

Perrigo Announces U.S. FDA Approval for Opill® OTC Daily Oral Contraceptive

DUBLIN, July 13, 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 (FDA) approved Opill®, a progestin-only daily oral contraceptive, for over-the-counter (OTC) use for all ages. Opill® is the first ever birth control pill available over the counter in the United States.

"Today marks a truly momentous day for women's health nationwide," said Perrigo President and Chief Executive Officer Patrick Lockwood-Taylor. "Opill® has the potential to radically transform women's access to contraception and is a true testament of Perrigo's unwavering commitment to deliver impactful solutions that truly make lives better."

Nearly 50 years of use and scientific evidence demonstrate that progestin-only pills such as Opill® are effective at preventing pregnancy and are safe for most women to use. OTC oral contraception has support from major medical organizations including the [American College of Obstetricians and Gynecologists](#), the [American Medical Association](#), the [Society for Adolescent Health and Medicine](#) and the [American Academy of Family Physicians](#).

"Today's approval is a groundbreaking expansion for women's health in the U.S., and a significant milestone towards addressing a key unmet need for contraceptive access," said Frederique Welgryn, Perrigo Global Vice President for Women's Health. "Perrigo is committed to making Opill®, which is now the most effective method available OTC at preventing pregnancy⁽¹⁾, accessible and affordable to women and people of all ages. I want to thank the FDA and its advisory panels, the Free The Pill coalition, the numerous medical organizations and advocacy groups, and all those who wholeheartedly supported this enormous undertaking that has made today a giant leap for women's empowerment."

Of the 6 million pregnancies in the U.S. each year, 45% are unintended. [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 for Opill® improves access to a contraceptive method that is effective and well tolerated for all ages of women and people who can get pregnant.

In May 2023, the FDA's 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® available for OTC use, outweigh the risks.

Opill®, which consists of 0.075 mg norgestrel, will be available in store and online at leading retailers across the U.S. early in the first quarter of 2024. For more information, please visit www.opill.com.

(1) *Trussell 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, which 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 the Company's control, including the availability of raw materials, labor or manufacturing issues, supply chain challenges, actions or omissions by distributors and retailers, market acceptance of new products, regulatory or legislative action, third party litigation, and other unforeseen issues. 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, could potentially impact the timing and availability of Opill[®] at retailers in the United States, and 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.

SOURCE Perrigo Company plc

For further information: Perrigo Contact, Bradley Joseph, Vice President, Global Investor Relations & Corporate Communications, (269)-686-3373, bradley.joseph@perrigo.com; Nicholas Gallagher, Senior Manager, Global Investor Relations & Corporate Communications, (269)- 686-3238, nicholas.gallagher@perrigo.com; Media Contact, Chrissy Faessen, Principal, Conway Strategic, (202)-559-0125, press@opill.com

Additional assets available online:  [Photos \(1\)](#)

<https://investor.perrigo.com/2023-07-13-Perrigo-Announces-U-S-FDA-Approval-for-Opill-R-OTC-Daily-Oral-Contraceptive>