Perrigo Receives Notification of Postponement for Joint FDA Advisory Committee to Review Opill® Daily Oral Contraceptive for Over-The-Counter (OTC) Use

DUBLIN, Oct. 26, 2022 /PRNewswire/ -- Perrigo Company plc (NYSE: PRGO) ("Perrigo" or "the Company"), a leading provider of *Consumer Self-Care Products,* today announced that it has received notification that the U.S. Food and Drug Administration (FDA) has postponed the joint meeting of the Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee, previously planned for November 18, 2022, to discuss the Company's application for Opill® once daily oral contraceptive for OTC use. The rescheduled date for the joint advisory committee meeting has not yet been determined.

FDA postponed the meeting in order to review additional information requested related to the Opill® Rx-to-OTC switch. In a notice received from the FDA, the Prescription Drug User Fee Act (PDUFA) date for Opill® has been extended by 90 days. The Company will continue to work collaboratively with the FDA to ensure a timely and thorough review.

Earlier this year, Perrigo's affiliate HRA Pharma filed its application with the FDA for the Rx-to-OTC switch of Opill®, a progestin-only daily birth control pill (also referred to as a mini pill or non-estrogen pill). If approved, Opill® would be the first ever daily birth control pill available OTC—without a prescription—in the U.S.

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 postponed FDA advisory committee meeting described above. While the Company believes that the FDA advisory committee meeting will be rescheduled, there can be no assurances that such meeting will occur, or that it will not be further postponed or rescheduled. Nor can the outcome of that meeting be predicted. In particular, there can be no assurance that the FDA will 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, 2021, and Form 10-Q for the quarter ended July 2, 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.

SOURCE Perrigo Company plc

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