

MUCOSIS ANNOUNCES PUBLICATION OF DATA DEMONSTRATING SAFETY AND PROTECTION BY MUCOSALLY ADMINISTERED MIMOPATH[®]-BASED PREFUSION-LIKE F RSV VACCINES

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A safe and protective intranasal RSV vaccine (SynGEM[®]) based on a recombinant prefusion-like form of the F protein bound to bacterium-like particles

Groningen, the Netherlands, Aug 12, 2013 -- Biotechnology company Mucosis B.V. today announced the publication in the peer-reviewed journal PLOS ONE of preclinical data showing that its innovative SynGEM[®] is safe and protective in animal models.

According to the report, SynGEM[®], a vaccine based on the Mimopath[®] vaccine technology allows presentation of a stable prefusion-like trimeric F protein, a feature considered important for the induction of functional immunity. Intranasally administered SynGEM[®] induced locally secreted IgA in the mucosal layers in addition to robust levels of systemic virus neutralizing antibodies both in mice and cotton rats. The response upon vaccination was fully protective in both animal models while no "enhanced disease" symptoms were induced, which were clearly observed with the formalin-inactivated RSV vaccine that failed in clinical trials in the 1960s. The preclinical results follow recent developments in RSV vaccine research that revealed a newly identified site of vulnerability which is only exposed in the prefusion F protein, named antigenic site ϕ . This pivotal antigenic site is an essential epitope required for effective induction of highly potent neutralizing antibodies in humans.

Dr. Kees Leenhouts, CSO of Mucosis: "Together with our partner at the University of Utrecht, a team led by Prof. Peter Rottier and Dr. Xander de Haan, we have succeeded in producing stable prefusion-like F antigen and formulating a vaccine candidate, SynGEM[®] that presents the prefusion F epitopes of antigenic site ϕ in a safe way to the immune system. In addition, our vaccine presents the protective epitope recognized by palivizumab. The intranasal application potentially results in an extra line of defense at the port of entry of the virus, which may also reduce virus shedding and hence may increase "herd" immunity. The vaccine candidate is therefore uniquely positioned to fill the gap of substantial unmet medical need by preventing RSV infections in people of all ages including those with the highest morbidity and mortality rates in the very young and elderly. Additionally, the non-invasive character of the vaccine candidate and the Generally Recognized as Safe (GRAS) nature of the core Mimopath[®] vaccine technology may lead to a greater acceptance of maternal vaccination strategies in order to protect premature newborns and infants through placental and/or breast milk transfer of antibodies".

"These positive animal data showing safe and effective protection against RSV provide further confirmation that the Mimopath[®] vaccine platform will play a key role in meeting significant unmet medical need around the globe," added Thomas S Johnston, Chief Executive Officer. "We remain focused on advancing the SynGEM[®] program into human trials, as we believe its unique prefusion-like structure offers the most complete approach to generating a meaningful immune response and thereby conferring protection in those that need it the most."

Mucosis is focused on the development the SynGEM[®] vaccine candidate in cooperation with its corporate, governmental and non-governmental partners. SynGEM[®] is designed to prevent infections with Respiratory Syncytial Virus (RSV), which affect over 60 million people worldwide ranging from the very young to the elderly with more than one million hospitalizations annually. An RSV vaccine does not yet exist.

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About Mucosis

Mucosis B.V. is a clinical-stage Dutch biotechnology company with a proprietary platform technology, Mimopath[®], on which it develops mucosal vaccines with improved efficacy. Mucosis's lead product is SynGEM[®], a vaccine to prevent RSV infection. In addition, the company develops PneuGEM[®], a vaccine to prevent diseases caused by pneumococcal bacteria and FluGEM[®], a vaccine to prevent influenza. Mimopath[®]-based vaccines can be administered needle-free in the nose and mouth, evoking a more natural immune response with a broader base of protection.

About Mimopath[®] technology

The Mimopath[®] technology is based on *Lactococcus lactis*, a Generally Recognized As Safe (GRAS) bacterium commonly used in the food industry. Mucosis has developed a robust technique to formulate the *L. lactis* bacteria into non-living bacterium-like particles (BLPs) that can be loaded with antigens from viral, bacterial, parasitic or tumor origin. The antigen-covered BLPs form a vaccine that can be delivered into the nose or mouth, without the need for a needle. These vaccines have been shown to raise protective immunity by activation of both the innate and the adaptive immune system.