HOOKIPA Pharma's Eseba-vec Highlighted in SITC Late-Breaker

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Phase 2 trial evaluating eseba-vec/pembrolizumab combination resulted in a 52% ORR in PD-L1 CPS>20 patients and encouraging PFS and OS data, supported by highly durable and tumor-specific T cell response, with good overall safety

NEW YORK and VIENNA, Nov. 11, 2024 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, "HOOKIPA", the "Company"), a clinical-stage biopharmaceutical company developing next generation immunotherapeutics for the treatment of cancer and serious infectious disease, today announced that clinical collaborator Alan Ho, MD, PhD, Chief of the Head and Neck Oncology Service at Memorial Sloan Kettering Cancer Center, presented updated Phase 2 data from a study evaluating eseba-vec in combination with pembrolizumab as front line (1L) therapy in the setting of human papillomavirus type 16 positive (HPV16+) relapsed or metastatic head and neck squamous cell carcinoma (R/M HNSCC) at the 39th Annual Meeting for the Society for Immunotherapy in Cancer (SITC2024), being held in Houston Texas from November 8 – 10, 2024.

The late-breaking poster presentation focused on results from a subset of patients (PD-L1 CPS ≥20, n=27, with 25 response evaluable patients). The data showed an overall response rate (ORR) of 52% for all eseba-vec doses tested, with a disease control rate (DCR) of 80%, as of the September 30, 2024 data cut-off. While progression free survival (PFS) and overall survival (OS) data are still maturing, preliminary median PFS is greater than 16 months, with a 12-month OS rate of 83%, and 66.7% of confirmed responders ongoing. In addition, the observed clinical activity is supported by a rapid, robust, and durable tumor antigen specific T-cell response. Data are generally consistent for the selected Phase 3 dose level, including a 55% ORR, which is an approximately 2-fold increase compared to historical pembrolizumab monotherapy data. Patients experienced manageable toxicity and a low level of serious treatment related adverse events (7.6%).

"The expanded data presented at SITC 2024 are encouraging to HOOKIPA. They provide highly consistent proof-of-concept results which suggest that the combination treatment could lead to improved clinical outcomes and survival in patients with HPV16+ R/M HNSCC CPS≥20 in the first line setting," said Mark Winderlich, PhD, Chief Research and Development Officer.

Dr. Ho commented, "As a medical oncologist who specializes in head and neck cancers, I am inspired by the results of the expanded eseba-vec/pembrolizumab Phase 2 study because of the potentially clinically meaningful response rate and encouraging PFS and OS data. In addition, the regimen has a manageable safety profile that ensures most patients can maintain treatment."

The late-breaking poster: *Eseba-vec (HB-200) plus pembrolizumab as first-line treatment of recurrent/metastatic HPV16-positive head and neck cancer: updated results in PD-L1 CPS ≥20 patients* will be available on November 11, 2024 on the HOOKIPA website on the "Scientific Publications" tab of the "Our Science" page.

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 Sciences, Inc. 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", "could", "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 and the potential of eseba-vec in combination with pembrolizumab to improve clinical outcomes and survival in patients. 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 (also known as HB200), 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 U.S. Securities and Exchange Commission (SEC), 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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