Hookipa Biotech Announces Publication in Clinical and Vaccine Immunology Highlighting Vaxwave® as an Effective Viral Vector for Vaccination against Congenital Cytomegalovirus Infections

- Cytomegalovirus (CMV) infection is the leading cause of congenital infection worldwide, occurring in 1 – 2.5 % of all new-borns in the developed world, conferring risk of deafness, impaired intellectual development, and death
- Publication in *Clinical and Vaccine Immunology* demonstrates that vaccination with Hookipa's Vaxwave® novel bivalent vaccine expressing human CMV glycoproteins gB & pp65 is protective against congenital guinea pig CMV infection
- Mortality rate of 8% for those vaccinated with Hookipa's HB-101 bivalent Vaxwave® vaccine versus 93% in control group

Vienna, Austria, 9 January 2017 - Hookipa Biotech AG, an immunotherapy company developing next-generation cancer immune therapeutics and vaccines based on the Company´s proprietary arenavirus vector platforms, announces publication in the January 2017 issue of the peer-reviewed journal *Clinical and Vaccine Immunology*[1], of data confirming the potential of Hookipa's HB-101 Vaxwave® to provide an effective and novel bivalent vaccine that confers better protection against congenital (maternal transmission) cytomegalovirus infection in the gold standard animal model, the guinea pig model, in reducing pup mortality.

The *Clinical and Vaccine Immunology* publication is based on collaborative work between Hookipa Biotech and a leading US Institution, the Centre for Infectious Diseases and Microbiology Translational Research and Department of Pediatrics, University of Minnesota Medical School, USA. The work was headed by Dr Mark R. Schleiss, with the research being supported by grants from the US National Institutes of Health (NIH), the Austrian Research Promotion agency, and funding from Hookipa Biotech. An accompanying editorial[2] by Professor David I. Bernstein highlights the value of Arenaviruses in general in eliciting strong and long lasting humoral and cellular immune responses.

The research by Schleiss et al. shows that a non-replicating lymphocytic choriomeningitis virus (rLCMV) vectored vaccine expressing a novel bivalent combination of human cytomegalovirus glycoproteins, a cytoplasmic tail-deleted gB [gB(dCt)] (a neutralizing antibody target) and pp65 (a T cell target) is more effective in the guinea pig model of congenital cytomegalovirus infection at inducing B & T cells, and improving pup survival, than a monovalent vaccine.

"Cytomegalovirus is one of the most significant viral pathogens during pregnancy. By preventing congenital human CMV infection, a preconception vaccine could provide a highly cost-effective public health advance," said Dr Schleiss. "Our study, in a guinea pig CMV congenital infection model, showed

[1] Additive Protection against Congenital CMV Conferred by Combined gB/pp65 Vaccination using a Lymphocytic Choriomeningitis Virus (LCMV) Vector by Mark R. Schleiss et al., posted online on 26 October 2016, doi: 10.1128/CVI.00300-16. Published in full in January 2017.

[2] Congenital Cytomegalovirus: A Now Problem, No, Really Now, by David I. Bernstein, posted online on 26 October 2016, http://cvi.asm.org/content/early/2016/10/20/CVI.00491-16.abstract

improved guinea pig pup survival, from a mortality of 93% in the control group, to 8% in the bivalent population. These are very encouraging data."

To measure protection against mortality and disease following rLCMV-vectored vaccination, the researchers initially evaluated the immunogenicity of gB and pp65 in mice and rabbits. The researchers then went on to analyse 63 litters of guinea pigs, yielding over 200 pups, across five groups covering both monovalent vaccine groups, gB(dCT) and pp65, the bivalent combination, and two control groups.

"The collaborative work published in the highly regarded journal *Clinical and Vaccine Immunology* adds significant validation for our Vaxwave® platform, further highlighting its versatility, and supporting the development of our lead vaccine candidate, the novel bivalent HB-101, to prevent CMV infections," stated Joern Aldag, Chief Executive Officer of Hookipa Biotech. "With strong pre-clinical safety and efficacy data obtained for an optimized Vaxwave® CMV vaccine candidate we are looking forward to the readout of preliminary HB-101 data from a Phase 1 dose escalation trial in Q1 2017. Of note, our arenavirus based expression technology does not elicit vector-neutralizing antibody responses, allowing for administration of homologous booster vaccination."

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About Hookipa Biotech
Hookipa Biotech is an immunotherapy company developing next-generation prophylactic vaccines and cancer immune therapeutics based on the company´s proprietary arenavirus vector platforms, Vaxwave® and TheraT®. Hookipa has raised EUR 11.5 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 broadly enabling Vaxwave® technology platform allows induction of strong humoral and cellular immune responses to viral, bacterial and tumor antigens, and to bind and neutralize pathogens and to recognize and eliminate pathogen-infected cells. The platform is one of the most promising new technologies for next generation immunotherapy & vaccines due to its ability to stimulate both potent B-cell and CD8+ T-cell immune responses. One of the most distinguishing features of this vector platform is its homologous prime-boosting capacity, and Vaxwave® based immunotherapy can 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.

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 Cytomegalovirus
Cytomegalovirus (CMV) is 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 CMV are at risk of deafness, impaired intellectual development, and death. Cytomegalovirus is also a severe pathogen for transplant recipients causing end organ diseases. The development of CMV vaccines is a high priority, widely known in the medical community and industry.

About the NIH
The National Institutes of Health (NIH), is a medical research agency that is part of the U.S. Department of Health and Human Services. The NIH is the largest public funder of biomedical research in the world, investing more than $32 billion a year to enhance life, and reduce illness and disability.

About the Centre for Infectious Diseases and Microbiology Translational Research (CIDMTR)
CIDMTR was founded in 2006 at the University of Minnesota, when Dr. Schleiss was recruited to become the centre co-director. He also is the Director of the Division of Pediatric Infectious Diseases and Immunology at the University of Minnesota Medical School (https://www.pediatrics.umn.edu/bio/infectious-diseases-and-immuno/mark-schleiss). CIDMTR engages in translational infectious diseases research of global importance, particularly as it impacts the health of children. The Schleiss laboratory has active programmes in both preclinical evaluation of CMV vaccines, and in new-born screening for congenital CMV infection in Minnesota (http://www.cmvscreening.org/).

Issued for and on behalf Hookipa Biotech AG by Instinctif Partners.

For further information please contact:

At the Company	**Media enquiries**
Joern Aldag Chief Executive Officer Hookipa Biotech AG Helmut-Qualtinger-Gasse 2 1030 Vienna Austria Office@Hookipabiotech.com	Sue Charles/Daniel Gooch Instinctif Partners (in London) +44 (0)20 7866 7905 hookipa@instinctif.com