



NEWS RELEASE

# First Nasally-Administered Pharmaceutical Treatment for Dry Eye Disease Approved by US FDA with Aptar's Nasal Pump System

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CRYSTAL LAKE, Ill.--(BUSINESS WIRE)-- AptarGroup, Inc. (NYSE:ATR), a global leader in drug delivery, consumer product dispensing and active material science solutions, today announced that its patented Cartridge Pump System (CPS), designed for the multidose delivery of preserved and non-preserved drug formulations, was recently reviewed by the U.S. FDA as the drug delivery device in the approval of Oyster Point Pharma's TYRVAYA™ (varenicline solution) Nasal Spray 0.03 mg/1, the first and only nasal spray approved for the treatment of the signs and symptoms of dry eye disease.

TYRVAYA™ Nasal Spray delivered using Aptar Pharma's CPS Nasal Pump System

TYRVAYA™, a highly selective cholinergic agonist, is the first

nasally-administered pharmaceutical therapy to treat the signs and symptoms of dry eye disease to have been approved by the U.S. FDA.

This approval makes Aptar's Cartridge Pump System a key component of the first and only U.S. FDA-approved pharmaceutical therapy to deliver treatment for the signs and symptoms of dry eye disease, an ophthalmic condition, via the nasal route and re-confirms Aptar's expertise for developing innovative drug delivery solutions.

Stephan B. Tanda, Aptar's President and CEO stated, "This approval further demonstrates the broad potential for Aptar's drug delivery solutions and the continued market opportunities for nasal drug delivery. We are pleased that our proven CPS nasal system is now a multidose delivery option for patients suffering from dry eye disease."

**About Dry Eye Disease**



Dry eye disease is a multifactorial chronic disease of the ocular surface characterized by a loss of homeostasis of the tear film, resulting in a multitude of symptoms. More than 340 million adults globally and approximately 38 million adults in the United States are estimated to suffer from dry eye disease.<sup>2,3</sup>

## Solution for Nasally Administered Treatments

Aptar Pharma's innovative, multidose Cartridge Pump System (CPS) is the result of over 15 years of development and experience in the delivery of preserved and unpreserved nasal formulations. Specifically designed to enable reliable, exact dosing and targeted medication delivery to the nasal mucosa, the versatile CPS Technology Platform is used for nasal drug delivery across a wide range of medical applications such as allergic rhinitis, pain, CNS as well as intra-nasal vaccination.

## Accelerated Drug Development Support via Aptar Pharma Services

The effort to bring TYRVAYA™ Nasal Spray to market included a Combination Product submission by Oyster Point Pharma to the FDA, which benefited from Aptar Pharma's Services offering - a comprehensive portfolio of stage-specific development packages. Aptar Pharma's dedicated Regulatory Affairs professionals and analytical scientists help customers proactively address regulatory needs to accelerate approval.

"We are pleased that Aptar Pharma's CPS Technology has been successfully reviewed by the U.S. FDA for Oyster Point Pharma's therapy for the treatment of the signs and symptoms of dry eye disease via the nose," said Gael Touya, President, Aptar Pharma. "This project once again underlines Aptar Pharma's ability to develop and deliver complex drug delivery systems, and demonstrates our expertise in partnering with customers through their successful drug development journeys."

## About Aptar

Aptar is a global leader in the design and manufacturing of a broad range of drug delivery, consumer product dispensing and active material science solutions. Aptar's innovative solutions and services serve a variety of end markets including pharmaceutical, beauty, personal care, home, food and beverage. Using insights, proprietary design, engineering and science to create dispensing, dosing and protective packaging technologies for many of the world's leading brands, Aptar in turn makes a meaningful difference in the lives, looks, health and homes of millions of patients and consumers around the world. Aptar is headquartered in Crystal Lake, Illinois and has 13,000 dedicated employees in 20 countries. For more information, visit [www.aptar.com](http://www.aptar.com).

This press release contains forward-looking statements. 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.

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1 TYRVAYA™ and the TYRVAYA logo are trademarks of Oyster Point Pharma, Inc. For further information visit [www.tyrvaya.com](http://www.tyrvaya.com).

2 Market Scope 2016 Dry Eye Products Report: A Global Market Analysis for 2015 to 2021

3 Paulsen AJ, Cruickshanks KJ, Fischer ME, Huang GH, Klein BE, Klein R, Dalton DS. Dry eye in the beaver dam offspring study: prevalence, risk factors, and health-related quality of life. *American Journal of Ophthalmology*. 2014 Apr;157(4):799-806.

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