FluGEM®
against influenza

Introduction

Mucosis' FluGEM® vaccine (*Fig.*) was designed to easily mix influenza antigens with BLPs and administer the vaccine by a simple spray in the nose. In animal models, intra-nasal vaccination of FluGEM induced strong systemic and mucosal responses, showing a more pronounced longevity of the immune response than standard intra-muscular vaccination[5]. Importantly, FluGEM showed superior protection against challenge with a non-homologous (e.g. drifted) viral strain. The efficacy of FluGEM was improved when the antigen was bound through the Protan linker to BLP.

In a randomized, double-blind, controlled phase I clinical trial in healthy adults, intra-nasal administration of FluGEM was found safe and well tolerated. Adequate immune responses (HI titers ≥40) were achieved after intra-nasal vaccination with a single vaccine dose. The titers against all three vaccine strains remained stable throughout the whole follow-up period of almost 6 months, which is in line with data found in animal models. In addition, local mucosal responses, as determined by influenza-specific IgA titers in nasal washes of vaccinated subjects increased approximately fourfold three weeks after the first vaccination. Finally, cellular responses were induced, as shown by an increase in the number of influenza-specific IFNγ-producing PBMCs[5].

[5] Front Immunol. 2013;4:282

The transfer package

The FluGEM influenza technology includes:

- An extensive IPR portfolio, protecting the BLP technology, Protan linker technology and the 'add and mix' technology for adjuvation of influenza vaccine antigens (WO 2011/040811, allowed in US and granted in EU plus multiple other countries).
- A tech transfer package including procedures for the production of BLPs and the Flu- GEM vaccine as well as QA and QC protocols and safety data.
- Clinical trial data: IMPD, Phase I clinical trial data.
- Preclinical data.
- GMP grade bacterial strains: Lactococcus Lactis MCB.

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

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.*

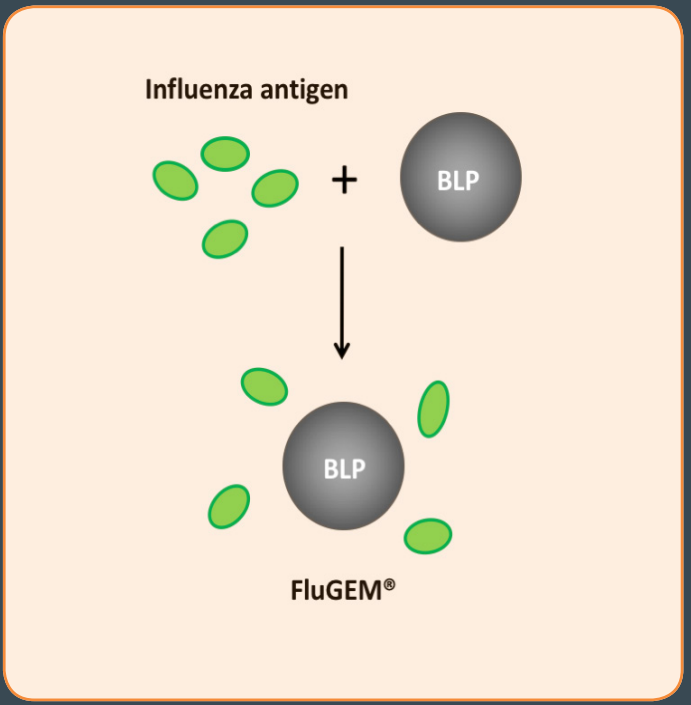

Figure: FluGEM

FluGEM is produced following a simple 'add and mix' approach using bacterium like particles (BLPs) and commercially available influenza antigen (split virus or subunit) produced on eggs or on cells. The vaccine is administered intranasally.

Contact

Ernst Soethout PhD
Virtuvax BV
Odijk, the Netherlands
e.soethout@virtuvax.nl
+31 6 2989 4729

Mr. Job Holtz LLM, trustee
Bout Advocaten
Groningen, the Netherlands
holtz@boutadvocaten.nl
+31 5 0314 0840