Perrigo and Catalent Announce FDA Approval of Perrigo's AB-rated Generic Version of ProAir® HFA

DUBLIN and SOMERSET, N.J., Feb. 24, 2020 /PRNewswire/ -- Perrigo Company plc (NYSE; TASE: PRGO) and its partner, Catalent Pharma Solutions, today announced that the U.S. Food and Drug Administration (FDA) has approved Perrigo's abbreviated new drug application for generic albuterol sulfate inhalation aerosol, the first AB-rated generic version of ProAir® HFA*. Perrigo is launching a limited quantity of generic albuterol sulfate inhalation aerosol and, in collaboration with its development and manufacturing partner Catalent, is ramping up production to meet future demand.

Generic albuterol sulfate inhalation aerosol is indicated in patients 4 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm. ProAir® HFA gross sales for the previous 12 months were approximately $1.4 billion, as measured by IQVIA.

Perrigo Executive Vice President and President, Rx Pharmaceuticals, Sharon Kochan stated, "Achieving FDA approval of this complex generic product was the outcome of an industry-leading collaboration in product development and regulatory expertise between Perrigo and Catalent that spanned over a decade. We are immediately launching with limited commercial quantities and anticipate that we will be in a position to provide a steady supply of this product by the fourth quarter of 2020. This approval and first-to-market generic launch is another vivid example of our team's commitment and ability to bring new specialized products to market that lower costs for consumers and payors."

"This is a significant technical achievement for both parties, as it is the first generic Metered-Dose Inhaler to be approved by the FDA in over twenty years," commented Jonathan Arnold, President, Oral and Specialty Delivery at Catalent. "The approval also highlights Catalent's commercial manufacturing capability and complements the extensive product development and clinical-scale production capabilities at our North Carolina facility for Metered-Dose and Dry Powder Inhalers, and unit/bi-dose nasal drug-device combination products."

**ProAir® HFA is a registered trademark of Teva Respiratory, LLC.*

About Perrigo

Perrigo Company plc (NYSE; TASE: PRGO) is dedicated to making lives better by bringing "Quality, Affordable Self-care Products™" that consumers trust everywhere they are sold. The Company is a leading provider of over-the-counter 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 http://www.perrigo.com.

About Catalent

Catalent is the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, cell and gene therapies, and consumer health products. With over 85 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and

ensuring reliable global clinical and commercial product supply. Catalent employs over 13,000 people, including approximately 2,400 scientists and technicians, at more than 35 facilities, and in fiscal year 2019 generated over $2.5 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit www.catalent.com. More products. Better treatments. Reliably supplied.™

Perrigo Forward-Looking Statement Notice

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 timing, amount and cost of any share repurchases; future impairment charges; the success of management transition; 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 Notice of Assessment (the "NoA") issued by the Irish tax authority and 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; 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 NoA and 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 healthcare policy; general economic conditions; fluctuations in currency exchange rates and interest rates; the consummation of announced acquisitions or dispositions and the success of such transactions, 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. Statements regarding the separation of the RX business, including the expected benefits, anticipated timing, form of any such separation and whether the separation ultimately occurs, are all subject to various risks and uncertainties, including future financial and operating results, our ability to separate the business, the effect of existing interdependencies with our manufacturing and shared service operations, and the tax consequences of the planned separation to the Company or its shareholders. Furthermore, the Company may incur additional tax liabilities in respect of 2016 and prior years or be found to have breached certain provisions of Irish company law in connection with the Company's restatement of previously-filed financial statements, which may result in additional expenses and penalties. These and other important factors, including those discussed under "Risk Factors" in the Company's Form 10-K for the year ended December 31, 2018, 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.

Catalent Forward-Looking Statement Notice

Statements concerning launch and future manufacturing and sales plans contained in this release are forward-looking statements. They involve known and unknown risks, uncertainties, and other factors that may cause actual results or performance to be different from those expressed or implied in this release. Catalent has based its forward-looking statements on its current expectations, assumptions, estimates and projections, which it believes to be reasonable, but various factors, including factors beyond Catalent's control, may affect future results or performance. Among the factors that may affect these forward-looking statements are: customer acceptance of the product and competing products, competitor responses to the launch of this product, changes to the overall economic climate in the United States or among potential purchasers of the product, changes to the healthcare reimbursement system in the United States, competing initiatives at Catalent or Perrigo, supply chain risks relating to the product, fluctuations in currency exchange rates that affect Catalent's ability to source the materials needed for the product, or potential third-party claims or litigation related to the product. These and other important factors, including those discussed under "Risk Factors" in the Catalent, Inc. Annual Report on Form 10-K for the year ended June 30, 2019, may affect future results or performance. Catalent makes the statements in this release only as of the date of this release, and Catalent disclaims any duty, except as required by law, to update or revise any forward-looking statement, regardless of the circumstances.

SOURCE Perrigo Company plc

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Additional assets available online: Photos (1)

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