HOOKIPA Pharma Announces FDA Clearance of its Investigational New Drug Application for HB-700 for the Treatment of KRAS-Mutated Cancers

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NEW YORK and VIENNA, Austria, April 24, 2024 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today announced that the Company has received clearance from the U.S. Food and Drug Administration (FDA) for its Investigational New Drug (IND) application for HB-700, a novel arenaviral therapeutic vaccine for the treatment of KRAS-mutated cancers.

HOOKIPA's HB-700 program is designed to treat KRAS-mutated lung, colorectal, pancreatic and other cancers by targeting the five most prevalent KRAS mutations in these disease indications: G12D, G12V, G12R, G12C and G13D. This program has the potential to benefit more patients than single mutation inhibitors.

The IND submission achieves a final $10 million milestone payment from Roche. Effective April 25, 2024, the Company will regain full control of the associated intellectual property portfolio and have full collaboration and licensing rights for the HB-700 program. The Company will publish preclinical data in an abstract at the American Society for Clinical Oncology (ASCO) 2024 Annual Meeting.

"We are proud to have another IND cleared for a potentially powerful oncology program. Our HB-700 program targets five KRAS-mutations found in multiple cancer indications with a single product candidate," said Joern Aldag, Chief Executive Officer at HOOKIPA. "Importantly, the submission of the IND results in us receiving a final $10 million milestone payment. We continue to define our clinical development strategy which includes the possibility of collaboration or partnership for this program."

About KRAS-mutated cancers
KRAS is a gene that acts as an on/off switch for cell growth. When there is a mutation, or error, in the gene, cells can grow out of control. KRAS mutations are among the most common mutations that cause cancer. While KRAS-mutated, tumor-specific treatments exist, there remains an opportunity to target a broader range of KRAS-mutations simultaneously and thereby potentially help more people impacted by these cancers.

About HB-700
HB-700 is an investigational arenaviral immunotherapy designed to treat KRAS-mutated lung, colorectal, pancreatic and other cancers. HB-700 is a replicating 2-vector therapy that targets the most common KRAS mutations (G12D, G12V, G12R, G12C and G13D) and may benefit more patients than single mutation inhibitors.

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 undisclosed programs. 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. 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.

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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