



HOOKIPA Pharma's LCMV-based Immunotherapy for HPV16+ Cancers Demonstrates High Immunogenicity, According to Peer Reviewed Article

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Peer reviewed article in *Oncolmmunology* demonstrates promising preclinical results for the novel cancer therapy targeting Human Papillomavirus 16 (HPV16) E6/E7

HPV is estimated to cause approximately 5% of the worldwide cancer burden

NEW YORK and VIENNA, Austria, Sept. 16, 2020 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics targeting infectious diseases and cancers based on its proprietary arenavirus platform, today announced a publication in the peer reviewed, open access journal *Oncolmmunology* of a paper on HB-201, an arenavirus vector-based immunotherapy for Human Papillomavirus 16-positive (HPV16+) cancers currently in clinical trials.

The paper shows that systemically administered HB-201 leads to:

- Dose-dependent induction of a robust, systemic cytotoxic T cell response directed against HPV16 proteins;
- Tumor infiltration of HPV16 specific cytotoxic T cells; and
- Significantly delayed tumor growth or complete tumor clearance accompanied with prolonged survival.

Mice that have cleared tumors post-HB-201 administration developed long-term protection, as demonstrated by the rejection of re-administered tumors. Furthermore, the combination of HB-201 with a checkpoint inhibitor (a-PD-1) increased the anti-tumor efficacy, with more than 77% of treated mice clearing established tumors.

HB-201 is one of HOOKIPA's lead oncology candidates. It targets HPV16 E6/E7 and is based on the Company's replicating LCMV (TheraT[®]) arenaviral vector platform. It is currently in Phase 1/2 clinical trials (NCT04180215) for HPV16+ cancers alone and in combination with an approved checkpoint inhibitor.

"HPV-associated cancers, especially head and neck cancers, remain a significant health concern, as no curative therapies are currently available. We are very pleased that these results suggest that the HB-201 program can be a promising therapy for HPV+ cancers," said Igor Matushansky, MD, PhD, HOOKIPA's Chief Medical Officer and Global Head of Research and Development.

Human Papillomavirus, or HPV, is estimated to cause about 5% of the worldwide burden of cancers. This includes approximately 99% of cases in cervical, up to 60% of head and neck, 70% of vaginal 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 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. The publication, "Live-attenuated lymphocytic choriomeningitis virus-based vaccines for active immunotherapy of HPV16-positive cancer", is available online in [Oncolmmunology](#).

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 reprograms the body's immune system.

HOOKIPA's proprietary arenavirus-based technologies, non-replicating (VaxWave[®]) and replicating (TheraT[®]), induce robust antigen-specific CD8⁺ T cells and pathogen-neutralizing antibodies. HOOKIPA's "off-the-shelf" viral vectors target antigen presenting cells in vivo to activate the immune system. Both technologies enable repeat administration to augment and refresh immune responses. As a monotherapy, our replicating arenavirus technology has the potential to induce CD8⁺ T cell response levels previously not achieved by other immuno-therapy approaches.

HOOKIPA's non-replicating prophylactic Cytomegalovirus (CMV) vaccine candidate is currently in a Phase 2 clinical trial for patients awaiting kidney transplantation. To expand its infectious disease portfolio, HOOKIPA entered into a collaboration and licensing agreement with Gilead Sciences, Inc. to research arenavirus-based 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 lead replicating arenavirus 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 June 30, 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.

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