Polydex Pharmaceuticals reports Phase III trial of Ushercell for HIV Prevention Halted

Toronto, Ontario, January 31, 2007 -- Polydex Pharmaceuticals Limited (NASDAQ:POLXF) reports that CONRAD, a reproductive health research organization, announced today that it has halted a Phase III clinical trial of Ushercell – a cellulose sulfate based topical microbicide gel being tested for HIV prevention in women – because preliminary results at some trial sites indicated that cellulose sulfate could lead to potential increased risk of HIV infection in women who use the compound. The trial was being conducted in South Africa, Benin, Uganda, and India.

Simultaneously, Family Health International (FHI) has halted a second Phase III cellulose sulfate trial in Nigeria. Although the FHI trial did not detect an increased HIV risk associated with cellulose sulfate, the decision was made as a precautionary measure, given the preliminary results in the CONRAD trial. Cellulose sulfate (CS) was one of four microbicides currently in effectiveness trials for prevention of HIV and other sexually transmitted infections.

At this point, it is not clear why use of cellulose sulfate was associated with an increased risk of HIV infection in the CONRAD trial. The Independent Data Monitoring Committee (IDMC), an independent advisory group of experts overseeing the trial, will conduct a detailed review of the data to better understand the findings, and help determine any implications for other microbicide studies.

Dr. Lut Van Damme, principal investigator of the CONRAD trial, stated: “It was our hope that this product would have helped women in protecting themselves from HIV. While the findings are unexpected and disappointing, we will learn scientifically important information from this trial that will inform future HIV prevention research.”

“Ushercell has shown a consistent safety profile up to this point, having undergone 11 rigorous clinical safety and contraceptive trials involving more than 500 participants before entering the HIV prevention trial”, says President and CEO George Usher, adding “CONRAD will continue to evaluate the findings to help us determine the biological cause of an increased sero-conversion rate detected in the preliminary analysis at some of the trial sites.”

Mr. Usher also said, “We will continue to evaluate Ushercell’s attributes including its potential use as a contraceptive product. Ushercell has demonstrated a high effectiveness rate in the prevention of pregnancy and is still viable for development as a contraceptive. In the meantime, in that Ushercell is still a candidate product in development, the Company’s current income has not been adversely affected by the halting of these trials.”
Recruitment for the CONRAD Phase III study began in July 2005. The study was conducted in areas of the world where HIV risk is greatest, and where infection occurs primarily through heterosexual intercourse. Half of the participating women were given cellulose sulfate, and half a placebo gel, in a double-blinded randomized trial design. All participants received intensive HIV prevention counseling at each monthly visit and all women were given high-quality condoms free of charge. Participants received regular testing and treatment for sexually transmitted infections. Pregnant women were not included in the study.

Participants were admitted into the study only after receiving detailed information about the purpose of the study and the possible health benefits and risks. During this process, the women’s understanding of the study was assessed prior to their signing a consent form. Each trial site is linked to local organizations that provide care for women who become HIV-infected during the trial. As part of the trial preparation, CONRAD set aside funding for women who become HIV-positive during the trial to ensure adequate health care, including ARV treatment as necessary.

“Developing new tools to prevent HIV – particularly for women – is an urgent priority,” said Dr. Henry Gabelnick, Executive Director of CONRAD. “We are committed to learning as much as possible from the trials of cellulose sulfate, and will use that knowledge to continue searching for compounds and collecting evidence to find a successful microbicide. Continued support for microbicide research is critical to our eventual success.”

CONRAD is a cooperating agency of USAID committed to improving reproductive health by expanding the contraceptive choices of women and men and by helping to prevent the transmission of HIV/AIDS and other sexually transmitted diseases. CONRAD is administered through the Department of Obstetrics and Gynecology at Eastern Virginia Medical School (EVMS) in Norfolk, VA and headquartered in Arlington, VA. www.conrad.org

Polydex Pharmaceuticals Limited, based in Toronto, Ontario, Canada, is engaged in the research, development, manufacture and marketing of biotechnology-based products for the human pharmaceutical market, and also manufactures bulk pharmaceutical intermediates for the worldwide veterinary pharmaceutical industry.

Please visit the Company’s website: www.Polydex.com.

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