HOOKIPA Pharma Doses First Patients with Eseba-vec as Adjuvant Therapy in Phase 2 Investigator Lead Trial for Head & Neck Cancer

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Study done in collaboration with Memorial Sloan Kettering and led by Dr. Winston Wong, Head and Neck Oncologist and Dr. Alan Ho, Chief of the Head and Neck Oncology Service

IIT will evaluate eseba-vec in patients who are HPV16+ after treatment for curative intent

Potential to expand the eseba-vec HNSCC opportunity into adjuvant care

Initial safety and efficacy data from IIT expected in 2026

NEW YORK and VIENNA, Oct. 30, 2024 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK) ("HOOKIPA" or the "Company"), a clinical-stage biopharmaceutical company developing next generation immunotherapeutics for the treatment of cancer and serious infectious diseases, today announced that researchers at Memorial Sloan Kettering Cancer Center (MSKCC) have dosed the first patients in an investigator initiated trial (IIT) of eseba-vec, HOOKIPA's human papillomavirus type 16 (HPV16+)-targeted investigational immunotherapeutic agent, in patients with minimal residual disease positive (MRD+) HPV-driven head and neck cancer.

"Based on the positive Phase 2 data generated to date in recurrent/metastatic (R/M) HNSCC, we believe eseba-vec has broad potential across HPV16+ cancers. We are enthusiastic to explore the potential of eseba-vec as an adjuvant treatment for patients with locally advanced HNSCC and continue our collaboration with Drs. Wong and Ho and the team at MSKCC," said **Mark Winderlich, PhD, Chief Research and Development Officer** at HOOKIPA. "We believe eseba-vec can help address unmet needs within the adjuvant setting and pave the way for us to help more patients with HNSCC."

Malte Peters, Chief Executive Officer of HOOKIPA added, "Eseba-vec was well tolerated and has demonstrated compelling efficacy in combination with pembrolizumab in HPV+ (R/M) HNSCC. We look forward to building on these promising findings with the expansion into adjuvant care. Our eseba-vec clinical development program in HNSCC continues to advance and we are on track to initiate our pivotal AVALON-1 Phase 2/3 study in the front-line setting for patients with HPV16+ oropharyngeal squamous cell carcinoma (OPSCC) in the fourth quarter of 2024. We expect initial safety and efficacy data from the IIT in 2026."

Winston Wong, MD, commented, "Targeted immunotherapeutic agents can play an important role in the care of patients with HPV16+ HSNCC. I am encouraged by the potential for eseba-vec in this setting based on promising Phase 2 combination data with pembrolizumab in the first line setting presented at this year's American Society for Clinical Oncology annual meeting showing rapid and durable activation of antigen-specific CD8+ T cells and promising clinical response rates, especially in the CPS 20 or higher subgroup. Patients who are HPV16+ after receiving standard of care treatment for curative intent may also benefit from an immunotherapy treatment and we are currently testing whether eseba-vec may be a new, effective adjuvant treatment option."

The Phase 2, randomized, double-blind, placebo-controlled study (NCT06373380) will evaluate the use of eseba-vec in patients with minimal residual disease positive (MRD+) HPV-driven head and neck cancer. The primary endpoint of the study is disease-free survival. Secondary endpoints include an assessment of safety and tolerability. The study is expected to enroll approximately 50 patients.

About eseba-vec
Eseba-vec (also known as HB-200) is an investigational immunotherapeutic agent being evaluated for HPV16 positive cancers. The first indication for eseba-vec is for the potential treatment of patients with HPV16+ recurrent/metastatic oropharyngeal squamous cell carcinoma (R/M OPSCC) with a PDL1 CPS of 20 or higher, in combination with pembrolizumab, in the first line (1L) setting. Eseba-vec has received Fast Track Designation from the U.S. Food and Drug Administration and PRIME designation from the European Medicines Agency for the treatment of 1L HPV16+ OPSCC. Eseba-vec was developed using HOOKIPA's proprietary arenavirus platform.

About HOOKIPA
HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical-stage biopharmaceutical company focused on developing next generation immunotherapeutics based on its proprietary arenavirus platform. The company's product candidates are designed to induce specific, robust and durable CD8+ T cells and antibodies to eliminate cancers and serious infectious diseases. HOOKIPA's pipeline includes biological therapies for oncology, targeting human papillomavirus type 16-positive (HPV16+) cancers, KRAS mutated cancers, and other targets. In addition, HOOKIPA has partnered with Gilead to develop therapies that are intended to provide functional cures for hepatitis B virus (HBV) and human immunodeficiency virus-1 (HIV-1). 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 "anticipates", "believes", "expects", "plans", "potential", "will", "would" or similar expressions and the negative of those terms. Forward-looking statements in this press release include HOOKIPA's statements regarding the potential of its product candidates to improve the care of the patients it seeks to treat, HOOKIPA's plans, strategies, expectations and anticipated milestones for its preclinical and clinical programs, including the timing of initiating clinical trials and patient enrollment, the availability and timing of results from preclinical studies and clinical trials and the expected safety profile of HOOKIPA's product candidates. 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, plans and timelines for the preclinical and clinical development of its product candidates, including the therapeutic potential, clinical benefits and safety thereof, expectations regarding timing, success and data announcements of current ongoing preclinical and clinical trials, the ability to initiate new clinical programs, the risk that the results of current preclinical studies and clinical trials may not be predictive of future results in connection with current or future preclinical and clinical trials, including those for eseba-vec, HB-700, HB-400 and HB-500, 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, and HOOKIPA's ability to continue as a going concern 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 Annual Report on Form 10-K for the year ended December 31, 2023, as well as discussions of potential risks, uncertainties, and other important factors in HOOKIPA's subsequent filings with the Securities and Exchange Commission, which are available on the SEC's website at https://sec.gov and HOOKIPA's website at www.hookipapharma.com. All information in this press release is as of the date of the release, and HOOKIPA undertakes no duty to update this information unless required by law.

Availability of Other Information About HOOKIPA

Investors and others should note that we announce material financial information to our investors using our investor relations website, www.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 investors and the public about our company, 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 social media channels listed on our investor relations website.

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