Mucosis Initiates First-in-Human Study of SynGEM®, a Needle-Free Nasal Spray RSV Vaccine

- Respiratory Syncytial Virus (RSV), a common contagious lung infection, is a global health threat responsible for up to 200,000 deaths worldwide annually

- UK Phase I trial supported with EUR 3.44 m from Wellcome Trust, taking place at Imperial College, London

Groningen, the Netherlands, November 7, 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 announces the start of a first-in-human study of its intranasal Respiratory Syncytial Virus (RSV) vaccine candidate, SynGEM®, at Imperial College London's Clinical Research Facility.

The first trial will recruit 48 healthy adults (36 vaccinated, 12 placebo) to assess the safety and immunogenicity of a prime-boost regime of two different intranasal doses of SynGEM®, in a randomised, double-blind Phase I study. Phase I is completed at day 180 post prime vaccine administration, with interim data readout expected in the first half of 2017. Phase II, due to start mid-2017, will recruit 108 adults (54 vaccinated, 54 placebo).

SynGEM® is based on a unique prefusion version of the F subunit of RSV, shown to raise more potent serum neutralizing antibodies against RSV compared with the postfusion F antigen approach others have used. Delivered via the mucous membranes in the nose, the Mucosis vaccine candidate is also able to recruit antibodies produced in the mucosal linings of the body, with the potential to effectively stop the virus from entering the body via the mucosal pathways, where over 90% of pathogens enter the body. SynGEM® is based on Mucosis' patented Mimopath® technology, which uses bacterium-like particles (BLP) derived from food-grade bacteria, to deliver the antigen in a more natural conformation and boost the body's immune response to the virus.

RSV is a common contagious infection of the lungs and respiratory pathways, eliciting cold-like symptoms in adults. Whilst RSV infection is normally mild in healthy adults, the infection can lead to serious and sometimes fatal diseases such as pneumonia and bronchiolitis, most often in susceptible populations such as the young and elderly. Every year in the US, RSV infections lead to 57,527 hospitalisations of children under 5 year's old[1] and are responsible for up to 200,000 deaths annually worldwide[2].

Professor Peter Openshaw, Professor of Experimental Medicine at Imperial College London and Physician in the Department of Respiratory Medicine at Imperial College Healthcare NHS Trust, "We are delighted to work with Mucosis on SynGEM®, a needle-free nasal spray vaccine that that is designed to raise not only systemic but also mucosal immunity at the site of entry of the virus. We will first test whether the vaccine induces the right sort of immunity in humans, and, if it does, then test whether it will prevent infection in adult volunteers. Previous research has shown that boosting immunity in the nose and lungs may be the best way of increasing defence against RSV, blocking the virus from gaining entry to the body."

"The start of this first-in-human study marks an important milestone in our progress towards a needle-free vaccine for prevention of RSV, a global health threat for which there is still no vaccine" said Tom Johnston, CEO of Mucosis. "We are pleased to be working with the support of the Wellcome Trust and a world-renowned university for this next step in the program, enabling us to take advantage of leading experts in the RSV field, and dedicated respiratory facilities. This second human trial of our Mimopath® platform builds on the successful proof of concept trial in influenza in 2012."

The Wellcome Trust awarded Mucosis with a €3.44 million (£2.77 million) translational fund earlier in the year to progress SynGEM® into phase I and IIa human clinical trials. On completion of the phase I study, a phase IIa study will involve a live viral challenge to assess the efficacy of SynGEM against RSV.

Details of the study can be found at www.rsvstudy.org

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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, entered human proof-of-concept studies in 2016. The annual global burden of RSV illness is significant, with 33.8 million estimated 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 disease. Global mortality was estimated at 253,500 deaths in 2010.

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 Capital, BioGeneration Ventures, NOM, BCHT & 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 is headquartered in Groningen, The Netherlands.

References

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