

## Perrigo's HRA Pharma Submits Application to FDA for First-Ever OTC Birth Control Pill

DUBLIN and ALLEGAN, Mich., July 11, 2022 /PRNewswire/ -- Perrigo Company plc (NYSE: PRGO), a leading global provider of *Consumer Self-Care Products*, today announced that HRA Pharma, a Perrigo company, has submitted its application to the United States Food and Drug Administration (FDA) for the first-ever over-the-counter (OTC) birth control pill in the United States.

The company has applied for an Rx-to-OTC switch for Opill<sup>®</sup>, a progestin-only daily birth control pill (also referred to as a mini pill or non-estrogen pill). If approved, this would be the first daily birth control pill available OTC without a prescription in the U.S.

"This historic application marks a groundbreaking moment in contraceptive access and reproductive equity in the U.S.," said **Frédérique Welgryn, Chief Strategic Operations and Innovation Officer at HRA Pharma**. "More than 60 years ago, prescription birth control pills in the U.S. empowered women to plan if and when they want to get pregnant. Moving a safe and effective prescription birth control pill to OTC will help even more women and people access contraception without facing unnecessary barriers."

Almost half of the more than 6.1 million pregnancies in the U.S. each year are unintended<sup>1</sup>. Access to a range of methods and ways to access contraception that meet people's needs will increase the likelihood of using effective birth control methods.

Major medical organizations, including the [American College of Obstetricians and Gynecologists](#), the [American Medical Association](#), and the [American Academy of Family Physicians](#), have expressed support for moving birth control pills OTC.

Opill<sup>®</sup> consists of 0.075 mg norgestrel and has been used to prevent pregnancy in millions of women in the U.S. since it was FDA approved in 1973. Nearly fifty years of use and scientific evidence show that progestin-only pills like Opill<sup>®</sup> are effective at preventing pregnancy and are safe<sup>2,3</sup> for most women to use. As a daily regular contraceptive, Opill<sup>®</sup> is to be used pre-conception to be effective at preventing pregnancy.

[Nearly one-third](#) of adult U.S. women who have ever tried to obtain a prescription or refill for contraceptive pill, patch, or ring reported difficulties doing so<sup>4</sup>.

Removing the prescription requirement with Opill<sup>®</sup> would improve access to a contraceptive method that is well tolerated and notably more effective at preventing pregnancy than all current methods available OTC.

"As a doctor, I am dedicated to empowering people to make decisions about pregnancy prevention. For many, a birth control pill may be the best option for them but requiring a prescription is an unnecessary obstacle that can put it out of reach," said **obstetrician-gynecologist, Melissa J. Kottke, MD, MPH, MBA**. "Removing the prescription requirement for a progestin-only birth control pill will be a historic advancement for pregnancy prevention and a remarkable achievement in community public health."

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- Grindlay K, Grossman D. Prescription birth control access among U.S. women at risk of unintended pregnancy. *J Womens Health*. 2016;25(3):249-254

## **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](http://www.perrigo.com).

## **Forward-Looking Statements**

Certain statements in this press release are "forward-looking statements." These statements relate to future events or the Company's future financial performance and 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 any forward-looking statements. In some cases, forward-looking statements can be identified by terminology such as "may," "will," "could," "would," "should," "expect," "forecast," "plan," "anticipate," "intend," "believe," "estimate," "predict," "potential" or the negative of those terms or other comparable terminology. The Company has based these forward-looking statements on its current expectations, assumptions, estimates and projections. While the Company believes these expectations, assumptions, estimates and projections are reasonable, such forward-looking statements are only predictions and involve known and unknown risks and uncertainties, many of which are beyond the Company's control, including: the effect of the coronavirus (COVID-19) pandemic and its variants and associated supply chain impacts on the Company's business; general economic, credit, and market conditions; the impact of the war in Ukraine and any escalation thereof, including the effects of economic and political sanctions imposed by the United States, United Kingdom, European Union, and other countries related thereto; the outbreak or escalation of conflict in other regions where we do business; future impairment charges; customer acceptance of new products; competition from other industry participants, some of whom have greater marketing resources or larger market shares in certain product categories than the Company does; pricing pressures from customers and consumers; resolution of uncertain tax positions, including the Company's appeal of the draft and final Notices of Proposed Assessment ("NOPAs") issued by the U.S. Internal Revenue Service and the impact that an adverse result in any such proceedings would have on operating results, cash flows, and liquidity; pending and potential third-party claims and litigation, including litigation relating to the Company's restatement of previously-filed financial information and litigation relating to uncertain tax positions, including the NOPAs; potential impacts of ongoing or future government investigations and regulatory initiatives; potential costs and reputational impact of product recalls or sales halts; the impact of tax reform legislation and/or changes in healthcare policy; the timing, amount and cost of any share repurchases; fluctuations in currency exchange rates and interest rates; the Company's ability to achieve the benefits expected from the sale of its Rx business and the risk that potential costs or liabilities incurred or retained in connection with the transaction may exceed the Company's estimates or adversely affect the Company's business or operations; the Company's ability to achieve the benefits expected from the acquisition of HRA Pharma and the risks that the Company's synergy estimates are inaccurate or that the Company faces higher than anticipated integration or other costs in connection with the acquisition; risks associated

with the integration of HRA Pharma, including the risk that growth rates are adversely affected by any delay in the integration of sales and distribution networks; the consummation and success of other announced and unannounced acquisitions or dispositions, and the Company's ability to realize the desired benefits thereof; and the Company's ability to execute and achieve the desired benefits of announced cost-reduction efforts and strategic and other initiatives. An adverse result with respect to the Company's appeal of any material outstanding tax assessments or pending litigation, including securities or drug pricing matters, could ultimately require the use of corporate assets to pay such assessments, damages from third-party claims, and related interest and/or penalties, and any such use of corporate assets would limit the assets available for other corporate purposes. These and other important factors, including those discussed under "Risk Factors" in the Company's Form 10-K for the year ended December 31, 2021, 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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