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Second-Generation Vaginal Films Address Issues with Current HIV Prevention Methods

SAN DIEGO, Nov. 14, 2017 —Sexual transmission is the main method of human immunodeficiency virus type 1 (HIV-1) infection in women. The effectiveness of topical microbicides for HIV-1 prevention can be inconsistent and insufficient, which are associated with low adherence rates and/or product misuse. To address these difficulties, researchers presenting at the 2017 <u>American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition</u> designed extended release vaginal films which could be effective in HIV prevention for up to seven days.

The team from the <u>University of Pittsburgh School of Pharmacy</u> and <u>Magee-Womens Research</u> <u>Institute</u> developed extended release topical microbicide products in the form of vaginal films. These films were tested in a nonhuman primate model at the <u>University of Washington</u>. The films use a combination of a modified natural polymer and functional biopolymer to prolong the time the dosage form remains in the vagina and delivers the antiretroviral drug.

"Vaginal films are desirable because they are convenient, non-messy, low-cost dosage forms which can be discreetly used," said researcher Jing Li at the University of Pittsburgh School of Pharmacy. "Since multiple applications of vaginal films can be undesirable, we developed an extended release film platform which does not require frequent administration."

The study, "Design of Advanced Mucoadhesive Coitally-Independent Vaginal Films for HIV Prevention," was conducted with five nonhuman primates using the second-generation thiomer PLA-CL film. Results demonstrated compatibility between the films and the cervical tissue as well as enhanced mucoadhesiveness and retention. The biodegradable film platform is similar to a mouthwash strip in that it dissolves in body fluids.

In <u>Phase I</u> studies, the first-generation films which provided on-demand drug delivery, were demonstrated to be safe, acceptable, and delivered sufficient amounts of drug to the vagina for protection from HIV infection.

Li added, "We believe that this more convenient dosing platform will be one that women are more likely to use in their day-to-day lives with the hope that this could decrease infection rates in this highly susceptible population."

The researchers next step will be putting highly potent antiretroviral drugs into the second-generation film and testing its ability to prevent HIV infection in human tissue.

<u>Design of an Advanced Mucoadhesive Coitally-Independent Vaginal Film for HIV Prevention</u> will be presented Tuesday, Nov. 14, 4:00 p.m. – 5:00 p.m. (PST), Poster Forum 6 in the San Diego Convention Center.

The <u>2017 AAPS Annual Meeting and Exposition</u> is taking place in San Diego November 12 – 15. It will bring together more than 6,000 scientists, business leaders, government officials, and students from around the world to share and learn the latest scientific advances and industry developments. The meeting will feature 100 scientific sessions and 2,200 posters, workshops, and short courses. Download the <u>AAPS mobile application</u> for additional information.

Editor's Note: All media must provide press credentials to attend this meeting and register on-site at San Diego Convention Center, main registration. To schedule an interview with Jing Li, or for any other press inquiries, please contact Stacey May at 703-459-7677 or mays@aaps.org or Hillarie Turner at hillarie@vaneperen.com. For the most up-to-date program information, please click here.

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About AAPS: The <u>American Association of Pharmaceutical Scientists</u> (AAPS) is a professional, scientific organization of approximately 9,000 members employed in academia, industry, government, and other research institutes worldwide. Founded in 1986, AAPS advances the capacity of pharmaceutical scientists to develop products and therapies that improve global health. Visit www.aaps.org and follow us on Facebook and Twitter @AAPSComms. The official Twitter hashtag for the meeting is: #AAPS2017.