Hookipa Biotech presents positive data from Phase 1 first-in-human trial of vaccine against cytomegalovirus

- Vaccine was safe and elicited a potent immune response
- Cytomegalovirus (CMV) infection is the leading cause of birth defects in the developed world, occurring in 1 – 2.5 % of all newborns and conferring risk of deafness and impaired intellectual development

Vienna, Austria, 4 May 2017 - Hookipa Biotech AG, a company pioneering a new class of immunotherapies for oncology and infectious diseases, today presented the un-blinded safety and immunogenicity data through month four from the Company's phase 1 first-in-human trial of HB-101, a vaccine against human cytomegalovirus (CMV), based on Hookipa's proprietary Vaxwave® platform. The data was presented at the CMV 2017 Conference (www.cmv2017.nl/home) in Leeuwenhorst, The Netherlands. Further follow-up safety and immunogenicity results through month 12 of the study are expected in November 2017.

Joern Aldag, Hookipa's CEO, said; "These clinical data show that Hookipa's Vaxwave® technology and, specifically, the bivalent CMV vaccine candidate HB-101 are safe and immunogenic. We are pleased to note that the vaccine elicited potently CMV-neutralizing antibodies and high frequencies of CMV-specific CD8+ T cells with as few as two doses of the vaccine. These results provide confidence that Hookipa can establish HB-101 as a best-in class CMV development program. Our team around Dr. Anders Lilja did an amazing job running this program and we are actively gearing up for Phase 2 efforts."

HB-101 is a bivalent CMV vaccine candidate based on Vaxwave® vectors expressing two human CMV antigens, the tegument protein pp65 and a truncated isoform of the fusion protein gB. The safety and immunogenicity of HB-101 were evaluated in a randomized, placebo-controlled, double-blind phase I dose-escalating trial (NCT02798692). Three cohorts of 18 subjects per cohort were enrolled. In each cohort, 14 subjects received a high, medium or low dose of the vaccine, respectively, and four received placebo. Vaccine and placebo were administered on day zero, and one and three months after first injection. Safety and reactogenicity data were collected and reviewed by an independent data and safety monitoring board. Immunogenicity readouts included humoral and cellular responses against gB, cellular responses against pp65, as well as humoral and cellular responses against the vector.

Over all three dose groups, 98% of the subjects who received vaccine, and zero percent of the subjects who received placebo, showed detectable CMV-neutralizing antibody titers after three doses (93% of the subjects in the lowest dose group and 100% of the subjects in the medium and high dose groups). In the highest dose group, 100% seroconversion was already observed after the second vaccination and 79% of the subjects who received vaccine in this group, showed titers within the range of seropositive controls. Similarly, all three dose groups of the

vaccine induced robust and statistically significant cellular immune responses when compared to placebo. When looking specifically at pp65-specific CD8+ T cells, a key biomarker for cellular immunity against cytomegalovirus, the medium and high dose groups induced clinically and statistically significant responses when compared to placebo.

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About Hookipa Biotech
Hookipa Biotech is developing next-generation immunotherapies for infectious diseases and cancer using novel proprietary arenavirus vector platforms. By end April 2017, Hookipa has raised EUR 15 million in non-dilutive funds and EUR 37 million equity investment from internationally renowned venture capital investors including Sofinnova Partners, Forbion Capital Partners, Boehringer Ingelheim Venture Fund, Takeda Ventures and BioMedPartners. Additional information on Hookipa is available at www.hookipabiotech.com.

About Vaxwave®
Hookipa´s Vaxwave® technology presents a completely new replication-defective viral vector platform designed to overcome the limitations of current technologies. Vaxwave® is based on lymphocytic choriomeningitis virus (LCMV) and in this vector the gene encoding the LCMV envelope protein, normally responsible for virus entry into target cells, has been deleted and replaced with a target gene of interest. The resulting vectors infect target cells and stimulate very potent and long-lasting immune responses, however they can no longer replicate and are therefore non-pathogenic and inherently safe.

About Cytomegalovirus
Cytomegalovirus (CMV) is a ubiquitous human pathogen that is the leading cause of congenital infection worldwide, occurring in 1 – 2.5 % of all newborns in the developed world. Newborns infected with CMV are at risk of deafness and impaired intellectual development. Cytomegalovirus is also a severe pathogen for transplant recipients causing end organ diseases. The development of CMV vaccines is a widely acknowledged public health priority.

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