Press Release

Mymetics' HIV vaccine candidate confirms promise in preclinical study with the Texas Biomedical Research Institute

Epalinges, April 11 2016 – Mymetics Corporation (OTCQB: MYMX), a pioneer in the research and development of virosome-based vaccines to prevent transmission of human infectious diseases across mucosal membranes, announced today that its innovative HIV vaccine candidate has shown to generate significant protection in groups of twelve female monkeys against repeated AIDS virus exposures during part of the preclinical study.

The blinded study was led by Dr. Ruth Ruprecht, Scientist & Director of the Texas Biomed AIDS Research Program and was funded by the Bill & Melinda Gates foundation. During the first part of the study the Mymetics' two-component virosome-based HIV vaccine was able to show significant efficacy of 87% in delaying the time to persistent infection versus the control group after 7 intravaginal virus challenges. The study aimed to mimic the exposure of women to semen from HIV-infected men, although the viral dose of each of these 7 animal challenges represented about 70,000 times the average human HIV dose passed during sexual intercourse from an HIV-infected male to an uninfected female.

During the second part of the study the animal viral challenge dose was increased by 50% starting from the 8th challenge onward, reaching more than 100,000 times the average amount of virus passed from an infected man to a female partner. At this virus dose, the vaccine did not show significant protection in the animals as the immune system was overloaded.

Dr. Ruth Ruprecht said, "We are encouraged by the initial strong protection provided by the vaccine candidate, which is in line with the results from an earlier primate study performed in China that we were asked to repeat. The fact that the vaccine-induced immune defenses were eventually overcome requires a careful analysis to understand the mechanisms of the initial vaccine action and to learn what other immune defenses can be enlisted to yield even more potent antiviral action. "

Sylvain Fleury, CSO of Mymetics, commented, "We are pleased that Mymetics HIV virosome-based vaccine could strongly prevent virus transmission under conditions that mimic male-to female sexual transmission. Especially as these protection results are coming from two studies conducted in two different countries, with two different sub-species of macaques, with different vaccine lots and without an adjuvant. The observed protection in genetically different animals raised in different housing and environmental conditions gives more weight to these observations."

Ronald Kempers, CEO of Mymetics, "We were very impressed with the professional and thorough work delivered by Dr. Ruprecht's team, including Dr. Samir Lakhashe, Staff Scientist at Texas Biomed, and look forward to understanding the mechanisms of action of our vaccine. This study proves that our HIV vaccine candidate can protect in very realistic settings and it provides a strong indication to possibly protect women against sexually transmitted HIV and come closer to an effective HIV vaccine in the future. Virosomes have a strong safety profile in children and adults and our virosome construct can easily be combined with other vaccine candidates and treatments, therefore we are hopeful that we can attract funding for the clinical development and move a step closer to an HIV vaccine."

The study involved 36 Indian origin rhesus macaques (monkeys) with 12 animals per group for more statistical power, compared two antigen vaccination regimens with placebo and was followed by intra-vaginal heterologous challenges with live virus.

This study was designed to replicate a successfully completed smaller study at the Institute of Laboratory Animal Science (ILAS) in Beijing, China in which the two-component vaccine protected all Chinese rhesus macaque monkeys against repeated virus exposures from persistent infection – an unprecedented result.[1] One of the vaccine components further showed a strong safety and tolerance profile in a Phase I clinical trial in human volunteers.[2]

With its HIV-1 (human immunodeficiency virus type 1) vaccine candidate, produced through its proprietary virosome technology, Mymetics aims to provide both a first line of defense through mucosal protection as well as a second line of defense against infection through the generation of blood antibodies. Mymetics has produced the tested HIV vaccine construct for clinical trials in liquid form and, since last year, is developing a new generation of needle-free and cold chain independent virosomal vaccine construct with the support of the European Horizon 2020 Program (MACIVIVA Project no. 646122), which would be very suitable for developing countries.

About HIV and the Mymetics vaccine approach

2.0 million people were newly infected by HIV in 2014, while an estimated 1.2 million people died of AIDS in that year (source: WHO). 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. However, results of a large Phase III clinical study in Thailand showed a modest protective effect of 31%, providing encouraging support for the feasibility of an effective HIV vaccine.

A vaccine that blocks HIV transmission across mucosal membranes represents a highly promising approach to preventing HIV infection. Mymetics' vaccine is based on the findings that certain people are not infected with HIV, even though they are exposed to it very frequently. Women and men who produce IgA antibodies against the HIV gp41 protein in their mucosal secretions have been found to display resistance to HIV transmission and infection. Mymetics has used its technology and expertise to design a vaccine candidate specifically intended to induce a mucosal antibody response against HIV while also inducing blood antibodies.

Despite highly efficient drugs for preventing or slowing down virus spreading, their costs remain much higher than prophylactic vaccine, and long-term side effects are well documented.

About Mymetics

Mymetics Corporation (OTCQB: MYMX) is a Swiss-based biotechnology company registered in the US and trades on the OTCQB venture stage marketplace for early stage and developing U.S. and international companies. Mymetics develops 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 and natural membrane 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.

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[1] Immunity, Feb 2011 Bomsel et al.

[2] PLOSONE Feb 2013, Leroux-Roels et al.

Mymetics currently has 5 vaccines in its pipeline: HIV-1/AIDS, intranasal Influenza, Malaria, Herpes Simplex Virus and, RSV vaccine. The company's intranasal Influenza vaccine and the HIV vaccine have successfully completed Phase I clinical trials in healthy human volunteers. A Phase 1b clinical trial for its Malaria vaccine on children in Tanzania has been completed, while the RSV and HSV vaccine candidates are in the preclinical phase. For further information, please visit mymetics.com.

About Texas Biomedical Research Institute

Texas Biomed, formerly the Southwest Foundation for Biomedical Research, is one of the world's leading independent biomedical research institutions dedicated to advancing health worldwide through innovative biomedical research. Located on a 200-acre campus on the northwest side of San Antonio, Texas, the Institute partners with hundreds of researchers and institutions around the world to develop vaccines and therapeutics against viral pathogens causing AIDS, hepatitis, herpes, hemorrhagic fevers, and parasitic diseases responsible for malaria, schistosomiasis and Chagas disease. The Institute also has programs in the genetics of cardiovascular disease, diabetes, obesity, psychiatric disorders and other diseases. For more information on Texas Biomed, go to www.TxBiomed.org.

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