



## Oyster Point Pharma to Present Analyses at the Women in Ophthalmology Summer Symposium

August 25, 2022

PRINCETON, N.J., Aug. 25, 2022 (GLOBE NEWSWIRE) -- Oyster Point Pharma, Inc. (Nasdaq: OYST), a commercial-stage biopharmaceutical company focused on the discovery, development, and commercialization of first-in-class pharmaceutical therapies to treat ophthalmic diseases, today announced the presentation of analyses at the Women in Ophthalmology (WIO) Summer Symposium, which is taking place in Monterey, California from August 25-28, 2022.

"We look forward to this year's WIO Summer Symposium, a curated meeting for women offering content in all subjects of importance to women ophthalmologists," said Marian Macsai, MD chief medical officer, Oyster Point Pharma. "Collectively, the TYRVAYA<sup>®</sup> data we're presenting show consistency in treatment effect with a favorable tolerability and safety profile for people living with dry eye disease, a condition that is more common in women."

### Details for the Oyster Point New Data Presentations are below:

**Title:** Fellow Eye Outcomes with Pharmacologic Neuro-Activator Nasal Spray in Dry Eye Disease: ONSET-1 & ONSET-2 Studies

**Authors:** Laura Periman, MD and Sathi Maiti, OD

**Date/Time:** Friday, August 26, 11:15 AM - 12:15 PM PDT

**Title:** OC-01 (varenicline solution) Nasal Spray for the Treatment of Dry Eye Disease Signs and Symptoms in Subjects with Autoimmune Disease: Integrated Data from ONSET-1 and ONSET-2

**Author:** Julie Schallhorn, MD, MS

**Date/Time:** Friday, August 26, 11:15 AM - 12:15 PM PDT

**Title:** Evaluation of OC-01 (varenicline solution) Nasal Spray 0.03mg Effectiveness Based on Menopausal Status: Post-hoc Analysis of ONSET-1 and ONSET-2 Clinical Trials

**Author:** Dagny Zhu, MD

**Date/Time:** Saturday, August 27, 9:10 - 9:55 AM PDT

### About Oyster Point Pharma

Oyster Point Pharma is a commercial-stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class pharmaceutical therapies to treat ophthalmic diseases. In October 2021, Oyster Point Pharma received FDA-approval for TYRVAYA<sup>®</sup> (varenicline solution) Nasal Spray for the treatment of the signs and symptoms of dry eye disease. Oyster Point has a growing pipeline of clinical and pre-clinical programs and continues to expand its research and development pipeline through internal innovation and external collaborations. Oyster Point is continuously striving to advance breakthrough science and deliver therapies seeking to address the unmet needs of patients with ophthalmic disease and the eye care professionals who take care of them. For more information, visit [www.oysterpointrx.com](http://www.oysterpointrx.com) and follow @OysterPointRx [Twitter](#) and [LinkedIn](#).

### About TYRVAYA<sup>®</sup> (varenicline solution) Nasal Spray

TYRVAYA<sup>®</sup> (varenicline solution) Nasal Spray 0.03 mg is a highly selective cholinergic agonist that is FDA-approved to treat the signs and symptoms of dry eye disease as a multidose nasal spray. The parasympathetic nervous system, the "rest and digest" system of the body, controls tear film homeostasis partially via the trigeminal nerve, which is accessible within the nose. The efficacy of TYRVAYA Nasal Spray in dry eye disease is believed to be the result of varenicline's activity at heteromeric sub-type(s) of the nicotinic acetylcholine (nACh) receptor where its binding produces agonist activity and activates the trigeminal parasympathetic pathway resulting in increased production of basal tear film as a treatment for dry eye disease. Varenicline binds with high affinity and selectivity at human  $\alpha 4\beta 2$ ,  $\alpha 4\alpha 6\beta 2$ ,  $\alpha 3\beta 4$ ,  $\alpha 3\alpha 5\beta 4$  and  $\alpha 7$  neuronal nicotinic acetylcholine receptors. The exact mechanism of action is unknown at this time.

### TYRVAYA<sup>®</sup> Important Safety Information

The most common adverse reaction reported in 82% of patients was sneezing. Events that were reported in 5-16% of patients were cough, throat irritation, and instillation-site (nose) irritation. There are no contraindications associated with TYRVAYA<sup>®</sup> (varenicline solution) Nasal Spray. Please see full Prescribing Information at [www.tyrvaya-pro.com/prescribinginformation](http://www.tyrvaya-pro.com/prescribinginformation).

### About Dry Eye Disease and the Role of Tear Film

Dry eye disease is a chronic condition that impacts an estimated 38 million people in the U.S. and is growing in prevalence.<sup>1,2</sup> It can cause persistent stinging, scratching, burning sensations, sensitivity to light, blurred vision, and eye fatigue. Dry eye disease is a multifactorial disease of the ocular surface characterized by disruption of the tear film. Human tear film is a complex mixture of more than 1,500 different proteins, including growth factors and antibodies, as well as numerous classes of lipids and mucins.<sup>3</sup> Natural tear film protects and lubricates the eyes, washes away foreign particles, contains growth factors and antimicrobial components, and creates a smooth surface that forms the primary refractive surface of the eye.

### Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding the future of the Company's business, the Company's future plans and strategies, commercial opportunities, interactions with regulators, regulatory approvals, preclinical and clinical results, future financial condition, the

timing of preclinical and clinical trials, including data from such trials and other expected milestones, the timing of insurance coverage determinations for TYRVAYA Nasal Spray and the potential therapeutic and clinical benefits of the Company's product candidates and other future conditions. The words "if approved," "may," "will," "should," "would," "expect," "plan," "pipeline," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The reader is cautioned not to rely on these forward-looking statements. All forward-looking statements contained in this press release are based on current expectations and assumptions of the Company, and are subject to a number of risks, uncertainties and assumptions, including, among other things: the Company's plans and potential for success relating to commercializing TYRVAYA, and the availability and sufficiency of third-party payor coverage and reimbursement in connection with TYRVAYA; the Company's estimates associated with the Company's plan to streamline operating expenses, including the associated reduction in force, and any resulting savings benefits the Company expects to achieve; the beneficial characteristics, safety, efficacy and therapeutic effects of TYRVAYA and the Company's preclinical and clinical product candidates; the Company's plans relating to the further development and manufacturing of TYRVAYA and its preclinical and clinical candidates, including potential additional indications or disease areas to be evaluated and pursued; the timing of initiation of the Company's future preclinical studies or clinical trials; the uncertainties inherent in pharmaceutical research and development, including the likelihood of positive preclinical study results, and the likelihood of clinical trials demonstrating the safety and efficacy of the Company's product or product candidates; the timing or likelihood of regulatory filings and approvals of TYRVAYA and our clinical and preclinical candidates, including in potential additional indications for TYRVAYA and potential filings in additional jurisdictions; the prevalence of dry eye disease and Neurotrophic Keratopathy (NK) and the size of the market opportunities for the Company's product candidates; the expected potential benefits of strategic collaborations with third parties and the Company's ability to attract collaborators with development, regulatory and commercialization expertise; existing regulations and regulatory developments in the United States and other jurisdictions; the Company's plans and ability to obtain or protect intellectual property rights throughout the world, including extensions of existing patent terms where available; the Company's continued reliance on third parties to conduct additional preclinical studies and clinical trials of its product candidates, and for the manufacture of its product and product candidates; economic factors, such as interest rate and currency exchange rate fluctuations; manufacturing difficulties or delays, internally or within the supply chain; product efficacy or safety concerns resulting in product recalls or regulatory action; financial instability of international economies and legal systems and sovereign risk; risks related to the impact of the COVID-19 global pandemic, such as the scope and duration of the outbreak, government actions and restrictive measures implemented in response, material delays and cancellations of medical procedures, supply chain disruptions and other impacts to the business, or on the Company's ability to execute business continuity plans, as a result of the COVID-19 pandemic; the Company's ability to recruit and retain key personnel needed to develop and commercialize its product and product candidates, and to grow the Company; the accuracy of the Company's estimates regarding expenses, future revenue, capital requirements and needs for additional financing; the Company's financial performance; market conditions; the sufficiency of the Company's existing capital resources to fund its future operating expenses and capital expenditure requirements; and the Company's expectations regarding the period during which it will qualify as an emerging growth company under the JOBS Act. A further list and descriptions of these risks, uncertainties and other factors can be found in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, including in the sections captioned "Special Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the Company's subsequent Quarterly Reports on Form 10-Q and other filings that it makes with the Securities and Exchange Commission from time to time. Copies of these filings are available online at [www.oysterpointrx.com](http://www.oysterpointrx.com). Any forward-looking statement made in this press release speaks only as of the date of this release. The Company does not undertake to update any forward-looking statement as a result of new information or future events or developments, except as required by law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

#### References:

1. Wirta, D., Vollmer, P., Paauw, J., Chiu, K. H., Henry, E., Striffler, K., ... & ONSET-2 Study Group. (2021). Efficacy and Safety of OC-01 (Varenicline) Nasal Spray on Signs and Symptoms of Dry Eye Disease: the ONSET-2 Phase 3, Randomized Trial. *Ophthalmology*. <https://doi.org/10.1016/j.ophtha.2021.11.004>
2. Market-Scope. 2020 Dry Eye Products Report: A Global Market Analysis for 2019 to 2025. October 2020.
3. Tsubota K, Pflugfelder S, Liu Z, Baudouin C. Defining dry eye from a clinical perspective. *Int J Mol Sci*. 2020;21(23):1-24. <https://pubmed.ncbi.nlm.nih.gov/33291796/>

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