



HOOKIPA Pharma announces publication of preclinical data of hepatitis B virus (HBV) therapeutic vaccine developed in collaboration with Gilead Sciences

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- HB-400, a novel arenaviral therapeutic vaccine, generates robust T cell responses specific to hepatitis B virus with high antibody levels in a preclinical setting
- A Gilead-led Phase 1 clinical trial to evaluate the safety and tolerability of HB-400 in humans is ongoing
- Peer-reviewed data published in *The Journal of Infectious Diseases*

NEW YORK and VIENNA, Austria, Oct. 18, 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 that *The Journal of Infectious Diseases* has [published preclinical data](#) on HB-400, an investigational therapeutic vaccine for chronic hepatitis B developed in collaboration with Gilead Sciences, Inc. (HB-400 is also referenced as GS-2829 and GS-6779.) The published data highlight HB-400 as a potential component in achieving a functional cure for chronic hepatitis B.

HB-400 is an alternating, 2-vector non-replicating arenaviral therapeutic vaccine for the treatment of chronic hepatitis B. It uses the Lymphocytic Choriomeningitis Virus and Pichinde Virus as arenaviral backbones, with each expressing three highly conserved hepatitis B virus antigens. HOOKIPA's alternating 2-vector approach is designed to optimize and focus the immune response against the target antigens. HB-400 is one of two independent development programs in HOOKIPA's collaboration and license agreement with Gilead Sciences, Inc.

The preclinical data published in *The Journal of Infectious Diseases* show that:

- Immunization with HB-400 induced robust, hepatitis B-specific T cell and antibody responses in non-human primates; and
- HB-400 vaccination cleared detectable serum hepatitis B antigens in a mouse model for chronic HBV infection, with near elimination of detectable hepatitis B antigen positive hepatocytes in the liver.

A Gilead-led Phase 1 clinical trial ([NCT05770895](#)) is currently underway to evaluate the safety and tolerability of repeated doses of HB-400 in healthy participants and individuals with chronic hepatitis B. Gilead is solely responsible for further development and commercialization of HB-400.

"The lack of curative therapies for chronic hepatitis B infection is a significant barrier to addressing the global burden of disease," said Joern Aldag, Chief Executive Officer at HOOKIPA. "We're pleased to see our novel arenaviral platform technology featured in this reputable journal, and we look forward to seeing how clinical results of Gilead's ongoing Phase 1 trial of HB-400 may further support its potential as a component of a functional cure regimen for hepatitis B."

About Hepatitis B

Hepatitis B virus is the leading cause of liver cancer, as well as a major cause of cirrhosis, liver failure and death globally. It is estimated that nearly 300 million people live with chronic hepatitis B infection, and there are 1.5 million new infections annually.

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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