Oyster Point Pharma to Present New Clinical Data at the American Society of Cataract and Refractive Surgery (ASCRS) 2022

April 19, 2022

PRINCETON, N.J., April 19, 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 data analyses at the American Society of Cataract and Refractive Surgery (ASCRS), being held on April 22-26.

“The data we’re presenting at ASCRS, the largest meeting of anterior segment surgeons, underscores Oyster Point Pharma’s commitment to improving the care for people suffering with dry eye disease, a chronic condition that impacts an estimated 38 million people in the U.S.,” said Marian Macsai, MD chief medical officer, Oyster Point Pharma. “We are pleased to share a number of data presentations from company-sponsored clinical trials at this year’s meeting highlighting the recently approved TYRVAYA ® (varenicline solution) Nasal Spray for the treatment of the signs and symptoms of dry eye disease and its potential benefits to broader patient populations.”

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: James Katz, MD, Mandy Hemphill, PhD, Andrea Gibson, PhD, Alan Kabat, OD, Laura Hendrix, MS
Date/Time: Friday, April 22, 2022
Location: Washington, DC – ASCRS Education Hub

Title: Symptom Score in Dry Eye Patients Exposed to Controlled Adverse Environment Following Treatment with OC-01/OC-02: Onset-1 and Pearl
Authors: Mark Milner, MD, Andrea Gibson, PhD, Puja Shah, OD, Laura Hendrix, MS
Date/Time: Friday, April 22, 2022
Location: ASC Washington, DC – ASCRS Education Hub

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 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 Twitter and LinkedIn.

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 α4β2, α4α6β2, α3β4, α3α5β4 and α7 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.

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.[1,2] 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.[3] 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 that reflect the current beliefs, expectations and assumptions of Oyster Point Pharma, Inc. regarding the future of the Company’s business, our future plans and strategies, commercial opportunities, regulatory approvals, preclinical and clinical results, future financial condition and other future conditions. Words such as “may,” “will,” “expect,” “potential” 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 the likelihood of positive preclinical study results, and the likelihood of clinical trials demonstrating the safety and efficacy of our 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 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 and product candidates; our ability to recruit and retain key personnel needed to develop and commercialize our product and product candidates, 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).

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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