Oyster Point Pharma Announces Enrollment of First Subject in the OLYMPIA Phase 2 Clinical Trial of OC-01 (varenicline) Nasal Spray for Patients with Neurotrophic Keratopathy

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PRINCETON, N.J., June 21, 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 therapies to treat ophthalmic diseases, today announced enrollment of the first subject in the OLYMPIA Phase 2 clinical trial of OC-01 (varenicline) nasal spray for the treatment of Stage 1 Neurotrophic Keratopathy (NK).

“This is an exciting milestone as we continue to develop this potentially new treatment option for patients with Stage 1 Neurotrophic Keratopathy,” said Jeffrey Nau, Ph.D., MMS, president and chief executive officer of Oyster Point Pharma. “We believe that NK affects more patients than are currently diagnosed as the disease has the potential to be undiagnosed or misdiagnosed. Stage 1 NK patients may present with additional ocular surface issues, including dry eye disease, which affects 38 million[1] patients.”

The OLYMPIA Phase 2 study is a multicenter, randomized, double-masked, placebo-controlled clinical trial to evaluate the safety and efficacy of OC-01 (varenicline) nasal spray in subjects with Mackie’s Classification Stage 1 Neurotrophic Keratopathy. The study is expected to enroll approximately 100 subjects at approximately 18 U.S. sites. In this clinical trial, OC-01 (varenicline) nasal spray will be administered three times a day, as compared to placebo (vehicle) nasal spray. The pre-specified primary endpoint of the trial will be the percentage of subjects who achieve complete resolution of fluorescein corneal staining at Day 56.

“NK is characterized as a degenerative disease of the cornea due to impairment of trigeminal innervation that results in corneal epithelial damage,” said Marian Macsai, M.D., chief medical officer of Oyster Point Pharma. “We believe that OC-01 nasal spray may activate natural tear production through the trigeminal parasympathetic pathway, bypassing the impaired corneal nerves to stimulate the production of natural tear film and potentially improve corneal sensitivity and healing.”

About Oyster Point Pharma
Oyster Point Pharma is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies to treat ophthalmic diseases.

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 and neurotrophic keratopathy. 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 activate natural tear film production. The 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 eye, as well as protecting and moisturizing the cornea. In December 2020, Oyster Point submitted to the U.S. Food and Drug Administration (FDA) a 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 is October 17, 2021, with a planned U.S. launch of OC-01 (varenicline) nasal spray in this indication in the fourth quarter of 2021, if approved by the FDA. 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 been established.

About Neurotrophic Keratopathy
Neurotrophic Keratopathy (NK) is a rare disease characterized by decreased corneal sensitivity and poor corneal healing. The most common causes of corneal sensation loss are viral infection (herpes simplex virus and herpes zoster keratoconjunctivitis), followed by chemical burns, physical injuries, and ocular surface surgery. In addition, systemic diseases such as diabetes and multiple sclerosis may decrease sensory nerve function or damage sensory fibers. NK can be classified broadly into three stages: Stage 1 (mild) consists of ocular surface irregularities and reduced vision, Stage 2 (moderate) exhibits a non-healing persistent defect of the corneal epithelium, and Stage 3 (severe) exhibits corneal ulceration, which may progress to corneal melting and perforation. If not adequately addressed, NK can lead to vision loss and a breakdown of corneal integrity, potentially leading to cornea transplantation.

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, our future plans and strategies, regulatory approvals, 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 product candidates, regulatory approvals, planned pre-clinical studies and clinical trials, expected results of pre-clinical 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: the uncertainties inherent in pharmaceutical research and development, including pre-clinical study and clinical trial results and additional analysis of existing data, and the likelihood of our pre-clinical studies and clinical trials demonstrating the 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 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; 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 pre-clinical and clinical development and manufacturing of our product candidates, including additional indications which we may pursue; the prevalence of dry eye disease and neurotrophic keratopathy and the size of the market opportunity 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; our ability to recruit and retain key personnel needed to develop and commercialize our product candidates, if approved, and to grow our company; 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 pre-clinical studies and clinical trials; 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; 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. 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.

1- Market Scope 2020 Dry Eye Products Report: A Global Market Analysis for 2019 to 2025

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