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PRESS RELEASE

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Mucosis announces positive proof-of-concept data for Mimopath® platform in humans

Dutch vaccine development company Mucosis B.V. today announced Phase I clinical data providing proof-of-concept that Mimopath®-based mucosal vaccines are safe and well tolerated as well as able to produce balanced immune responses in both circulating blood and the respiratory tract.

Mucosis, in conjunction with the Centre for Human Drug Research (CHDR; Leiden, the Netherlands), conducted the clinical trial to assess the safety, tolerability, and immunogenicity of nasally administered FluGEM®, a Mimopath®-based mucosal influenza vaccine containing bacterium-like particles (BLPs) in addition to a standard amount of trivalent split influenza antigen. This Phase I study, which began in March of 2011, was a randomized, blinded, placebo-controlled study and enrolled 60 human subjects 18 to 49 years of age who received either standard amounts of trivalent split influenza antigen or FluGEM® vaccine containing increasing doses of BLPs.

Nasal FluGEM® was well tolerated with no vaccine-related serious adverse events, and the rate of overall events was comparable to that in the control group. Moreover, FluGEM® induced strong hemagglutination inhibition (HAI) antibody responses against the influenza H1N1, H3N2, and B strains. The systemic HAI responses met the seroconversion criteria for licensure as outlined in the EMA guidance document for influenza vaccine licensure, a difficult-to-reach endpoint for mucosal vaccination. Seroconversion rates (i.e., percentage of subjects with a 4-fold or higher rise in HAI titer from baseline) ranged from 54% for H3N2, 46% for H1N1, and 50% for B strains. In addition, a potent mucosal immune response was observed in 77% of the subjects, as evidenced by secretion of influenza specific immunoglobulin A molecules in the nasal cavity.

Dr. Govert Schouten, CEO of Mucosis: “We are extremely pleased with the recent results of our Mimopath® proof-of-concept study in humans. We now look forward to advancing our platform through the SynGEM® respiratory syncytial virus and PneuGEM® pneumococcal vaccine programs. In these innovative programs, we apply our core Mimopath® technology to deliver vaccine antigens via the most relevant route of administration – the mucosa. We will further develop the FluGEM® vaccine candidate in cooperation with corporate, governmental and non-governmental partners. We also continue to roll out our licensing program that allows partners to leverage our Mimopath® technology for use in fields outside our focus of respiratory tract infections.”

Mucosis’s lead vaccine candidate, 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 viral 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 safe 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 raise protective immunity by activation of both the innate and the adaptive immune system.