Hookipa Biotech Initiates First-in-Human Study of Cytomegalovirus Vaccine

Vienna, Austria, 20 July 2016 - Hookipa Biotech AG, a company pioneering a new class of immunotherapies and vaccines, based on its proprietary viral vector platform Vaxwave®, today announces the start of a first-in-human study to evaluate the safety and immunogenicity of its vaccine candidate, HB-101, against human cytomegalovirus (HCMV). Part of the herpes family of viruses, HCMV is one of the most significant viral pathogens during pregnancy and in immunocompromised patients.

HB-101 is a bivalent vaccine containing two recombinant, replication-deficient lymphocytic choriomeningitis virus (rLCMV) vectors, one expressing the pp65 protein and one a truncated gB protein of cytomegalovirus. HB-101 is based on Hookipa's viral vector platform, Vaxwave®, which can be applied repeatedly to boost the immune system and stimulate both potent B-cell and CD8+ T-cell immune responses.

The randomized, placebo-controlled Phase I study will recruit a total of 54 healthy, male and female subjects, negative for HCMV, at the Center for Vaccinology, Ghent University Hospital (CEVAC). Enrolled as three successive cohorts of 18 volunteers, each cohort will receive either a low dose, a middle dose or a high dose of the vaccine (n=14 volunteers), or placebo (n=4). The vaccine will be administered intra-muscularly at day 0, month 1 and month 3. The trial will run for 15 months, with interim immunogenicity data expected in Q4 2016 and Q1 2017.

The primary endpoint of the study is safety. Safety data from each cohort will be reviewed by an independent group of experts from the Data and Safety Monitoring Board (DSMB), before dosing of the next cohort begins. Secondary endpoints are humoral and cellular immune responses induced by the vaccine. The first cohort has already received the low dose. Enrolment of the second cohort will start shortly.

Jörn Aldag, CEO of Hookipa, said "Development of a CMV vaccine has been ranked at the highest priority by the US Institute of Medicine. Obtaining approval for the first-in-human study of our HB-101 vaccine, and the commencement of the clinical trial is an important milestone for Hookipa, and provides validation of our Vaxwave viral vector platform. The trial follows strong pre-clinical data for HB-101 and we are confident that this will be reflected in the outcome of the study. "

Further details of the trial can be found online at ClinicalTrials.gov:
https://clinicaltrials.gov/ct2/show/NCT02798692?term=hookipa&rank=1

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About HB-101
Hookipa's lead investigational product candidate, HB-101, is a bivalent vaccine for the prevention of CMV based on Vaxwave® vectors expressing an optimised form of gB antigen and pp65 antigen.

About HCMV
Human cytomegalovirus (HCMV) is one of the most significant viral pathogens during pregnancy and in immunocompromised patients. HCMVis a ubiquitous beta-herpesvirus that is the leading cause of congenital infection worldwide, occurring in 1 – 2.5 % of all newborns in the developed world.

Newborns infected with HCMV are at risk of deafness, impaired intellectual development, and death. Antiviral prophylactic strategies are limited by toxicities, drug–drug interactions and development of antiviral resistance. A safe and protective vaccine against HCMV is highly desirable in view of the potential positive impact on HCMV-associated morbidity and mortality as well as healthcare costs. Development of a CMV vaccine has been ranked at the highest priority by the US Institute of Medicine.

About Hookipa Biotech

Hookipa Biotech is a company developing next-generation cancer immune-therapeutics and vaccines using novel, proprietary arenavirus vector platforms. Hookipa has raised € 11 million in non-dilutive funds and € 27 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 broadly enabling Vaxwave® technology platform is based on replication-defective lymphocytic choriomeningitis virus vectors that allow induction of strong humoral and cellular immune responses to viral, bacterial and tumor antigens. Strong therapeutic efficacy data have been generated in various pre-clinical models. One of the most distinguishing features of this vector platform is its homologous prime-boosting capacity, allowing Vaxwave® based immunotherapy to be applied repeatedly to boost the immune system and generate potent CD8+ T cell responses against targeted antigens. Vaxwave® is patent-protected by issued patents and patent applications worldwide.

Issued for and on behalf Hookipa Biotech AG by Instinctif Partners. For further information please contact:	
At the Company Jörn Aldag Chief Executive Officer Hookipa Biotech AG Office@Hookipabiotech.com	**Media enquiries** Sue Charles/ Daniel Gooch/ Alex Bannister Instinctif Partners hookipa@instinctif.com +44 (0) 20 7866 7905