

Data published in *PLOS ONE* show Mymetics' HIV-1 Innovative vaccine is safe and elicits strong immunogenicity

- Vaccine-induced mucosal antibodies may contribute to reduce sexually transmitted HIV-1
- Immunogenicity of the HIV-1 vaccine confirmed both in serum and at the mucosal sites
- Intramuscular and subsequent intranasal administration with HIV-1 vaccine MYM-V101 were safe and well tolerated in humans

Epalinges, Switzerland, 21 February 2013 – Results from a randomized study published in *PLOS ONE*¹ today demonstrate that Mymetic' innovative HIV-1 (Human Immunodeficiency Virus type 1) vaccine is safe and well tolerated and demonstrates a high level of immunogenicity in a Phase I trial involving 24 healthy women. The publication highlights that vaccine-induced mucosal antibodies may contribute to reduce sexually transmitted HIV-1. Mymetics Corporation is a pioneer in the development of vaccines that use the human mucosal system, the body's first line of defense, to prevent transmission of infectious diseases.

Ronald Kempers, CEO of Mymetics, commented: *"These results in female volunteers strongly confirm the validity of our innovative approach and represent a major milestone for the development of a prophylactic HIV-1 vaccine capable of establishing an efficient front-line defense at the mucosal level. Preclinical studies in non-human primates already generated extremely promising data demonstrating 100% protection against multiple intra-vaginal challenges with a live virus."*

Providing Mymetics obtains additional sources of financing for this project, the company plans to test its prophylactic HIV-1 vaccine candidate in a combined Phase I and II trial to investigate an additional HIV-1 antigen and a further optimized vaccine formulation.

All vaccinated women rapidly developed lipopeptide P1-specific serum antibodies, confirming the high efficacy of the influenza virosome as carrier/adjuvant for inducing a Th2 (T helper type 2) response. This antibody concentration represents billions of molecules of antibodies in the vaginal secretion and it is believed to be sufficient for preventing sexually transmitted HIV-1 within the first minutes or hours following the virus entry in the vaginal cavity.

"The vaccine is designed for blocking the virus passage across the mucosal tissues or stopping early cell infections at the mucosal site from where it could spread and reach other immune organs and destroy the immune system," added Sylvain Fleury, Chief Scientific Officer of Mymetics.

Until the completion of this double blind, randomized, placebo controlled Phase I trial, the capacity of an HIV-1 vaccine to induce mucosal antibodies in the genital and rectal tracts of women after intramuscular and intranasal administrations was unknown. This Phase I study confirms Mymetics' previous pre-clinical study conducted on non-human primates, which was published in February 2011 in the journal *Immunity*.

¹ Randomized Phase I: Safety, Immunogenicity and Mucosal Antiviral Activity in Young Healthy Women Vaccinated with HIV-1 Gp41 P1 Peptide on Virosomes

Press release

In this vaccine Mymetics used a sequence of the P1 peptide in combination with the influenza virosomes from its industrial partner Pevion Biotech.

About the Phase I trial

The placebo-controlled Phase I trial involved 24 healthy women randomized in two groups to monitor the safety and immunogenicity of the HIV-1 vaccine. A low dose group received 10µg/dose and a high dose group received 50µg/dose. In each group, eight subjects received the vaccine MYM-V101 and four subjects received the placebo. Two doses were given intramuscularly at week 0 and week 8 followed by two doses given intranasally at week 16 and week 24.

The Phase I, placebo-controlled, double-blinded study, was conducted at a single site, the Center for Vaccinology (CEVAC) at the University of Ghent (Belgium) with Prof. Dr. G. Leroux-Roels as principal investigator. The clinical study was managed by Kinesis-Pharma, the CRO of Mymetics. The functional antiviral activity of these mucosal antibodies was demonstrated by the inhibition of HIV-1 transcytosis, as reported by Dr. Morgane Bomsel (INSERM/Cochin Institute, France), a key academic partner.

The Mymetics HIV-1 vaccine approach

With its vaccine, Mymetics aims to provide a first line of defense through mucosal protection as well as a second line of defense against infection through the generation of blood antibodies.

A vaccine that blocks early HIV-1 transmission across mucosal membranes and early infection underneath the mucosa represents a highly promising but, until now, poorly investigated approach to preventing HIV-1 transmission/infection.

Today, there is evidence in favor of multiple separate immune compartments with local mucosal cells producing mucosal IgG and IgA that may circulate or not to other compartments. Each immune compartment can be partially or totally complementary to the others. A sub-group of women and men who produce mucosal IgA antibodies against the HIV-1 gp41 protein in their mucosal secretions have been found to display resistance to HIV-1 transmission and infection.

Mymetics has used its technology and expertise to design a vaccine specifically intended to induce a mucosal antibody response against HIV-1, while also inducing blood antibodies.

About Mymetics

Mymetics Corporation is a Swiss-based biotechnology company registered in the US (OTC BB: MYMX) developing next-generation preventative vaccines for infectious diseases. The company's vaccines are designed to induce protection against early transmission and infection, focusing on the mucosal immune response as a first-line defense, which, for some pathogens, may be essential for the development of an effective prophylactic vaccine.

Mymetics currently has 5 vaccines in its pipeline: HIV-1/AIDS, Influenza, Respiratory Syncytial Virus, Malaria and Herpes Simplex Virus. The company's HIV-1 vaccine has completed a Phase I clinical trial in healthy human volunteers. A Phase 1b clinical trial for its Malaria vaccine on children in Tanzania has been completed, while the HSV vaccine candidate is in the preclinical phase. The RSV vaccine candidate is expected to enter a Phase I trial beginning 2014. The Influenza vaccine has finished a Phase 1 with Solvay Pharmaceuticals (now Abbott).

Press release

Being 100% privately funded and financed by its main shareholders, the company is currently exploring several new investment and partner opportunities to secure financing to further advance the development of its vaccines.

The link to the *PLOS ONE* article: <http://dx.plos.org/10.1371/journal.pone.0055438>

For further information, please visit www.mymetics.com.

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