HOOKIPA Pharma Presents Positive Biomarker and Translational Data on HB-200 Monotherapy at Society for Immunotherapy of Cancer 2023

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- HB-200 monotherapy induced a robust increase in circulating tumor-specific CD8+ T cells in all evaluable Phase 1 patients with heavily pretreated HPV16+ head and neck cancer
- T cell responses were high quality, durable and suggest an association with clinical benefit based on disease control
- Totality of data reinforce the value proposition of HOOKIPA's arenaviral platform in driving T cell responses necessary for tumor control

NEW YORK and VIENNA, Austria, Nov. 03, 2023 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today announced updated Phase 1 clinical, biomarker and translational data on HB-200 as a monotherapy in heavily pretreated patients with recurrent/metastatic Human Papillomavirus 16-positive (HPV16+) head and neck cancer. The data show HB-200 monotherapy induced robust, high-quality and durable tumor-specific T cell responses, which showed a trend of clinical benefit measured by a 44 percent disease control rate in a difficult-to-treat patient population. The data were presented in a poster presentation (abstract #679) at the 2023 Society for Immunotherapy of Cancer (SITC) Annual Meeting.

"The data presented at SITC expand the body of evidence that HB-200 monotherapy has the ability to induce targeted T cells necessary for tumor control, which can translate into tumor shrinkage and encouraging clinical activity, especially in a difficult-to-treat population," said Joern Aldag, Chief Executive Officer at HOOKIPA. "As the data have matured, we have consistently delivered best-in-class T cell activation, and we continue to see the durability and functionality of tumor-specific T cells induced by HB-200. We look forward to sharing continued analyses of HB-200 across all arms of our trial in the future."

HB-200 Phase 1 biomarker results (NCT04180215)
As of March 31, 2023, 93 patients with HPV16+ recurrent/metastatic cancer were treated in the Phase 1 trial of HB-200. The goal of the trial was to determine the recommended dose for further evaluation in a Phase 2 study. All patients were heavily pretreated with a median of 3 prior therapies (range 1-11).

Biomarker and translational data results
HB-200 demonstrated a robust increase in tumor-specific CD8+ T cells in all evaluable patients with HPV16+ head and neck cancers. These results are from intracellular staining of blood samples from 35 patients across all four dose levels tested in Phase 1. An analysis of 29 of these patients—treated at either the recommended phase 2 dose (RP2D) or RP2D-1—showed that T cell increases were rapid and sustained for at least 8 months, and T cell function improved over time with repeat dosing. Quantity and quality of T cells are considered important for tumor infiltration and subsequent tumor control.

Importantly, paired biopsy data suggest an association between the induction of robust, high-quality, tumor-specific T cells after HB-200 treatment and best overall response. Paired biopsy data from 13 heavily pretreated patients show that patients who achieved disease control after treatment with HB-200 monotherapy generally had greater CD8+ T cell infiltration in tumors and the tumor microenvironment compared to patients with a best overall response of disease progression.

Additional Phase 1 data
The poster presentation also includes updated clinical activity and safety data from the Phase 1 study. As of the August 7 data cut-off, there were 27 evaluable patients with HPV16+ head and neck cancers who received HB-200 at the at RP2D or RP2D-1. Among these difficult-to-treat patients, HB-200 demonstrated a 44 percent disease control rate, with 1 confirmed partial response and 11 patients with stable disease. While overall survival is still maturing, median overall survival is approximately 13 months, with a median follow-up period of 6.3 months.

Phase 1 data also consistently demonstrate that HB-200 was generally well tolerated among 93 patients treated across all dose-level cohorts. Treatment-related adverse events grade 3 or above were reported in 11.8 percent of patients (n=11), while those leading to treatment discontinuation were reported in only 2.2 percent of patients (n=2). This favorable tolerability profile highlights the potential of HB-200—and arenaviral immunotherapies in general—to be safely combined with other immunotherapies.

Data presentation details:

- *Title:* Characterization of tumor-specific CD8+ T cell responses in patients with recurrent/metastatic HPV16-positive head and neck cancer receiving HB-200 monotherapy as second or later-line treatment in a Phase 1 study
- *Presenter:* Dr. Winston Wong, Head and Neck Oncologist at Memorial Sloan Kettering Cancer Center and a trial investigator
- *Abstract:* 679

About HB-200
HB-200 is HOOKIPA's lead oncology candidate engineered with the company's proprietary replicating arenaviral vector platform. It comprises two single-vector compounds with arenaviral backbones based on lymphocytic choriomeningitis virus and pichinde virus. Both express the same transgene encoding an E7E6 fusion protein derived from HPV16. HB-200 is an alternating 2-vector immunotherapy designed to further focus the immune response against the encoded antigen. HB-200 in combination with pembrolizumab received Fast Track Designation from the U.S. Food and Drug Administration for the treatment of 1st-line recurrent/metastatic HPV16+ head and neck cancers.

About the HB-200 trial (NCT04180215)
This Phase 1/2 clinical trial is an open-label trial evaluating HB-200 for the treatment of advanced HPV16+ cancers. Phase 1 assessed various dose levels, regimen, and modes of administration in a post-standard of care setting. Based on safety and tolerability, initial anti-tumor activity and T cell response data, HB-200 advanced for further development in Phase 2. The Phase 2 part of the trial is open label with primary endpoints of efficacy based on objective response and disease control rate as defined by RECIST 1.1 and iRECIST. The trial is evaluating HB-200 in combination with pembrolizumab in the 1st-line and 2nd-line plus settings, as well as HB-200 alone in the post-standard of care setting.

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, 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

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 public health crises, the impact of public health crises 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, 2023, which is available on the SEC'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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