HOOKIPA Announces First Patient Enrolled in Phase 2 Trial Evaluating HB-200 and Pembrolizumab for Treatment of Head and Neck Cancer and Reports FDA's Fast Track Designation

January 18, 2022

- First patient dosed with HB-200 and pembrolizumab combination for treatment of 1st-line advanced/metastatic head and neck cancer in Phase 2 arm of ongoing Phase 1/2 trial
- Fast Track Designation granted for HB-200 in combination with pembrolizumab for treatment of 1st-line head and neck cancer

NEW YORK and VIENNA, Austria, Jan. 18, 2022 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, announced that the first patient has been dosed with HB-200 in combination with pembrolizumab for the treatment of 1st-line advanced/metastatic Human Papillomavirus 16 Positive (HPV16+) squamous cell head and neck cancers (HNSCC) in a Phase 2 arm of the ongoing Phase 1/2 trial (NCT04180215). In addition, the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to the Company's novel immunotherapy candidates, single-vector HB-201 and alternating 2-vector HB-202/HB-201, both in combination with pembrolizumab, for the treatment of 1st-line advanced/metastatic HPV16+ HNSCC.

"Given our HB-200 clinical data to date, we believe that combining HB200 with pembrolizumab in earlier line settings has the potential--by inducing unprecedented levels of tumor antigen-specific CD8+ T cells--to overcome the limitations of checkpoint inhibitor monotherapy," said Joern Aldag, Chief Executive Officer at HOOKIPA. "We're eager to work closely with the FDA through the development process as we hope to bring new options to patients with HNSCC. Fast Track Designation for our lead oncology candidates is a great recognition of the promise of our versatile arenaviral platform to deliver novel immunotherapies which can address unmet needs in cancer."

The Company reiterates its HB-200 program guidance as follows:

- Additional Phase 1 monotherapy data in mid-2022;
- Initial 1st-line data and post-standard of care (2nd+ line) data, both in combination with pembrolizumab, in 2H 2022;
- Initiation of the randomized 1st-line Phase 2 study (pembrolizumab vs. pembrolizumab + HB-200) in 1H 2023.

Fast Track Designation is granted by the FDA for products that demonstrate the potential to address unmet medical needs in serious or life-threatening conditions. The designation, which is based on a review of pre-clinical and clinical data, enables early and frequent communication with the FDA through the drug development process, a rolling submission of a New Drug Application, as well as eligibility for Accelerated Approval and Priority Review if relevant criteria are met. Fast Track Designation was granted to the planned Phase 2 randomized trial of HB-201 and HB-202/HB-201 in combination with pembrolizumab for the treatment of 1st-line advanced/metastatic HPV16+ HNSCC.

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. 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. HOOKIPA's HB200 program includes HB-201, which is being tested clinically as a single vector therapy and HB-201 used as an alternating vector combination with HB-202.

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 check point inhibitors. The trial is evaluating HB-201 as a monotherapy, as an alternating 2-vector therapy with HB-202, and 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 study also includes exploratory objectives on immunogenicity and pharmacodynamic biomarkers. The Phase 2 part of the trial, assessing HB-201 and HB-202/HB-201 in combination with pembrolizumab in 1st- and post-standard of care (2nd+) line settings, is ongoing.

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 to address unmet needs in cancer.

The company is leveraging its proprietary, versatile platform to engineer a broad pipeline of differentiated arenaviral therapeutics. These novel immunotherapies induce robust antigen-specific killer T cells to a broad range of self and non-self antigens, including viral antigens, tumor-associated antigens and neoantigens. HOOKIPA's platform technology uses replicating viral vectors based on the target cancer, with the potential to induce killer T cell response levels previously not achieved by other immunotherapy approaches.

HOOKIPA's pipeline includes wholly-owned investigational arenaviral immunotherapeutics targeting Human Papilloma Virus 16-positive cancers, prostate cancer, KRAS-mutated cancers (including colorectal, pancreatic and lung), and other undisclosed oncology indications. In addition, the company aims to develop functional cures of Hepatitis B Virus and HIV in collaboration with Gilead.

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 quarterly report on Form 10-Q for the quarter ended September 30, 2021, which is available on the Securities 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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