1 February 2007

International AIDS Society Statement on Announcement that Two Phase III Trials of HIV Microbicide Candidate Ushercell Have Been Halted

The International AIDS Society (IAS), the world’s leading independent association of HIV professionals, acknowledges today’s announcement that two Phase III trials of Ushercell (a cellulose sulfate based topical gel being testing for HIV prevention in women) have been halted due to preliminary results at some sites indicating potential increased risk for HIV among women who use the compound. The findings of increased risk were identified at some sites in a trial sponsored by CONRAD, a cooperating agency of USAID administered through the Department of Obstetrics and Gynecology at Eastern Virginia Medical School in the United States. The CONRAD trial was being conducted in South Africa, Benin, Uganda and India. While emphasizing the urgent need for the timely development of an effective microbicide to protect women from HIV infection, the IAS also recognizes the utmost importance of safety, and applauds the decision to halt the studies to evaluate the preliminary findings.

Family Health International, sponsor of the second halted trial in Nigeria, had not found similar results but halted the trial as a precautionary measure, given the preliminary results in the CONRAD trial. At this point, it is not clear why the use of cellulose sulfate was associated with increased risk for HIV infection among women in the CONRAD-sponsored trial. Earlier trials of the same compound involving 500 participants did not indicate safety concerns.

“While extremely disappointing, this setback is also an opportunity to learn why some women who used Ushercell were found to be at increased risk of HIV infection,” said Dr. Pedro Cahn, President of the IAS and Director of Fundación Huesped in Buenos Aires, Argentina. “This will strengthen future microbicide research and increase our overall knowledge of how such compounds work.”

“The importance of developing a safe and effective microbicide to protect women from HIV infection cannot be understated,” said Dr. Cahn. “We must give women the tools to protect themselves, independent of their partners’ actions.”

The halted trials were two of six Phase III microbicide trials underway at the start of 2007. Four additional Phase III trials of other candidates are ongoing.

Further data on microbicides and other biomedical prevention tools will be discussed during the upcoming IV IAS Conference on HIV Pathogenesis, Treatment and Prevention in Sydney.

About the IAS
The IAS is the world’s leading independent association of HIV professionals, with over 10,000 members in 171 countries. IAS is the principal organizer of the International AIDS Conference and in July 2007 will host the 4th IAS Conference on HIV Pathogenesis, Treatment and Prevention in Sydney, Australia (www.ias2007.org).
Media enquiries to:
Karen Bennett (Switzerland)
Tel: +41 22 710 0832
Karen.bennett@iasociety.org

Mallory Smuts (Switzerland)
Tel: +41 22 710 0822
Mallory.smuts@iasociety.org

Regina Aragon (USA)
Tel: +1 510 836 5510
rraragon@pacbell.net