Oyster Point Pharma Announces FDA Acceptance for Filing New Drug Application for OC-01 (varenicline) Nasal Spray for the Treatment of Signs and Symptoms of Dry Eye Disease

March 2, 2021

- *Prescription Drug User Fee Act (PDUFA) target action date is October 17, 2021*
- *U.S. Food and Drug Administration (FDA) has stated that it does not intend to hold an advisory committee meeting to discuss this application*
- *Planned U.S. launch of OC-01 (varenicline) nasal spray in fourth quarter of 2021, if approved by the FDA*

PRINCETON, N.J., March 02, 2021 (GLOBE NEWSWIRE) -- Oyster Point Pharma, Inc. (Nasdaq: OYST), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class pharmaceutical therapies to treat ocular surface diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) for OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease. The Prescription Drug User Fee Act (PDUFA) target action date for OC-01 (varenicline) nasal spray is October 17, 2021. At present, FDA has stated that it does not intend to hold an advisory committee meeting to discuss this application.

The NDA submission was supported by safety and efficacy results from the Phase 3 ONSET-2, Phase 2b ONSET-1, and Phase 2 MYSTIC clinical trials in over 1,000 subjects with mild, moderate or severe symptoms of dry eye disease. In these clinical trials, OC-01 (varenicline) nasal spray demonstrated statistically significant improvements, as compared to control, in Schirmer's Score (an objective, reproducible, and quantifiable measure of natural tear film production), which was the primary endpoint in all trials. Key secondary endpoints in ONSET-1 and ONSET-2 included change from baseline in symptoms as assessed by eye dryness score. In both of these pivotal trials, there was statistically or nominally statistically significant improvement in symptom scores at Day 28, and in ONSET-2 as early as Day 14, in patients treated with OC-01 (varenicline) nasal spray as compared to control. All doses studied in the clinical trial program were well-tolerated with no serious drug related adverse events.

"The FDA acceptance of our NDA for OC-01 (varenicline) nasal spray represents a major milestone towards our goal of bringing novel and potentially transformational therapies to patients with ocular surface diseases," said Jeffrey Nau, Ph.D., M.M.S., president and CEO of Oyster Point Pharma. "We look forward to continued interaction with the FDA during the review."

About OC-01 (varenicline) Nasal Spray
OC-01 (varenicline) nasal spray is a highly selective cholinergic agonist being developed as a multidose preservative-free nasal spray to treat the signs and symptoms of dry eye disease. 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. Administered as a preservative-free, aqueous nasal spray, in pre-clinical and clinical studies, OC-01 (varenicline) nasal spray was shown to have a novel mechanism of action with activation of the trigeminal parasympathetic pathway in the nasal cavity to stimulate natural tear film production. 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. This complex tear film is responsible for forming the primary refracting surface of the cornea, as well as protecting and moisturizing the cornea. OC-01 (varenicline) nasal spray is an investigational new drug and has not been approved for any use in any country. The safety and efficacy of OC-01 (varenicline) nasal spray have not previously been established.

About Dry Eye Disease
Dry eye disease is a chronic, progressive condition that impacts more than 30 million people in the United States and is growing in prevalence. An estimated 16 million adults in the U.S. have been diagnosed with dry eye disease, a multifactorial condition of the ocular surface characterized by disruption of the tear film. A healthy tear film protects and lubricates the eyes, washes away foreign particles, contains growth factors and antimicrobial components to reduce the risk of infection, and creates a smooth surface that contributes refractive power for clear vision. Dry eye disease can have a significant impact on a person's day-to-day quality of life, as it can cause persistent stinging, scratching, burning sensations, sensitivity to light, blurred vision and eye fatigue. Despite the large prevalence of dry eye and the burden of the disease, there remains a significant unmet need for effective therapies.

About Oyster Point Pharma, Inc.

Oyster Point Pharma is a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of first-in-class pharmaceutical therapies to treat ocular surface diseases. Oyster Point Pharma's lead product candidate, OC-01 (varenicline) nasal spray, a highly selective cholinergic agonist, is being developed as a nasal spray to treat the signs and symptoms of dry eye disease. In pre-clinical and clinical studies, OC-01 (varenicline) nasal spray was shown to have a novel mechanism of action via activation of the trigeminal parasympathetic pathway to stimulate the glands and cells responsible for natural tear film production, known as the lacrimal functional unit. 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 the "Company regarding the future of the Company's business, its future plans and strategies, regulatory approvals and clinical results. All statements other than statements of historical facts contained in this press release, including express or

implied statements regarding business strategy, product candidates, regulatory approvals, planned preclinical studies and clinical trials, expected results of clinical trials, and their timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. The words “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: the timing or likelihood of regulatory filings and approvals for our product candidates; our ability to obtain and maintain regulatory approvals of our product candidates; our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy; the success of competing therapies that are or may become available; the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates; our plans relating to the further development and manufacturing of our product candidates, including the size, number and additional indications or disease areas to be evaluated and pursued; the impact of the COVID-19 pandemic on our business, operations, and regulatory and clinical development timelines, plans and expectations; the size of the market opportunities and prevalence of dry eye disease and Neurotrophic Keratopathy (NK) for our product candidates, the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates, and other positive results; the timing of initiation of our future clinical trials, and the reporting of data from our current and future trials; 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 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; 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). The Company is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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