficacy defined by RECIST 1.1. The trial also includes exploratory objectives on T cell response and pharmacodynamic biomarkers.

The Phase 2 part of the trial is open-label with a primary endpoint of preliminary anti-tumor activity, defined by RECIST 1.1, for objective response rate and disease control rate. Secondary endpoints including safety, overall survival, progression-free survival and duration of response. Phase 2 is ongoing, evaluating HB-201 in combination with pembrolizumab in 1st-- and 2nd-line plus settings, with additional arms planned based on final Phase 1 results.

About Human Papillomavirus-driven Cancers
Human Papillomavirus, or HPV, is a common viral infection estimated to cause about 5 percent of the worldwide cancer burden. This includes up to 60 percent of head and neck, 89 percent of cervical, 78 percent of vaginal, 88 percent of anal, 67 percent of vulvar and 50 percent of penile cancers.

While there are numerous HPV types associated with cancer, HPV16 is the most common cause of cancer. Most HPV infections 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, based on its proprietary arenavirus platform, that 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+ cell responses and pathogen-neutralizing antibodies. HOOKIPA's pipeline includes its wholly-owned investigational arenaviral immunotherapeutics targeting HPV16+ cancers, prostate cancer, KRAS-mutated cancers (including colorectal, pancreatic and lung), and other undisclosed programs. 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. For further information, please contact:

Media	**Investors**
Michael Szumera	Matt Beck
Executive Director - Communications	Executive Director - Investor Relations
michael.szumera@hookipapharma.com	matthew.beck@hookipapharma.com
+1 917 561 8905	+1 917 209 6886

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 March 31, 2022 which is available on the Security and Exchange Commission's website at www.sec.gov and HOOKIPA's website at www.hookipapharma.com.