Oyster Point Pharma Completes Enrollment in ONSET-2 Pivotal Phase 3 Clinical Trial of OC-01 Nasal Spray for Dry Eye Disease and Provides COVID-19 Business Update

March 30, 2020

ONSET-2 Phase 3 Top-Line Data Expected by End of Q2 2020

NDA Submission Expected During 2H 2020

PRINCETON, N.J., March 30, 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, announced completion of enrollment in its pivotal Phase 3 ONSET-2 clinical trial of OC-01 nasal spray for the treatment of signs and symptoms of dry eye disease on March 14, 2020. In addition, Oyster Point Pharma provides a business update regarding the COVID-19 pandemic.

The ONSET-2 trial is a multicenter, randomized, double-masked, placebo-controlled clinical trial to evaluate the safety and efficacy of OC-01 nasal spray for treating the signs and symptoms of dry eye disease. Total enrollment in the study was 758 subjects, slightly more than the original target of 750 subjects at 22 U.S. centers. The study is designed to investigate two doses of OC-01 nasal spray, 0.6mg/ml and 1.2 mg/ml, as compared to placebo (vehicle) nasal spray. The pre-specified primary endpoint of the trial is the assessment of tear production as measured by the percentage of subjects with a 10 mm or greater change from baseline Schirmer's Score at Week 4. Secondary symptom endpoints are the assessment of patient-reported symptoms of dry eye disease as measured by the Eye Dryness Scale (EDS) at Week 4. Oyster Point Pharma is currently on track to deliver top-line data from ONSET-2 by the end of Q2 2020.

"At Oyster Point Pharma, we take the health and safety of our team, clinical trial subjects, healthcare colleagues, and our local communities very seriously. We recognize that the ongoing pandemic is challenging healthcare delivery and the medical infrastructure worldwide", said Jeffrey Nau, Ph.D., M.M.S., President and CEO of Oyster Point Pharma. "We remain in close connection with clinical trial centers to ensure the safety of our trial subjects as well as business continuity with our manufacturers and suppliers. I am very proud of what our team has accomplished during the current climate with the completion of enrollment in our second registrational trial, ONSET-2. Also, we feel incredibly fortunate to have completed enrollment with limited impact to our study operations and data collection."

Due to the COVID-19 pandemic, Oyster Pharma Point has experienced an impact to select clinical trial sites during the month of March where ophthalmology practices were closed, or subjects were unable to attend protocol specified visits. This impact was limited primarily to Day 28 study visits, with minimal impact to earlier timepoints and data collection. In close cooperation with the excellent staff at the study's clinical centers, Oyster Point Pharma has instituted additional safety measures for ongoing clinic visits and implemented remote collection of data where applicable. Based on the data collected to date for the primary endpoint, and assuming consistency with the effect size seen in the ONSET-1 clinical trial, the study is expected to have approximately 99% power to detect a difference for each dose tested. Similarly, for the secondary endpoints assessing symptoms using the EDS scale, and assuming the effect size seen in the ONSET-1 clinical trial, the study is expected to have approximately 98% power to detect a difference.

"OC-01 nasal spray represents a novel approach to treating patients with dry eye disease via a unique mechanism of action to increase natural tear film production," said Dr. Nau. "We believe that, if approved, OC-01 nasal spray will be able to improve both signs and symptoms of dry eye disease with a favorable tolerability profile. The novel delivery of OC-01 as a nasal spray spares the ocular surface and enables our innovative mechanism of action, which would provide eye care practitioners and patients unique benefits relative to the existing standards of care."

About OC-01 Nasal Spray
OC-01 is a highly selective nicotinic acetylcholine receptor (nAChR) agonist, being developed as a preservative-free nasal spray to treat the signs and symptoms of dry eye disease (DED). 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, OC-01's novel mechanism of action activates 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 coating is responsible for forming the primary refracting surface of the cornea, as well as protecting and moisturizing the cornea.

About Oyster Point Pharma
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 nicotinic acetylcholine receptor (nAChR) agonist, is being developed as a nasal spray to treat the signs and symptoms of dry eye disease. OC-01 nasal spray's novel mechanism of action re-establishes tear film homeostasis by activating the trigeminal parasympathetic pathway to stimulate the glands and cells responsible for natural tear film production, known as the lacrimal functional unit (LFU).

About Dry Eye Disease
Dry eye disease is a chronic, progressive condition that impacts more than 30 million Americans and is growing in prevalence. An estimated 16 million U.S. adults 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.

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 or future financial and operating performance and our plans for and the anticipated benefits of new hires, our product candidates, the timing, objectives and results of the clinical studies and anticipated regulatory and development milestones, including expectations regarding timing of reporting of topline data from our ONSET-2 clinical trial, expectations regarding the impact of the COVID-19 pandemic on patient visits and expectations regarding the powering of the ONSET-2 clinical trial. 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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