The Mimopath® vaccine platform

A versatile technology inducing a balanced local immune response

Introduction

MUCOSIS developed vaccines based on an innovative formulationand adjuvant technology. The technology enables needle-free administration via mucosal routes, such as the nose and the mouth. In addition, the company developed innovative vaccines in the field of influenza and pneumococcal diseases.

The proprietary technology Mimopath® is the driving force behind this mucosal vaccination approach; one that is versatile and needle free and uses the safe and well recognized Lactococcus Lactis bacterium commonly found in the food industry. The bacteria are formulated into non-living, non-toxic, bacterium like particles (BLPs) that can be covered with antigens from various origins. These BLPs act as a potent adjuvant and delivery vehicle for intranasal immunization, capable of eliciting strong mucosal responses as well as Th1-type cell-mediated immunity^{1,2}. Be it antigens of viral, bacterial, parasitic or tumour origin, the BLPs can be loaded with complex multimeric antigens and used for multiple routes of administration, for which the Protan technology was developed (fig). To date, over 40 different antigens of bacterial, viral, or parasitic nature have been successfully overexpressed as Protan fusions. Mixing of an antigen-Protan solution with BLPs results in a strong non-covalent binding, covering the BLPs completely with the antigen. The Mimopath technology provides an excellent delivery platform as well as a safe adjuvant technology for intranasal application, tested in phase I clinical trials.

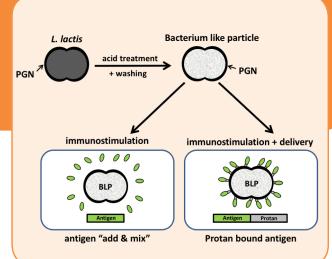


Figure: Mucosis' Mimopath technology

Mucosis' Mimopath platform including Protan binding technology. Safe food-grade bacteria of the Lactococcus lactis strain are formulated into bacterium like particles (BLPs, upper panel), which are then used as either 1) an immunostimulant by simply mixing with vaccine antigens ("add & mix" lower left panel); this format is of particular interest in the reformulation of existing vaccines to enable mucosal application; or 2) an immunostimulant and delivery platform by binding recombinant subunit antigens expressing a fused PGN-binding tag (Protan) to the PGN domain that is naturally presented on the BLP ("Protan bound antigen" lower right panel). After binding the antigen, BLPs are easily recovered, washed and formulated in a suitable buffer.

Company history • Mucosis had developed vaccines for over 10 years, until the share holders discontinued financing in June 2017. The shareholders' decision was based upon the immunogenicity data of a phase I clinical trial with the Mucosis RSV vaccine, which required a new phase I study using a higher dose. The District Court of 'Noord-Nederland, locatie Groningen', the Netherlands, declared bankruptcy on June 27 and appointed Mr. R. G. Holtz LLM as trustee. On behalf of the trustee, sale of the Mucosis assets is executed by Ernst Soethout of Virtuvax BV.

The transfer package

The Mucosis technology includes:

- An extensive IPR portfolio (see below).
- An extensive tech transfer package including all-encompassing procedures for the production of BLPs as well as QA and QC protocols and safety data thereof.
- Clinical trial data: IMPD and Phase I clinical trial data for FluGEM.
- GMP grade bacterial strains: Lactococcus Lactis MCB and WCB.

The package is available for acquisition and for complete or partial licensing.

Reference	Priority date	Technology
WO 02/101026	11 Jun 01	Methods for binding AcmA-type protein anchor fusions to cell-wall material of micro-organisms
WO 2007/011216	20 July 05	Bifunctional protein anchors
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WO 2011/040811	02 Oct 09	Adjuvanted vaccine formulations, in particular influenza vaccines for intranasal delivery
WO 2012/128628	22 Mar 11	Immunogenic compositions in particulate form and methods for producing the same
WO 2004/102199	16 May 03	Method for selecting and producing vaccine components and vaccines based thereon, describing pneumococcal proteins and their use as vaccine component.
WO 2014/140083	14 Mar 13	Heat stable RSV prefusion F constructs

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² Mucosal Immunol 3 (2010) 159-171.

¹ AAPS Journal 12 (2009) 109