



## Oyster Point Pharma to Present New Scientific Analyses at World Cornea Congress VIII

September 27, 2022

### Two Featured Presentations will Include a Post-Hoc Analysis of TYRVAYA® (varenicline solution) Nasal Spray and Tear Film Cytokine Research

PRINCETON, N.J., Sept. 27, 2022 (GLOBE NEWSWIRE) -- Oyster Point Pharma, Inc. (Nasdaq: OYST), ("Oyster Point Pharma", or "the Company"), a commercial-stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class pharmaceutical therapies to treat ophthalmic diseases, today announced it will present new scientific analyses at World Cornea Congress VIII, which is taking place in Chicago, Illinois from September 28-29, 2022.

"We look forward to presenting our post-hoc analyses on the clinical benefits of TYRVAYA® (varenicline solution) Nasal Spray as well as the results of evaluating inflammatory cytokine levels in tears in healthy and dry eye disease patients at this year's World Cornea Congress, an event that highlights the progress that has been made in both clinical and research endeavors of the international cornea community," said Marian Macsai, MD chief medical officer, Oyster Point Pharma.

Two of the four scientific analyses will be featured paper presentations, including analyses comparing the levels of inflammatory cytokines in the tear film in relation to the presenting signs and symptoms scores in patients with and without dry eye disease. A second paper presentation will feature a post-hoc analysis from clinical trials of OC-01 (varenicline solution) nasal spray analyzing its efficacy in patients with and without antidepressant/anti-anxiety agent use.

"It is important to identify the underlying causes of tear film disruption in dry eye disease in order to target treatment efforts," said Francis Mah, MD. "We studied the amount of basal tear film and its impact on inflammatory cytokines in healthy and dry eye disease patients to evaluate the possible influence of increased basal tear production on tear cytokine concentrations. We are excited to share the results of our study at World Cornea Congress."

"Antidepressants and anti-anxiety agents can have anticholinergic side effects that may reduce tear production. <sup>1-4</sup> As such, we analyzed the efficacy of TYRVAYA for the treatment of dry eye disease in patients with and without systemic antidepressant/anti-anxiety agent use," said Christopher E. Starr, MD, FACS. "I am encouraged by the results of our research and look forward to presenting this featured paper presentation at World Cornea Congress."

#### The Following are Details for Featured Paper Presentations:

**Title:** Pro and Anti-Inflammatory Cytokine Levels in Tears of Dry Eye Subjects

**Authors:** Francis Mah, MD; Marian Macsai, MD; Puja Shah, OD; Laura Hendrix, MS; Eric Carlson, PhD

**Date/Time:** Wednesday, September 28, 4:00 – 5:30 PM CDT

**Title:** Efficacy of OC-01 (varenicline solution) 0.03mg for Treatment of Dry Eye Disease Signs and Symptoms in Subjects with and without Antidepressant/Anxiolytic Use: Post-hoc Analysis of ONSET-1 and ONSET-2 Clinical Trials

**Authors:** Christopher Starr, MD, FACS; Andrea Gibson, PhD; Gretchen Blemker, OD; Laura Hendrix, MS

**Date/Time:** Thursday, September 29, 10:30 AM – 12:00 PM CDT

#### The Following are Details for Poster Presentations via Electronic Portal:

**Title:** Efficacy of OC-01 (varenicline solution) 0.03 mg for Treatment of Dry Eye Disease Signs and Symptoms in Subjects with and without Systemic Anticholinergic Use: Post-hoc Analysis of ONSET-1 and ONSET-2 Clinical Trials

**Authors:** Brent Kramer MD, Terry Kim MD, Laura Hendrix MS, Marian Macsai MD, and Andrea Gibson PhD

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

**Authors:** Lisa Nijm, MD, JD; Andrea Gibson, PhD; Gretchen Blemker, OD; Laura Hendrix, MS

#### 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 (varenicline solution) Nasal Spray for the treatment of the signs and symptoms of dry eye disease. Oyster Point Pharma 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 Pharma 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](https://twitter.com/OysterPointRx) and [LinkedIn](https://www.linkedin.com/company/oysterpointrx).

#### About TYRVAYA® (varenicline solution) Nasal Spray

TYRVAYA (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® 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 (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>5,6</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>7</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.oysterpointx.com](http://www.oysterpointx.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. Vehof J, Snieder H, Jansonius N, Hammond CJ. Prevalence and risk factors of dry eye in 79,866 participants of the population-based Lifelines cohort study in the Netherlands. *Ocul Surf.* 2021;19:83-93. Doi:10.1016/j.jtos.2020.04.005
2. Dankis M, Aydogdu O, Tobin G, Winder M. Acute Inhibitory Effects of Antidepressants on Lacrimal Gland Secretion in the Anesthetized Rat. *Invest Ophthalmol Vis Sci.* 2021;62(7):8. doi:10.1167/iovs.62.7.8
3. Askeroglu U, Alleyne B, Guyuron B. Pharmaceutical and herbal products that may contribute to dry eyes. *Plast Reconstr Surg* 2013;131(1):159-167.
4. Dana R, Bradley JL, Guerin A, Pivneva I, Evans AM, Stillman IÖ. Comorbidities and Prescribed Medications in Patients With or Without Dry Eye Disease: A Population-Based Study. *Am J Ophthalmol.* 2019;198:181-192.

doi:10.1016/j.ajo.2018.10.001

5. 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>
6. Market-Scope. 2020 Dry Eye Products Report: A Global Market Analysis for 2019 to 2025. October 2020.
7. 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/>

**Investor Contact**

Arty Ahmed  
(646) 436-4702  
aahmed@oysterpointrx.com

**Media Contact**

Karen Castillo-Paff  
(347) 920-0248  
kpaff@oysterpointrx.com