Mymetics Realizes Successful Phase I Study with Its Innovative HIV Vaccine MYM-V101

- **Intra-muscular and subsequent Intra-nasal administrations with HIV-1 vaccine MYM-V101 were safe and well tolerated in humans**
- **Data demonstrate strong immunogenicity of the HIV-1 vaccine both in serum and at the mucosal sites**

Epalinges, Switzerland, 26 May 2011 – Mymetics Corporation, 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, announced today that its innovative HIV-1 (Human Immunodeficiency Virus type 1) vaccine proved to be safe and well tolerated and demonstrated a high level of immunogenicity in a Phase I trial involving 24 healthy women.

Jacques-François Martin, CEO of Mymetics, commented: "Until the completion of this Phase I trial, the capacity of our HIV-1 vaccine to induce mucosal antibodies in the genital and rectal tracts of women was unknown. Preclinical studies in non-human primates generated extremely promising data demonstrating 100% protection against multiple intra-vaginal challenges with a live virus. These new results in female volunteers strongly confirm the validity of our 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."

All vaccinated women rapidly developed lipopeptide P1-specific serum antibodies, confirming the high efficacy of the influenza virosomes as carriers/adjuvants for inducing a Th2 (T helper type 2) response. All vaccinated subjects also developed lipopeptide P1-specific antibodies in vaginal and rectal secretions. 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.

"This study confirms the safety profile of virosomes and the promising anti-HIV-1 mucosal responses elicited by our MYM-V101 vaccine. We will now plan the next Phase I/II trials to test an additional HIV-1 antigen and a further optimized vaccine formulation. Mymetics will also continue its efforts to develop a vaccine formulation suitable for developing countries that is able to convey cross-clade protection," added Sylvain Fleury, Chief Scientific Officer of Mymetics.

"Although participation in the study necessitated repeated visits and examinations, many young women volunteered and the required number of volunteers was rapidly attained. The vaccine administrations and study procedures were well tolerated, leading to excellent compliance," said Prof. Leroux-Roels, Principle Investigator of the Mymetics trial from the Faculty of Medicine at the University of Ghent, Belgium.

Mymetics co-developed the current HIV-1 vaccine with its industrial partner Pevion Biotech, using proprietary virosome technology. The next trial will also involve the industrial partner Px-Therapeutics (Grenoble, France) for its expertise in recombinant protein production and GMP grade for clinical trials. 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. 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*. A larger study in non-human primates is currently planned.

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 directed by Kinesis-Pharma.

About HIV and the Mymetics vaccine approach

About 2.6 million people were newly infected with HIV-1 in 2009 while an estimated 1.8 million people died of AIDS in that year. HIV-related illness remains one of the leading global causes of death and is projected to remain so in the coming decades. There is as yet no vaccine available against HIV-1. However, results of a large Phase III clinical study on an HIV-1 vaccine in Thailand, reported in September 2009, showed a modest protective effect of 31%, providing encouraging support for the feasibility of an effective HIV-1 vaccine.

Traditional approaches to creating a vaccine against HIV-1 have aimed to elicit specific blood neutralizing antibodies or cytotoxic T cells (CTLs), two important defense mechanisms. Despite their importance as protection mechanisms, neither approach seems suitable for protecting against initial mucosal transmission of HIV-1.

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. Obstacles have included a lag in knowledge about the mucosal immune system and its antibody response, as well as the invasiveness of the methods required and the sensitivity of the tests needed to detect mucosal antibodies, compared with blood. In the vaccine field, there was a general belief that serum and mucosal antibodies were equivalent because serum IgGs in secretions were thought to be serum-derived. 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. Mymetics' core technology and expertise are in the use of virosomes, lipid-based carriers containing functional fusion viral proteins, in combination with rationally designed antigens. 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 is led by an international and experienced management team and is supported by a strong Scientific Advisory Board composed of

renowned experts. The company has established contacts with world leaders in vaccine development.

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 RSV and HSV vaccine candidates are in the preclinical phase. The Influenza vaccine has been out-licensed to Solvay Pharmaceuticals (now Abbott). For further information, please visit www.mymetics.com.

About Pevion Biotech
Pevion Biotech Ltd. is an independent Swiss vaccine company that develops innovative vaccines for unmet medical needs based on its clinically and commercially validated virosome technology. Its proprietary clinical pipeline includes a first-in-class candidiasis vaccine. Pevion has in-house development capability and expertise, including a state-of-the-art and industrially scalable GMP manufacturing process. Located near Bern, Pevion was founded in 2002 as an industrial spin-off of Bachem AG (SWX: BANB) and Berna Biotech, now Crucell (SWX: CRX). For further information, please visit www.pevion.com.

Contact
Ronald Kempers
CFO and COO
Mymetics Corporation
Tel: +41 21 653 4535

Media
Christophe Lamps
Senior Partner
Dynamics Group
Mobile: + 41 79 476 26 87
Email: cla@dynamicsgroup.ch

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