Aptar 🖊

Aptar Awarded US FDA Contract to Study Opportunities for Low Global Warming Potential Propellants for Metered Dose Inhalers

Crystal Lake, Illinois, December 4, 2023 – AptarGroup, Inc. (NYSE: ATR), a global leader in drug and consumer product dosing, dispensing and protection technologies, is announcing a contract with the U.S. Food and Drug Administration (FDA) to study the challenges with developing low Global Warming Potential (low-GWP) propellant metered dose inhalers (MDIs).

Moreover, Aptar's study will help to define the potential target product profile of low-GWP propellant MDIs to achieve comparability in critical quality attributes (CQAs) to existing MDIs.

With this study, Aptar will support the FDA with its industry-leading research and development center and respiratory team, which is enhanced by state-of-the-art technologies and the know-how to develop complex orally inhaled and nasal drug products (OINDP). Additional capabilities Aptar can provide include pilot manufacturing / process, analytical methods offering alternative pathways to clinical trials, formulation development, metering valve technology and more.

The result of Aptar's study is designed to provide the FDA with information related to the formulation, manufacture, device design and quality aspects related to low-GWP propellant MDIs and their utility to replace existing propellant MDIs. Moreover, the study is expected to support the ongoing FDA efforts to provide guidance on the regulatory framework with respect to the evaluation and approval of low-GWP propellant MDIs. The results of the study will be reviewed and discussed with the agency as detailed case studies, which can then be published as scientific publications and conference presentations.

Guillaume Brouet, VP of Aptar Pharma Analytical Regulatory and Scientific Affairs, said, "Our leading OINDP research company, Nanopharm, alongside with our pharma segment's research and development team, is delighted to support the FDA on this important study to better define the design space for developing low-GWP MDIs with equivalent performance to existing propellant MDIs."

The contracted work, including "optional contract line items", is valued at up to approximately \$6 million.

About Aptar

Aptar Pharma is part of AptarGroup, Inc., a global leader in drug and consumer product dosing, dispensing and protection technologies. Aptar serves a number of attractive end markets including pharmaceutical, beauty, food, beverage, personal care and home care. Aptar Pharma's analytical, laboratory and regulatory services add value at every stage of the drug development process, accelerating and de-risking the program along the way. Nanopharm Ltd., an Aptar Pharma company, is a leading provider of specialized analytical and product development services, with a focus on orally inhaled and nasal drug products. Aptar is headquartered in Crystal Lake, Illinois and has 13,500 dedicated employees in 20 countries. For more information, visit www.aptar.com.

This press release contains forward-looking statements, including regarding the outcome and value of the Aptar Pharma/Nanopharm study. Words such as "expects," "anticipates," "believes," "estimates," "future," "potential," "continues" and other similar expressions or future or conditional verbs such as "will," "should," "would" and "could" are intended to identify such forwardlooking statements. Forward-looking statements are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and are based on our beliefs as well as assumptions made by and information currently available to us. Accordingly, our actual results or other events may differ materially from those expressed or implied in such forward-looking statements due to known or unknown risks and uncertainties that exist in our operations and business environment including, but not limited to: the successful integration of acquisitions; the regulatory environment; and competition, including technological advances. For additional information on these and other risks and uncertainties, please see our filings with the Securities and Exchange Commission, including the discussion under "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Forms 10-K and Forms 10-Q. We undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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