New contraceptive approved by FDA, offers additional option for women

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Don Waller stands outside the College of Pharmacy building on Tuesday, Aug. 4, 2020. Credit: Joshua Clark/University of Illinois Chicago

A first-of-its-kind contraceptive developed at the University of Illinois Chicago has been approved by the U.S. Food and Drug Administration.

The new contraceptive, called Phexxi, is a non-hormonal vaginal gel that can be used on-demand to prevent pregnancy.

The contraceptive is the fourth drug developed by researchers at UIC to achieve FDA approval. This milestone solidifies the university's role as a leader in innovation and drug development in Chicago, according to UIC Vice Chancellor for Innovation TJ Augustine.

"This is a great example of UIC's tremendous strength in drug discovery and innovation, building on the success of the other three UIC-developed drugs on the market. It really illustrates that our faculty members not only conduct groundbreaking research but are also passionate about taking that research to the point where it can have a positive impact on people's lives," Augustine said.

The gel—which is a combination of lactic acid, citric acid and potassium bitartrate —works by keeping vaginal pH levels in a range that is inhospitable to sperm.

UIC's Donald Waller developed the contraceptive in collaboration with Lourens Zaneveld of Rush University Medical Center. Development of the contraceptive gel began more than 20 years ago.

"The driver behind this innovation was to provide women with more control and more options for safely preventing pregnancy and sexually transmitted infections," said Waller, professor of pharmacology and toxicology at the UIC College of Pharmacy. "There are many women who feel that hormonal, long-acting birth control is not a viable option, and there are women who struggle to access prescription or implanted birth control due to lack of insurance or access to health care.

"We started by looking at natural defenses—both against pregnancy and against pathogens, such as gonorrhea and other STDs. We found that

many of the mechanisms that allow sperm to penetrate the egg parallel the ability of pathogens to infect cells," Waller said.

Waller said that semen, when introduced into the vagina, has the effect of neutralizing the natural defenses of the vagina. This neutralizing effect maintains sperm viability and also lowers the vagina's natural barriers against infections.

"With this formulation—which relies on common non-hormonal ingredients like lactic acid—we found a way to use one of the vagina's natural defenses: its acidic pH," Waller said.

Waller's gel, which is co-patented by UIC and Rush, was licensed to Evofem Biosciences, Inc. in 2003. Evofem developed the gel for commercial use through clinical trials and FDA approvals.

According to an Evofem news release, Phexxi is expected to hit the market early next month, alongside a telehealth program to support access for women.

Waller said the FDA's approval of Phexxi shows the strength of the concept that inspired the gel.

"There is a need for in-the-moment options that give women control, and I think many women will appreciate that such an option does not rely on steroid hormones," Waller said. "My hope is that women feel empowered with options to protect themselves."

Phexxi joins Prezista, Shingrix and Tice BCG in UIC's portfolio of FDA-approved therapies.

Prezista, the first treatment for multi-drug resistant HIV, was approved by the FDA in 2006. Its development was led by UIC's Arun Ghosh,

from the College of Liberal Arts and Sciences, in collaboration with the National Institutes of Health. In 2011, UIC and the NIH donated the patent rights to Medicines Patent Pool, a United Nations-backed public health organization that grants licenses for generic manufacturing and purchasing of therapeutics to encourage improved access and affordability in developing countries. The drug is licensed to Janssen Therapeutics.

Using the royalty income generated by the Prezista patent, the college has established four new endowed chairs in order to recruit and retain highly accomplished natural sciences faculty.

Shingrix was approved by the FDA in 2017 as a vaccine against shingles, a form of chickenpox in adults. Its development was originated by UIC's Abbas Vafai, from the College of Medicine, before a third party under contract with the university licensed the vaccine to pharmaceutical company GSK.

Tice BCG, originally a vaccine for tuberculosis, was approved in 1990 for the treatment of bladder cancer. Its original development as a TB vaccine was led by UIC's Sol Rosenthal, from the College of Pharmacy, before the university contracted exclusive manufacturing rights to the immunotherapy to Organon Teknika, a subsidiary of Merck.

Provided by University of Illinois at Chicago

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