HOOKIPA Announces FDA Clearance of its IND Application for HB-202/201 Clinical Trial to Treat HPV-Positive Cancers

June 17, 2020

NEW YORK and VIENNA, Austria, June 17, 2020 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK), a company developing a new class of immunotherapeutics targeting infectious diseases and cancers based on its proprietary arenavirus platform, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) Application for HB-202. This IND allows HOOKIPA to initiate an additional arm in its Phase 1/2 clinical trial for HB-201 (NCT04180215) for the treatment of Human Papillomavirus 16-positive (HPV 16^+) cancers. With the IND clearance of HB-202, HOOKIPA will be able to examine not only the safety and efficacy of HB-201 alone but also HB-201 in combination with HB-202 as an alternating two-vector therapy.

In preclinical studies, HOOKIPA has observed that the sequential administration of HB-202 and HB-201 induced tumor specific CD8 T cell levels that were greater than levels achieved after the repeat administration of either agent alone. The presence of tumor specific CD8 T cells are believed to be an indicator of anti-tumor activity.

HB-202 and HB-201 have been engineered from different viruses of the arenavirus family. Both constructs express the same non-oncogenic but highly antigenic, E7/E6 fusion protein derived from HPV16. In a mouse model of $HPV16^+$ tumors, single doses of HB-202 were shown to be similarly effective as single doses of HB-201. The combination of HB-202 and HB-201 in the same model has been shown to eliminate the tumor and prevent recurrence in a certain number of mice. In 2021, HOOKIPA expects to also combine HB-202/201 with an approved checkpoint inhibitor.

Joern Aldag, HOOKIPA's Chief Executive Officer, said: "This is a tremendous achievement for HOOKIPA's oncology platform and new applications of our arenavirus technologies. I commend the HOOKIPA team for its steadfast focus on the execution of this project under difficult, COVID-19 pandemic circumstances. We are eager to continue screening and treating patients at our HB-201 clinical sites as they are coming back online, and look forward to treating the first HB-202/201 patient later this year."

About Human Papillomavirus (HPV) - associated head and neck cancers
HPV is estimated to cause about 5% of the worldwide burden of cancers, including approximately 99% of cervical cancers, 25% to 60% of head and neck cancers, 70% of vaginal cancers, and 88% of anal cancers. The majority of these cancers are caused by the HPV serotype 16. Most infections with HPV 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 can potentially lead to cancer, since expression of these proteins leads to alterations in cell cycle control, which in turn predisposes these cells to becoming cancerous.

About HOOKIPA
HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical stage biopharmaceutical company developing a new class of immunotherapeutics targeting infectious diseases and cancers based on its proprietary arenavirus platform that is designed to reprogram the body's immune system.

HOOKIPA's proprietary arenavirus-based technologies, VaxWave ®, a replication-deficient viral vector, and TheraT®, a replication-attenuated viral vector, are designed to induce robust antigen specific $CD8^+$ T cells and pathogen-neutralizing antibodies. Both technologies are designed to allow for repeat administration to augment and refresh immune responses. TheraT® has the potential to induce $CD8^+$ T cell response levels previously not achieved by other immuno-therapy approaches. HOOKIPA's "off-the-shelf" viral vectors target dendritic cells in vivo to activate the immune system.

HOOKIPA's VaxWave ®-based prophylactic Cytomegalovirus (CMV) vaccine candidate is currently in a Phase 2 clinical trial in CMV-negative patients awaiting kidney transplantation from living CMV-positive donors as well as CMV-positive patients awaiting kidney transplantation from CMV-positive or -negative donors. To expand its infectious disease portfolio, HOOKIPA has entered into a collaboration and licensing agreement with Gilead Sciences, Inc. to jointly research and develop functional cures for HIV and chronic Hepatitis B infections.

In addition, HOOKIPA is building a proprietary immuno-oncology pipeline by targeting virally mediated cancer antigens, self-antigens and next-generation antigens. The TheraT® based lead oncology product candidates, HB-201 and HB-202, are in development for the treatment of Human Papilloma Virus 16-positive cancers. The Phase 1/2 clinical trial for HB-201 was initiated in December 2019. The HB-202 IND application was cleared by the FDA in June 2020.

Find out more about HOOKIPA online at www.hookipapharma.com.

HOOKIPA 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 the coronavirus (COVID-19) disease outbreak or similar public health crises, the impact of COVID-19 on the enrollment of patients and timing of clinical results for HB-101 and other programs, and

other matters that could affect the sufficiency of existing cash to fund operations and HOOKIPA's ability to achieve the milestones under the agreement with Gilead. 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 March 31, 2020 which is available on the Security and Exchange Commission'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.

For further information, please contact:

Media
Nina Waibel
Senior Director - Communications
nina.waibel@hookipapharma.com

Investors
Matt Beck
Executive Director - Investor Relations
matthew.beck@hookipapharma.com

Media enquiries
Instinctif Partners
hookipa@instinctif.com
+44 (0)20 7457 2020