Oyster Point Pharma Submits New Drug Application to the U.S. Food and Drug Administration for OC-01 (varenicline) Nasal Spray for the Treatment of Signs and Symptoms of Dry Eye Disease

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The NDA submission is based on efficacy and safety results from a comprehensive clinical trial program conducted in patients with a broad range of dry eye disease.

PRINCETON, N.J., Dec. 18, 2020 (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 it has submitted a 505(b)(2) New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease.

The NDA submission is 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 dry eye disease.

The MYSTIC, ONSET-1 and ONSET-2 clinical trials showed statistically significant improvements in Schirmer's Score (an objective, reproducible, and quantifiable measure of natural tear film production), as compared to control, which was the primary endpoint in all studies. 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 studies, there was statistically or nominally statistically significant improvement in symptom scores at Day 28, and in ONSET-2 as early as Day 14, as compared to control. All doses studied in the clinical trial program were well-tolerated with no serious drug related adverse events.

"The submission of Oyster Point's first NDA is a major step towards our goal of bringing novel and transformative therapies to patients with ocular surface diseases," said Jeffrey Nau, Ph.D., M.M.S., president and CEO of Oyster Point Pharma. "We have intently focused on the advancement of OC-01 nasal spray from formulation through clinical development and regulatory submission over the last three years. We look forward to continued interaction with the FDA during the review process."

"We are excited by the potential of OC-01 nasal spray, if approved, becoming a meaningful addition to the eye care practitioner's treatment armamentarium, and the potential to create a paradigm shift in how practitioners and their patients treat dry eye disease," stated Marian Macsai, M.D., chief medical officer of Oyster Point Pharma.

About ONSET-1, ONSET-2, and MYSTIC
The ONSET-1 Phase 2b and the ONSET-2 Phase 3 pivotal clinical studies were each multicenter, randomized, double-masked, vehicle-controlled trials in adult subjects with dry eye disease in the U.S. The main eligibility criteria for both studies included a physician's diagnosis of dry eye disease, a baseline Schirmer's Score of £ 10 mm, and symptom criteria of an eye dryness score from 0-100 (VAS scale). OC-01 nasal spray was administered as a single spray into each nostril twice-daily, and the primary and key secondary endpoints, including improvement in Schirmer's Score and eye dryness score, as compared to control, were measured at Day 28. ONSET-1 and ONSET-2 studies of OC-01 nasal spray enrolled a broad population of mild, moderate, and severe subjects. The MYSTIC Phase 2 clinical trial was a single-center, randomized, double-masked, vehicle-controlled trial in adult subjects with dry eye disease in Mexico. The MYSTIC trial evaluated Schirmer's Score of enrolled subjects after 84 days of twice-daily administration of OC-01 nasal spray, as compared to control.

About OC-01 Nasal Spray
OC-01 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 indication 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 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 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.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions and on information currently available to us. The forward-looking statements in this press release represent our views as of the date of this press release. These statements may include but are not limited to statements regarding future events, and any potential impacts of any government measures in response thereto, including the potential timing and likelihood of NDA acceptance, review and approval of OC-01 nasal spray, and the potential that OC-01 nasal spray may be commercialized, and the timing, objectives and results of clinical studies and anticipated regulatory and development milestones, or future financial and operating performance and our plans for, or timing of, the anticipated benefits of new hires, our product candidates, or results of clinical studies, regulatory or development milestones or potential commercialization of any product candidate. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Forward-looking statements may involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. Important factors that could cause our actual results to differ materially are detailed from time to time in the “Risk Factors” section in reports we file with the Securities and Exchange Commission, copies of which are posted on our website and are available from us without charge. However, new risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties.

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