

Mucosis presents preclinical data demonstrating protection by its intranasal SynGEM® RSV vaccine candidate

SynGEM® RSV vaccine candidate provides safe protection against challenge

Dutch biotechnology company Mucosis B.V. presented preclinical data at the MODERN VACCINES ADJUVANTS FORMULATION conference (MVAFF 2013) in Lausanne, Switzerland, demonstrating that SynGEM® provides protection against RSV both in the mouse and cotton rat model while no “enhanced disease” symptoms were observed. SynGEM® is a novel Mimopath®-based mucosal RSV vaccine candidate that will be administered through simple intranasal delivery.

Mucosis presented recent findings from the company’s respiratory syncytial virus (RSV) vaccine development program. The company reported that the Mimopath® technology allows presentation of a stable prefusion trimeric F protein, a feature considered important for the induction of functional immunity*. Intranasally administered SynGEM® induced locally secreted IgA in the mucosal layers and 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.

Dr. Kees Leenhouts, CSO of Mucosis stated: “Mucosis will continue to develop the SynGEM® vaccine candidate based on our innovative antigen and mucosal vaccine carrier technology in cooperation with corporate, governmental and non-governmental partners. Recent developments in RSV vaccine research revealed the newly identified site of vulnerability in the prefusion F protein, which was named antigenic site ϕ^{**} . This pivotal antigenic site contains essential epitopes required for effective induction of highly potent neutralizing antibodies. We believe that SynGEM® presents these same prefusion F epitopes of antigenic site ϕ in a safe way to the immune system. 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 company’s lead vaccine candidate is therefore in an excellent position to fill the gap of a substantial unmet medical need and prevent RSV infections worldwide in millions of people of all ages including those with the highest morbidity and mortality rates in the very young and elderly. The non-invasive character of the vaccine candidate and the GRAS nature of the applied vaccine technology may also contribute 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”.

* Structure of RSV Fusion Glycoprotein Trimer Bound to a Prefusion-Specific Neutralizing Antibody. McLellan JS, Graham BS. *et al.* Science. 2013 Apr 25.

** NIH Study Offers Clues to Making Vaccine for Infant Respiratory Illness: *Scientists See Vulnerable Spot on Respiratory Syncytial Virus Protein* (<http://www.niaid.nih.gov/news/newsreleases/2013/Pages/RSV.aspx>)

About Respiratory Syncytial Virus

The human respiratory syncytial virus (RSV) is a major cause of seasonal epidemics of severe lower respiratory tract disease. Worldwide an estimated 64 million RSV infections occur annually, resulting in the death of approximately 160,000 individuals. While RSV attacks all age groups, the most severe disease occurs in (i) the elderly, (ii) patients with chronic lung disease, (iii) persons with impaired immunity and (iv) very young infants (≤ 2 years of age). There is currently no vaccine available to prevent disease caused by RSV.

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 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 raise protective immunity by activation of both the innate and the adaptive immune system.