



## **Aptar's Nasal Unidose Device Approved by US FDA for First Needle-Free Rescue Treatment for Severe Hypoglycemia**

Crystal Lake, Illinois, July 25, 2019 – AptarGroup, Inc. (NYSE: ATR), a global leader in dispensing and drug delivery solutions, today announced that its Unidose Powder System was recently approved by the U.S. Food and Drug Administration (FDA) for an intranasal, needle-free rescue treatment drug intended to treat severe hypoglycemia in people with diabetes. This marks the first FDA approval of a prescription drug using Aptar's patented Unidose Powder System and is Aptar's first combination of a drug delivery device with a protective active packaging container.



Photo : Courtesy of Aptar

This approval again demonstrates Aptar's expertise in developing patient-friendly drug delivery solutions for breakthrough medicines. Aptar offers a broad portfolio of innovative technologies and wide array of services to meet the highest quality standards of the pharmaceutical industry.

### **Solution for Nasally Administered Powder Treatments**

Aptar's Unidose Powder System is a single-use, ready-to-use one-step nasal delivery device which can deliver a powder formulation in an emergency situation quickly and easily. During such an event, the patient or caregiver presses a small plunger on the bottom of the device to release the drug in a single powder puff into the nose, where the drug can be quickly absorbed via the nasal mucosa. Aptar's Unidose Powder System is an alternative to injectable kits that may require assembly, including a multistep, time-consuming process of mixing powder and liquid.

### **Patented Unidose and Bidose Technology Platforms**

Aptar's Unidose and Bidose platforms are robust, primeless, and easy-to-use systems with 360° functionality and precise nasal drug delivery. They offer biotech and pharmaceutical companies effective and reliable single or two-shot intranasal delivery for a variety of medicines including potential life-saving drugs and treatments of severe conditions. The devices can also integrate wireless connectivity technologies.

## **Unidose Device Protected by Aptar's Integrated Active Packaging Container**

This is the first approval and customer launch combining the technologies of Aptar Pharma and Aptar CSP Technologies. The novel container, which protects and stores the Unidose Powder System, was developed by Aptar CSP Technologies, the global material science unit of Aptar, providing innovative, highly engineered advanced active packaging solutions that protect sensitive drug products. The container incorporates Aptar's three phase Activ-Polymer™ technology which ensures extended moisture protection for the shelf-life of the drug, mitigating the impact of changing environmental conditions associated with temperature and relative humidity.

## **Accelerated Development Support via Aptar Pharma Services**

This innovative therapy in the field of diabetes is an example of a Combination Product submission, and benefited from Aptar Pharma's Services offering, a comprehensive portfolio of stage-specific development packages. Aptar's dedicated Regulatory Affairs experts and analytical scientists help customers proactively address regulatory needs to accelerate approval.

"We are pleased to announce that Aptar Pharma's Unidose Powder System has been approved by the FDA for the first intranasally-delivered, needle-free rescue treatment for severe hypoglycemia that provides a more patient-friendly delivery approach. Our active packaging container helps to protect the device and better ensure its quality until the moment of use," commented Gael Touya, President, Aptar Pharma. "This project marks a nearly 10-year customer collaboration and once again demonstrates Aptar Pharma's ability to help our customers develop and launch complex treatments with patient-friendly delivery systems worldwide."

Stephan Tanda, Aptar's President and CEO added, "This successful approval confirms the value that we are bringing to our customers in the highly competitive pharmaceutical and biotech industries. With decades of experience in the long-term testing and development phases that are required by regulatory agencies, we are building a stronger solutions platform for the future, and this launch is a glimpse of that future. Our lab and analytic service capabilities combined with our unique drug delivery devices and active packaging solutions create tremendous value for our customers and help them secure approval. The ultimate end result is that we help expand access to life-saving treatments with our patient-friendly systems."

## **About Aptar**

Aptar Pharma and Aptar CSP Technologies are part of AptarGroup, Inc. Aptar is a leading global supplier of a broad range of innovative dispensing, sealing and active packaging solutions for the beauty, personal care, home care, prescription drug, consumer health care,

injectables, food and beverage markets. Aptar uses insights, design, engineering and science to create innovative packaging technologies that build brand value for its customers, and, in turn, make a meaningful difference in the lives, looks, health and homes of people around the world. Aptar is headquartered in Crystal Lake, Illinois and has over 14,000 dedicated employees in 18 different countries. For more information, visit [www.aptar.com/pharma](http://www.aptar.com/pharma) and [www.csptechnologies.com](http://www.csptechnologies.com).

*This press release contains forward-looking statements. Words such as "future" and other similar expressions or future or conditional verbs such as "will" are intended to identify such forward-looking 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 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 Form 10-Ks and Form 10-Qs. We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.*

# # #

**Investor Relations Contact:**

Matt DellaMaria

AptarGroup, Inc.

+1 815 477 0424

[matt.dellamaria@aptar.com](mailto:matt.dellamaria@aptar.com)

**Media Contact:**

Aptar Pharma

Carolyn Penot

+33 1 39 17 20 38

[carolyn.penot@aptar.com](mailto:carolyn.penot@aptar.com)