

Evoform Biosciences and Orion Biotechnology Launch Collaboration to Develop MPT Product Candidate to Include HIV Prevention

SAN DIEGO, Dec. 16, 2021 /[PRNewswire](#)/ -- Evoform Biosciences, Inc. (NASDAQ: EVFM) and Orion Biotechnology Canada Ltd. today announced that they have entered into a collaboration agreement to evaluate the compatibility and stability of Orion's novel CCR5 antagonist, OB-002, in Evoform's Phexxi® (lactic acid, citric acid and potassium bitartrate) vaginal gel with the goal of developing a Multipurpose Prevention Technology (MPT) product candidate for indications including the prevention of HIV in women.

The World Health Organization reported in 2020 that approximately 37.6 million people globally were living with HIV and an estimated 1.5 million individuals were newly diagnosed as HIV-positive. There are limited methods available to prevent transmission of HIV, and no products are approved to simultaneously prevent pregnancy, STIs and HIV.

This collaboration will focus on determining compatibility and stability of OB-002 in Phexxi and is expected to yield results in the third quarter of 2022. Assuming positive results, the companies will seek government and philanthropic funding for subsequent clinical trials of the MPT vaginal gel product candidate.

"For too long, women have had to assemble a grab-bag of products to protect against pregnancy, various STIs, and HIV," said Sandra Pelletier, Chief Executive Officer of Evoform Biosciences. "This partnership with Orion aims to develop a first-of-its-kind product with potential to revolutionize the way women protect their sexual and reproductive health: no unintended pregnancies, no STIs, and no HIV -- all in one applicator."

Ian McGowan, Chief Medical Officer of Orion Biotechnology, added, "It is unacceptable that we are still seeing high rates of new HIV infections among women each year and there is clearly a compelling need to expand the HIV prevention portfolio. Orion is very excited to be collaborating with Evoform to address this important issue and develop an MPT product for women across the world."

In trials to date of Orion's novel CCR5 antagonist, OB-002 has demonstrated best-in-class *in vitro* potency. OB-002 was 100% effective in blocking transmission of HIV infection in a non-human primate model.¹ A 15-subject Phase 1 study of vaginally administered OB-002 gel demonstrated that the OB-002 gel was safe and well tolerated, with no evidence of systemic absorption.²

Phexxi is a hormone-free, on-demand prescription contraceptive vaginal gel that was launched in the U.S. in September 2020. Top-line data is expected from Evoform's pivotal Phase 3 trial for the prevention of chlamydia and gonorrhea in women in the second half of 2022.

¹ Veazey *et al.* Topical OB-002 is highly effective in preventing vaginal transmission of SHIV1623P in a non-human primate (NHP) model of HIV infection. *JID*, 2009.

² McGowan *et al.* Evaluation of the Safety, Acceptability, and Pharmacokinetic Profile of a Gel Formulation of OB-002 in Healthy Volunteers. *AIDS Res Hum Retroviruses*, 2021.

About Evofem Biosciences

Evofem Biosciences, Inc., (NASDAQ: EVFM) is developing and commercializing innovative products and product candidates to address unmet needs in women's sexual and reproductive health, including hormone-free, woman-controlled contraception and protection from certain sexually transmitted infections (chlamydia and gonorrhea). The Company's first FDA-approved product, Phexxi® (lactic acid, citric acid and potassium bitartrate), is a hormone-free, on-demand prescription contraceptive vaginal gel. It comes in a box of 12 pre-filled applicators and is applied 0-60 minutes before each act of sex. Learn more at phexxi.com and evofem.com.

Phexxi® is a registered trademark of Evofem Biosciences, Inc.

About Orion Biotechnology

Orion Biotechnology Canada Ltd. is a clinical stage company unlocking the therapeutic potential of G Protein-Coupled Receptors (GPCRs) with a novel drug modality, proven discovery platform and best-in-class molecules. The company is advancing a diversified pipeline of potential first-in-class/best-in-class antagonist and agonist therapies against high-value GPCR targets in oncology, immunology and other serious diseases. Orion is led by a highly experienced team with world leading expertise in GPCR pharmacology and peptide/protein engineering. Visit <https://orionbiotechnology.com> to learn more.

Forward-Looking Statements

This press release includes "forward-looking statements," within the meaning of the safe harbor for forward-looking statements provided by Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995 including, without limitation, statements related to anticipated cost, funding, timing and potential outcome of the collaboration or the development of any product candidate for the prevention of HIV in women. Various factors could cause actual results to differ materially from those discussed or implied in the forward-looking statements, including market and other conditions, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Important factors that could cause actual results to differ materially from those discussed or implied in the forward-looking statements, or that could impair the value of Evofem Biosciences' assets and business, are disclosed in the Company's SEC filings, including its Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 4, 2021. All forward-looking statements are expressly qualified in their entirety by such factors. The Company does not undertake any duty to update any forward-looking statement except as required by law.

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