



HOOKIPA to present Phase 1 safety, tolerability and preliminary anti-tumor activity data on HB-201 and HB-202 for the treatment of advanced HPV16+ cancers at ASCO

May 20, 2021

- Data from first-in-human Phase 1 study of arenaviral therapeutics, including first data on HB-201/HB-202 alternating 2-vector therapy and expanded data on HB-201, to be featured as oral presentation
- Early dose escalation study will highlight antigen-specific CD8+ T cell data, anti-tumor activity and overall tolerability of HB-201 and HB-201/HB-202
- HOOKIPA's arenaviral platform poised to deliver a new class of potent immunotherapeutics in cancer treatment

NEW YORK and VIENNA, Austria, May 20, 2021 (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 first data on HB-201/HB-202 alternating 2-vector therapy and expanded data on HB-201 will be featured as an oral presentation at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place June 4-8, 2021. HB-201 and HB-202, novel arenaviral therapeutics and HOOKIPA's lead oncology candidates, are being evaluated in an ongoing, first-in-human Phase 1/2 clinical trial (NCT04180215) for the treatment of advanced Human Papillomavirus 16-positive (HPV16+) cancers. The oral presentation will highlight safety, tolerability, immunogenicity and preliminary anti-tumor activity data from about 40 evaluable patients as of March 31.

"We're thrilled that our novel arenaviral immunotherapeutics for HPV16+ cancers, HB-201 and HB-202, are being featured at ASCO. We believe our selection as an oral presentation speaks to the strength of the data and the potential of our arenaviral therapeutics to redefine success in cancer treatment," said Joern Aldag, Chief Executive Officer at HOOKIPA. "Following the preliminary HB-201 data shared in December and our translational data presentation at AACR, we're excited to share expanded data from more patients and additional doses, including first results on HB-201/HB-202 alternating 2-vector therapy, as well as detailed safety, tolerability, translational data and preliminary anti-tumor activity results. We believe these data are very encouraging for such an early-stage program."

The abstract, outlined below, is available on the [ASCO website](#):

- First report of the safety/tolerability and preliminary anti-tumor activity of HB-201 and HB-202, an arenavirus-based cancer immunotherapy, in patients with HPV16+ cancers
 - Abstract # 2502, oral presentation
 - Monday, June 7, 3:00 - 6:00pm EDT
 - Presenter: Alan L. Ho, M.D., Ph.D., Memorial Sloan Kettering Cancer Center

Investor Event

At the conclusion of the planned ASCO conference events on June 7, 2021, HOOKIPA will host a live webcast event "Advancing Novel Immunotherapies: HOOKIPA ASCO Data Review" at 6:30 p.m. EDT. Joern Aldag, Chief Executive Officer, and Igor Matushansky, Chief Medical Officer, will provide an overview of the ASCO oral data and future plans for HOOKIPA's oncology program. Dmitry Zamarin, M.D., Ph.D., Translational Research Director in Gynecologic Medical Oncology at Memorial Sloan Kettering Cancer Center and co-investigator in this study, will also offer commentary on the significance and implications of the translational findings. The webcast and the presentation will be available within the Investors & Media section of HOOKIPA's website at <https://ir.hookipapharma.com/events>. To participate in a live Q&A at the end of the prepared remarks, please register [here](#). An archived replay will be accessible for 30 days following the event.

About HB-201/HB-202

HB-201 and HB-202 are HOOKIPA's lead oncology candidates engineered with the company's proprietary replicating arenaviral vector platform. Each single-vector compound uses a different arenavirus backbone (LCMV for HB-201 and PICV for HB-202), while expressing the same antigen, an E7E6 fusion protein derived from HPV16. In pre-clinical studies, alternating administration of HB-201 and HB-202 resulted in a ten-fold increase in immune response and better disease control than either compound alone.

About the trial

This Phase 1/2 clinical trial is an open-label trial exploring different dose levels and dosing schedules in individuals with treatment-refractory HPV16+ cancers who progressed on standard of care, including check point inhibitors. The primary endpoint of the Phase 1 is a recommended Phase 2 dose based on safety and tolerability. Secondary endpoints include anti-tumor activity as defined by RECIST 1.1 and immunogenicity.

The trial is evaluating HB-201 as a single-vector monotherapy, as an alternating two-vector therapy with HB-202, and in combination with a PD-1 inhibitor. Participants receive HB-201/HB-202 intravenously or, for patients with an accessible lesion, the first dose can be delivered via intratumoral injection followed by intravenous dosing. Dosing every three weeks and every two weeks is being explored, as well as different dose levels.

About Human Papillomavirus

Human Papillomavirus, or HPV, is estimated to cause about 5 percent of the worldwide burden of cancers. This includes approximately 99 percent of cases in cervical, up to 60 percent of head and neck, 70 percent of vaginal and 88 percent 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.

About HOOKIPA

HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical-stage biopharmaceutical company focused on developing novel immunotherapies that mobilize and amplify targeted T cells and antibodies, the body's natural infection killers, to fight or prevent serious disease.

HOOKIPA is developing a broad pipeline of potential first-in-class arenaviral immunotherapies in oncology and infectious disease. We are leveraging our proprietary, flexible platform to engineer arenaviral therapeutics that induce robust antigen-specific CD8+ T cells and pathogen-neutralizing antibodies to a broad range of self and non-self antigens, including viral antigens, tumor-associated antigens and neoantigens. Our immunotherapies are designed to use either non-replicating or replicating viral vectors based on the target disease, with the potential to induce CD8+ T cell response levels previously not achieved by other immunotherapy approaches.

HOOKIPA's pipeline include three ongoing clinical trials in Human Papilloma Virus 16-positive cancers and Cytomegalovirus, as well as preclinical research in prostate cancer, HIV and Hepatitis B. The latter two are in collaboration with Gilead Sciences, Inc.

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 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 annual report on Form 10-Q for the financial year ended March 31, 2021 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