

FDA Joint Advisory Committee Votes in Favor of Perrigo's Opill® Daily Oral Contraceptive for OTC Use

DUBLIN, May 10, 2023 /PRNewswire/ -- Perrigo Company plc (NYSE: PRGO), a leading provider of *Consumer Self-Care Products*, announced today that the U.S. Food and Drug Administration's (FDA) Nonprescription Drugs Advisory Committee (NDAC) and the Obstetrics, Reproductive, and Urologic Drugs Advisory Committee (ORUDAC) voted unanimously 17 to 0, with no abstentions, that the benefits of making Opill®, a progestin-only daily oral contraceptive, available for over-the-counter (OTC) use outweighs the risks. The joint committee's vote, while not binding, will be considered by the FDA when making its final decision regarding the potential approval of Opill® for OTC use, which is expected later this year.

"Today's vote to recommend a switch of Opill® to OTC is a new, groundbreaking chapter in reproductive health. Perrigo is proud to lead the way in making contraception more accessible to women in the U.S.," said Perrigo President and Chief Executive Officer Murray S. Kessler. "We are motivated by the millions of people who need easy access to safe and effective contraception. Today's outcome reflects Perrigo's steadfast commitment to women and people, and their health."

Opill® consists of 0.075 mg norgestrel, which has been used to prevent pregnancy in millions of women in the U.S. since it was approved by the FDA in 1973. Nearly 50 years of use and scientific evidence show that progestin-only pills such as Opill® are effective at preventing pregnancy and are safe for most women to use.

The Opill® OTC development program, conducted over the last eight years, included several Label Comprehension studies (LCS) that demonstrated consumers could understand the OTC label, and an actual use trial, ACCESS (**A**dherence with **C**ontinuous Dose Oral **C**ontraceptive: **E**valuation of **S**elf-**S**election and Use), which showed that consumers could use Opill® correctly based on the label, and follow the dosing instructions. Notably, adherence in the ACCESS study, taking the pill daily, was no different from published data on oral contraception adherence in the prescription setting⁽¹⁾.

Additionally, Perrigo's data package included [a published pregnancy impact model](#) that estimated the number of unintended pregnancies Opill® OTC could prevent, demonstrating the significant impact the switch to OTC could have on personal and public health in the United States. Overall, data demonstrate that consumers can use Opill® safely and effectively as guided by the proposed labeling and highlight the benefits of removing the prescription barrier to oral contraception access.

"Today's vote reflects the strong data showing that Opill® can be used safely and effectively over-the-counter," said Frederique Welgryn, Perrigo Global Vice President for Women's Health. "FDA's approval of Opill® for over-the-counter use would address a key unmet need for contraceptive access, be a groundbreaking expansion for women's health nationwide and a step forward toward ensuring people can have improved access to contraception without unnecessary barriers."

[Nearly one-third](#) of adult U.S. women who have ever tried to obtain a prescription or refill

for a contraceptive pill, patch, or ring reported difficulties doing so. Removing the prescription requirement with Opill[®] would improve access to a contraceptive method that is well tolerated and notably more effective at preventing pregnancy than all current methods available OTC⁽²⁾.

OTC oral contraception has support from major medical organizations including the [American College of Obstetricians and Gynecologists](#), the [American Medical Association](#), and the [American Academy of Family Physicians](#). If approved, Opill[®] would be the first birth control pill available over-the-counter in the U.S.

(1) *Bosworth, 2018; Burnier, 2019; Potter, 1996; Fox, 2003; Hou, 2010.*

(2) *Trussel et al, Contraceptive technology. 21st ed. 2018.*

About Perrigo

Perrigo Company plc (NYSE: PRGO) is a leading provider of *Consumer Self-Care Products* and over-the-counter (OTC) health and wellness solutions that enhance individual well-being by empowering consumers to proactively prevent or treat conditions that can be self-managed. Visit Perrigo online at www.perrigo.com.

Forward-Looking Statements

Certain statements in this press release relate to future events and may therefore be considered "forward-looking statements". Forward-looking statements involve known and unknown risks, uncertainties and other factors, that may cause the actual results, levels of activity, performance or achievements of the Company or its industry to be materially different from those expressed or implied by such statements. Often such factors may be beyond our control, including risks and uncertainties regarding the occurrence and timing of regulatory activities, such as the Timing of the FDA's final decision regarding the availability of Opill[®] daily oral contraceptive over-the-counter. In particular, there can be no assurance that the FDA will follow the advisory committee's recommendation or approve the sale of daily oral contraceptives without a prescription in the United States. The foregoing and other important factors, including those discussed under "Risk Factors" in the Company's Form 10-K for the year ended December 31, 2022, as well as the Company's subsequent filings with the United States Securities and Exchange Commission, may cause actual results, performance or achievements to differ materially from those expressed or implied by these forward-looking statements. The forward-looking statements in this press release are made only as of the date hereof, and unless otherwise required by applicable securities laws, the Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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