HOOKIPA Doses First Patient in a Phase 2 Clinical Trial of Prophylactic Vaccine Candidate HB-101 against Cytomegalovirus

New York, US and Vienna, Austria, December 17, 2018 - HOOKIPA Pharma Inc. ("HOOKIPA"), a company developing a new class of immunotherapies targeting infectious diseases and cancers based on its proprietary arenavirus platform, today announced that it has dosed the first patient in its randomized, placebo-controlled, Phase 2 clinical trial to evaluate the safety and efficacy of HB-101, a bivalent prophylactic vaccine for cytomegalovirus (CMV), in CMV-negative patients awaiting kidney transplantation from living CMV-positive donors.

HB-101 is based on HOOKIPA´s non-replicating Vaxwave®* technology and expresses two human CMV antigens, the tegument protein pp65, which induces CMV-specific T cells and a truncated isoform of the fusion protein gB, which elicits the production of CMV-neutralizing antibodies.

The clinical trial will be conducted at approximately 35 centers worldwide and will include a total of 150 male and female patients, aged 18 years or older. The patients will be randomized to receive either HB-101 or placebo at a ratio of 2:1 prior to kidney transplantation. Patients enrolled will be scheduled to have a living donor kidney transplantation after receiving two to three doses of HB-101.

Joern Aldag, HOOKIPA's Chief Executive Officer said: "We are extremely pleased to dose our first patient in our global Phase 2, multicenter trial of our HB-101 candidate to develop a potentially life-saving therapy for patients undergoing solid organ transplantation. HB-101 is the first subunit vaccine designed to elicit robust CMV-specific CD8+ T cell responses and CMV-neutralizing antibodies to enter Phase 2 clinical trials. This trial, together with our planned proof-of-concept trial in cancer immunotherapy, is a big step towards validating our arenavirus technology platform."

Dr. Igor Matushansky, HOOKIPA's Global Head of Research and Development added: "This trial aims to assess the safety and immunogenicity of HB-101 and assess its efficacy compared to that of placebo in mitigating CMV viremia and in decreasing the use of anti-viral drugs to treat CMV viremia."

In December 2016, HOOKIPA completed the active phase of a randomized, placebo controlled double blinded dose-escalating Phase 1 trial in healthy volunteers evaluating the safety and immunogenicity of HB-101. In addition to demonstrating that HB-101 was well-tolerated, all three dose-groups receiving the candidate vaccine showed robust and statistically significant cellular and humoral immune responses when compared to placebo[1].

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[1] HOOKIPA Pharma Inc. (2017). Hookipa Biotech presents positive data from Phase 1 first-in-human trial of vaccine against cytomegalovirus [Press release]. Available at: https://www.hookipapharma.com/investors/press-releases/hookipa-biotech-presents-positive-data-from-phase-1-first-in-human-trial-of-vaccine-against-cytomega/ (Accessed: December 12, 2018).

About HOOKIPA
HOOKIPA Pharma Inc. 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.

Our 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, Vaxwave® and TheraT®, are designed to allow for repeat administration while maintaining an immune response. TheraT® has the potential to induce CD8+ T cell response levels previously not achieved by other published immuno-therapy approaches. Our "off-the-shelf" viral vectors target dendritic cells in vivo to activate the immune system.

We have successfully completed a Phase 1 trial of a Vaxwave®-based prophylactic vaccine to protect against cytomegalovirus infection. We have initiated enrollment for a Phase 2 trial in cytomegalovirus-negative patients awaiting kidney transplantation from cytomegalovirus-positive donors. To expand our infectious disease portfolio, we have entered into a collaboration and licensing agreement with Gilead Sciences, Inc. to jointly research and develop functional cures for HIV and Hepatitis B infections. We are building a proprietary immuno-oncology pipeline by targeting virally mediated cancer antigens, self-antigens and next-generation antigens.

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

*Registered in Europe; Pending in the US.

About Cytomegalovirus
Cytomegalovirus (CMV) is a common opportunistic pathogen in patients who have undergone solid organ transplantation. The majority of recipients who are CMV-negative acquire a primary infection from a CMV-positive donor organ. Viral replication in the recipient results in the virus entering the bloodstream, which can progress to end-organ disease. Active CMV infection correlates with a higher risk of other infections, post-transplant lymphoma, organ rejection, and overall morbidity and mortality. To prevent CMV infection and disease, transplant centers routinely employ either a prophylactic or preemptive strategy using ganciclovir or its oral prodrug valganciclovir. The prophylactic approach is effective in preventing end-organ disease while on anti-viral prophylaxis, but patients remain at significant risk of developing viremia and late-onset disease once prophylaxis treatment ceases. Late-onset disease can also be caused by strains of CMV that have developed resistance to ganciclovir, which then requires the use of more toxic second-line therapies. The preemptive approach requires close monitoring of CMV DNAemia via polymerase chain reaction (and, as a result, is often limited by practical considerations, given the need for frequent blood draws).

Issued for and on behalf of HOOKIPA Pharma Inc. by Instinctif Partners. For further information please contact:

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