Oyster Point Pharma Announces Publication in Ophthalmology of ONSET-2 Phase 3 Data on TYRVAYA™ (varenicline solution) Nasal Spray

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PRINCETON, N.J., Nov. 15, 2021 (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 that results from the multicenter, randomized, double-masked, vehicle-controlled Phase 3 clinical trial (The ONSET-2 study) of TYRVAYA™ Nasal Spray (varenicline solution) have been published in *Ophthalmology.*[1] 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.

“This Phase 3 study of TYRVAYA nasal spray shows consistent outcomes as compared to the ONSET-1 Phase 2b trial. These results show clinically meaningful improvements in basal tear film production,” said Jeffrey Nau, Ph.D., MMS, President and Chief Executive Officer of Oyster Point Pharma. Dr. Nau continued, "These results are notable as TYRVAYA is the first and only cholinergic agonist nasal spray approved by the FDA to treat patients with the signs and symptoms of dry eye disease, leveraging this novel mechanism of action of activating the trigeminal parasympathetic pathway.”

About ONSET-2 Study
The ONSET-2 Phase 3 pivotal clinical study was a multicenter, randomized, double-masked, vehicle-controlled trial in adult subjects at least 22 years of age with dry eye disease in the U.S. The main eligibility criteria for the studies included a physician’s diagnosis of dry eye disease, a baseline Schirmer’s Score of ≤10 mm. Patients could have an Eye Dryness Score from 0-100 mm (visual analog scale). TYRVAYA ™ Nasal Spray was administered as a single spray into each nostril twice-daily. The primary and key secondary endpoints, including improvement in Schirmer’s Score and Eye Dryness Score (EDS) as compared to vehicle control, were measured at Day 28. The ONSET-2 study of TRYVAYA Nasal Spray enrolled a broad population of mild, moderate, and severe dry eye disease subjects, as measured by Eye Dryness Score at baseline (range 2-100 mm).

About TYRVAYA™ (varenicline solution) Nasal Spray
TYRVAYA (varenicline solution) Nasal Spray 0.03 mg (formerly referred to as OC-01) 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 α4β2, α4α6β2, α3β4, α3α5β4 and α7 neuronal nicotinic acetylcholine receptors. The exact mechanism of action is unknown at this time. 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.

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.[2,3] 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.[4] 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.

About Oyster Point Pharma, Inc.
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 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 and follow @OysterPointRx on Twitter and LinkedIn.

Forward-Looking Statements
This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 that reflect the current beliefs, expectations and assumptions of Oyster Point Pharma, Inc. (the “Company,” “we” or “our”) regarding the future of the Company’s business, our future plans and strategies, regulatory approvals, preclinical and clinical results, future financial condition and other future conditions. All statements other than statements of historical facts contained in this press release, including express or implied statements regarding future results of operations and financial position, business strategy, product candidates, regulatory approvals, expected research and development costs, planned preclinical studies and clinical trials, expected results of preclinical studies or clinical trials, and their timing and likelihood of success, expected research and development costs, as well as plans and objectives of management for future operations, are forward-looking statements. The words "if approved," “may,” “will,” “should,” “would,” “expect,” “plan,” “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. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: our plans and potential for success relating to commercializing TYRVAYA; the beneficial

characteristics, safety, efficacy and therapeutic effects of TYRVAYA and our preclinical and clinical product candidates; our plans relating to the further development and manufacturing of TYRVAYA and our preclinical and clinical candidates, including potential additional indications or disease areas to be evaluated and pursued; the timing of initiation of our future preclinical studies or clinical trials; the uncertainties inherent in pharmaceutical research and development, including preclinical study and clinical trial results and additional analysis of existing data; the likelihood of clinical trials demonstrating safety and efficacy of our product candidates, and other positive results; 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 our product candidates; the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory and commercialization expertise; existing regulations and regulatory developments in the United States and other jurisdictions; our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available; our continued reliance on third parties to conduct additional preclinical studies and clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials, and potentially for commercial supply; our ability to recruit and retain key personnel needed to develop and commercialize our product candidates, if approved, and to grow our company; the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; our financial performance; market conditions; the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements; our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and other risks described in the “Risk Factors” section included in our public filings that we have made and will make with the Securities and Exchange Commission (SEC).

Reference:

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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/
4. Willcox, M. D., Argüeso, P., Georgiev, G. A., Holopainen, J. M., Laurie, G. W., Millar, T. J., ... & Jones, L. (2017). TFOS DEWS II tear film report. *The ocular surface*, *15*(3), 366-403.

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