

# Evofem Announces Padagis Will Not Seek FDA Approval to Market a Generic Version of Phexxi® Until Evofem's Phexxi Patents Expire

***-- Padagis Determined They Will Not Challenge the Phexxi Patents --***

***-- Evofem Has Phexxi Patent Protection Through 2033 --***

SAN DIEGO, Sept. 27, 2023 /PRNewswire/ -- **Evofem Biosciences, Inc.**, (OTCQB: EVFM) today announced that Padagis Israel Pharmaceuticals Ltd. (Padagis) has withdrawn the Paragraph IV certification in its previously-submitted Abbreviated New Drug Application (ANDA) for a generic version of Phexxi® (lactic acid, citric acid and potassium bitartrate) and has instead converted to a Paragraph III certification. With this pivot to Paragraph III certification, rather than challenging the Phexxi patents and seeking approval of the ANDA prior to expiration of any of those patents, Padagis is instead now asking the U.S. Food and Drug Administration (FDA) to wait until after all the Phexxi patents expire before issuing final approval of the ANDA. The latest-expiring Phexxi patents do not expire until 2033.

Padagis previously submitted its ANDA in April 2023 requesting permission to manufacture and market a generic version of Phexxi. That ANDA contained a Paragraph IV certification, in response to which Evofem initiated patent infringement litigation against Padagis. As a result of its conversion to a Paragraph III certification, Padagis is effectively no longer challenging the Phexxi Patents; accordingly, the parties have submitted a stipulation to dismiss the case.

Phexxi is currently protected by four patents, each of which are listed in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the 'Orange Book.' All four patents would need to expire or be deemed invalid or not infringed before a generic version of Phexxi could be marketed.

## **About Evofem Biosciences, Inc.**

Evofem Biosciences, Inc., is commercializing innovative products to address unmet needs in women's sexual and reproductive health. The Company's first FDA-approved product, Phexxi, 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](https://phexxi.com) and [evofem.com](https://evofem.com).

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

## **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 patent expiration dates, FDA approval of a generic version of Phexxi®, and marketing of a generic version of Phexxi. 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 are disclosed in the Company's SEC filings, including its Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 10, 2022, its Quarterly Report on Form 10-Q for the quarter ended June

30, 2023 filed with the SEC on August 14, 2023 and any subsequent filings. 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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