

Mymetics publishes data from groundbreaking HIV vaccine study

- **Results of successful preclinical HIV vaccine trial published in scientific journal *Immunity***
- **Vaccine provided 100% protection against multiple intra-vaginal challenges with live virus**

Epalinges, Switzerland, 15 February 2011 – Mymetics Corporation, a pioneer in the development of vaccines preventing mucosal transmission of human infectious diseases, announced today that a paper describing detailed results of a successful preclinical trial on its innovative HIV-1 (Human Immunodeficiency Virus type 1) vaccine was recently published in the leading scientific journal *Immunity*.

Jacques-François Martin, CEO of Mymetics, commented, “The publication of these results is a highly significant milestone, not just for Mymetics but for the entire HIV vaccine field. Our strategy of inducing mucosal immunity is a major breakthrough in 15 years of thinking on the design of HIV vaccines. These data provide strong confirmation of the validity of our approach, which has now gained the keen interest of key opinion leaders, both in the HIV field and for the development of other vaccines.”

The small-scale study on Chinese macaques, conducted by Mymetics at the Institute of Laboratory Animal Science (ILAS) in Beijing, China, demonstrated 100% protection in one arm of the study against multiple intra-vaginal challenges with heterologous live virus. None of the 5 vaccinated animals seroconverted to the p27*gag* antigen while all 6 placebo-vaccinated animals became rapidly infected and seroconverted. HIV-specific vaginal IgA and IgG antibodies were detected in most vaccinated animals. An *in vitro* assay showed a correlation between protection and the induction of mucosal antibodies capable of blocking the passage of HIV-1 across a cell monolayer. Protected animals also had blood IgG antibodies but these totally lacked virus-neutralizing activity. These results are unprecedented for this type of HIV-1 vaccine study and confirm the importance of non-neutralizing antibodies for preventing HIV-1 transmission and early infection events, opening the door to new vaccine designs.

The study was performed in close collaboration with Dr. Morgane Bomsel from the Cochin Institute and INSERM, Paris, who originally described the gp41-derived peptide P1, which is part of the Mymetics vaccine, and demonstrated the importance of this area of gp41 for mucosal protection. Key analyses were conducted in her laboratory.

Mymetics co-developed the HIV-1 vaccine with its industrial partner Pevion Biotech, using proprietary virosome technology, as well as with Px-Therapeutics for its expertise in judicious antigen design and the improvement of antigens to face upscale and GMP production. With its vaccine, Mymetics aims to provide both a first line of defense through mucosal protection and a second line of defense against infection through the generation of blood antibodies.

In January 2011, the Mymetics vaccine successfully completed a Phase I trial in healthy female volunteers, for which final results will be reported in the coming weeks. In parallel, Mymetics will continue its efforts to develop a vaccine formulation suitable for warm countries and offering cross-clade protection, and is planning for the next clinical trials.

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 because they may act too late in the infection process or not be produced in sufficient quantities in some mucosal compartments. Both approaches have been largely unsuccessful to date, and importantly, no protection has been seen with heterologous challenges, in which the virus strain used to infect the animal differs from the strain used in the vaccine. Reasons for the lack of success in the past include the selection of antigens that poorly mimic native viral proteins and folding, as well as the ability of HIV-1 to escape the CTL response through mutations. A CTL response has the further drawback of requiring infection to have already occurred.

A vaccine that blocks HIV-1 transmission across mucosal membranes represents a highly promising but, until now, poorly investigated approach to preventing HIV-1 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. However, mucosal antibodies, mostly of the functionally distinct IgA type as opposed to the IgG type found in the blood, are produced in high quantities and may prevent HIV-1 from reaching the bloodstream. Women and men who produce 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 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 entered a new proof-of-concept preclinical trial following unprecedented results in a first study, and has also successfully 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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