



Mucosis Secures €3.7M from Wellcome Trust to Fund Clinical Trials of its Respiratory Syncytial Virus Vaccine in Partnership with Imperial College London

Funding will enable new intranasal vaccine SynGEM[®] to be tested in phase I and IIa human clinical trials

Groningen, the Netherlands, January 20, 2016 – Mucosis B.V., a clinical stage biotechnology company using a proprietary technology platform to develop next-generation and needle-free human vaccines for infectious diseases, today announced that it has secured a €3.7 million (£2.77 million) translational fund award from the Wellcome Trust to progress its proprietary intranasal Respiratory Syncytial Virus (RSV) vaccine, SynGEM[®], into phase I and IIa human clinical trials. The trials will be led by world-leading expert in RSV and member of Mucosis's Scientific Advisory Board, Professor Peter Openshaw FRCP FMedSci and Dr. Christopher Chiu of the National Heart & Lung Institute, Imperial College London.

Professor Peter Openshaw, Professor of Experimental Medicine at Imperial College London and Honorary Physician in the Department of Respiratory Medicine at the St Mary's Campus of the Imperial College NHS Trust welcomed the news, commenting "RSV is one of the few major infectious diseases for which there is still no vaccine. Contracting under Mucosis, this funding will enable us to analyse the immune responses generated by SynGEM[®] and increase our understanding of protective immunity in the respiratory system."

RSV is a major cause of severe lower respiratory tract infections such as pneumonia and represents a large unmet medical need. According to the WHO¹, the global RSV disease burden is estimated at 64 million cases and 160,000 deaths every year, as well as associated increased allergy and asthma rates. While RSV infects all age groups, the most severe cases occur in the elderly, patients with chronic lung disease, individuals with impaired immunity and very young infants.

The Wellcome Trust translational fund award will be used to fund a Phase I dose-finding and safety study, followed by a novel phase II challenge study to assess the efficacy of the SynGEM[®] vaccine against controlled infection with RSV.

SynGEM[®] is based on Mucosis's proprietary bacterium-like-particle (BLP) based Mimopath[®] platform, which allows the vaccine to be delivered via mucosal routes, primarily the nose, making the vaccine needle-free. The BLPs carry a unique stable prefusion form of the F vaccine antigen, which has been shown to raise more potent neutralizing antibodies against RSV compared with the postfusion F antigen. SynGEM[®] is able to elicit the production of Immunoglobulin A (IgA) antibodies more effectively than intramuscular injections because a higher concentration of IgA is produced in mucosal linings than all other types of antibody combined in the blood. There is evidence that IgA plays an important role in the defence against RSV in humans, making SynGEM[®] more effective as a vaccine against RSV.

"We are delighted that the Wellcome Trust has recognized the potential of SynGEM[®] to address the global health challenge of combatting RSV infections by contributing funds to this program," said Tom Johnston, CEO of Mucosis. "SynGEM[®] has performed exceptionally well in pre-clinical trials and we are pleased to have secured additional funding to more quickly advance a needle-free vaccine for RSV into the clinic."

¹ WHO. 2009. Initiative for Vaccine Research (IVR). Respiratory syncytial virus and parainfluenza viruses. Disease burden. WHO, Geneva, Switzerland.

Mucosis also secured €2m additional equity financing from its current investors. These funds will enable Mucosis to complete GMP manufacturing, and to advance the Investigational Medicinal Product Dossier (IMPD) submission materials for clinical trial approval in 2016. Together with an earlier secured €5m from the Netherlands Enterprise Agency (RVO) for the development of SynGEM[®], Mucosis is now in an excellent position to advance its clinical program.

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Note for Editors

About Mucosis www.mucosis.com

Mucosis B.V. (Mucosis) is a clinical-stage biotechnology company using a proprietary technology platform to develop next-generation needle-free human vaccines for infectious diseases. Mucosis's investigational patient-friendly vaccines can be delivered via the nose or mouth to elicit a more natural immune response with a broader base of protection. The company is developing multiple programs for its clinical-stage proprietary Mimopath[®] platform vaccine technology for several routes of administration including those that provide additional mucosal protection, where over 90% of pathogens enter the human body.

Mucosis's lead product SynGEM[®], a stabilized recombinant vaccine delivered intranasally to prevent respiratory syncytial virus (RSV) infection, will enter human proof-of-concept studies in 2016. The annual global burden of RSV illness is significant. Nair *et al.* (Lancet, 16 April 2010) estimated that in 2005 there were up to 33.8 million new episodes of RSV-associated acute lower respiratory infection (ALRI) worldwide in children under 5, and over 3.4 million hospital admissions associated with severe RSV-associated ALRI disease. Global mortality was estimated at 66,000 to 199,000 children younger than 5 years having died from RSV-associated ALRI in 2005.

The company has also developed PneuGEM[®], a vaccine to prevent diseases caused by pneumococcal bacteria, and FluGEM[®], a vaccine against influenza. FluGEM[®] served as a successful proof of concept for the Mimopath[®] platform in human clinical testing.

Mucosis has raised over EUR 20m in dilutive and non-dilutive funding, with key investment partners including MedSciences, BioGeneration, NOM & Utrecht Holdings. The company has strategic partnerships in US, Asia and the EU with organisations including the US National Institutes of Health, China-based Changchun BCHT Biotechnology co., Utrecht University, and the Netherlands Enterprise Agency. Mucosis's management is highly experienced in the design, development and commercialisation of vaccines. Mucosis employs over 10 staff at its headquarters in Groningen, The Netherlands.

About the Wellcome Trust www.wellcome.ac.uk

The Wellcome Trust is a global charitable foundation dedicated to improving health. It supports bright minds in science, the humanities and the social sciences, as well as education, public engagement and the application of research to medicine.

The Trust's investment portfolio gives the foundation independence to support such transformative work as the sequencing and understanding of the human genome, research that established front-line drugs for malaria, and Wellcome Collection, the Trust's free venue for the incurably curious that explores medicine, life and art.

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