HOOKIPA Pharma to Host Investor Call on HB-200 and Planned Path to Registration

April 10, 2024 at 7:01 AM EDT

- HOOKIPA announces alignment with FDA on pivotal trial design and protocol for HB-200 in combination with pembrolizumab
- HB-200 program receives Priority Medicines (PRIME) designation from EMA

NEW YORK and VIENNA, Austria, April 10, 2024 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, HOOKIPA or the Company), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today announced that members of HOOKIPA's Executive Team will host an investor call summarizing the Company's constructive regulatory interactions with the U.S. Food & Drug Administration (FDA) and the European Medicines Agency (EMA). HOOKIPA and the FDA have aligned on the design and protocol of the Company's upcoming pivotal Phase 2/3 clinical trial of HB-200 in combination with pembrolizumab. The investor call will be held on April 25, 2024, at 8:00 a.m. ET. Complete details and registration information are included below.

The Company also announced that EMA has granted PRIME designation for the investigational product HB-200 in combination with pembrolizumab for the treatment of patients with Human Papillomavirus 16-positive (HPV16+) recurrent/metastatic PD-L1 CPS ≥ 20 oropharyngeal squamous cell carcinoma (OPSCC) in the first line setting. PRIME designation is intended to expedite development and review of drug candidates, alone or in combination with other drugs. Eligibility and approval are based on preliminary clinical evidence and indicate that the drug candidate may offer substantial improvement over existing therapies.

"There is a significant unmet need for patients with OPSCC, and we are excited to share our pivotal Phase 2/3 trial design and demonstrate how we hope to provide better treatment options for these patients," said Joern Aldag, Chief Executive Officer of HOOKIPA. "We have had positive conversations with our regulators as we have outlined our clinical trial plans for HB-200. The FDA is aligned on our clinical trial design and protocol, while EMA's PRIME designation is additional validation for the potential of our HB-200 program. We look forward to sharing more details on our upcoming call."

Call Details:
HOOKIPA HB-200 Phase 2/3 Clinical Trial Update
Thursday, April 25, 2024, 8:00 a.m. ET
Webcast Registration
Dial-in Registration

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, KRAS-mutated cancers, and other unnamed indications. 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

This press release contains 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," "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 positively impact quality of life and alter the course of disease in the patients it seeks to treat and HOOKIPA's expectations regarding the design and protocol of the Company's upcoming pivotal Phase 2/3 clinical trial of HB-200 in combination with pembrolizumab. 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 risk that results of preclinical studies and clinical trials may not be predictive of future results in preclinical studies or 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 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 www.sec.gov and HOOKIPA's website at http://hookipapharma.com/. In addition, any forward-looking statements represent HOOKIPA's views only as of today and should not be relied upon as representing its views as of any subsequent date. HOOKIPA explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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 (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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