Oyster Point Pharma's OC-01 Nasal Spray Meets Primary Endpoint in Phase 2 Mystic Trial in Subjects With Dry Eye Disease

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- OC-01 nasal spray showed a statistically significant improvement in Schirmer's score at Day 84 in both doses tested compared to control
- OC-01 nasal spray is a preservative-free, aqueous, nicotinic agonist nasal spray designed to activate the trigeminal parasympathetic pathway to stimulate natural tear production
- Conference call and live webcast tomorrow, January 13, at 8:30 a.m. ET to review MYSTIC top-line data

PRINCETON, N.J., Jan. 12, 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 the positive top-line results from its Phase 2 MYSTIC study in Dry Eye Disease.

"The results from the MYSTIC study further validate the novel mechanism of action of OC-O1 nasal spray and its ability to stimulate natural tear production via the trigeminal parasympathetic pathway," said Dr. Preeya Gupta, Associate Professor of Ophthalmology at Duke University Eye Center and member of Oyster Point Pharma's medical advisory board. "There is a significant need for a treatment approach that can be delivered chronically through a novel route of administration that allows patients to stimulate their own natural tear film and address the underlying disease process."

Efficacy and Safety Results

Results showed a statistically significant improvement in Schirmer's score from baseline at Day 84 in both doses as compared to control.

Results for the study eye (primary endpoint) indicated:

- The 1.2 mg/ml dose had a mean change in Schirmer's score of 11.0 mm ($p<0.05$ vs. control);
- The 0.6 mg/ml dose had a mean change in Schirmer's score of 10.6 mm ($p<0.05$ vs. control).
- The vehicle control group had a mean change in Schirmer's score of 6.2 mm.

In the eye that was not designated as the study eye (fellow eye), results were consistent (exploratory endpoint):

- The 1.2 mg/ml dose had a mean change in Schirmer's score of 10.0 mm ($p=0.01$ vs. control);
- The 0.6 mg/ml dose had a mean change in Schirmer's score of 8.7 mm ($p<0.05$ vs. control).
- The vehicle control group had a mean change in Schirmer's score of 4.5 mm.

The study demonstrated that OC-01 nasal spray was well-tolerated at the two doses tested. The number of subjects reporting any treatment-emergent adverse event (TEAE) was 10 out of 41 (24% percent) in each OC-01 nasal spray dose group and 10 out of 41 (24% percent) in the vehicle control group. There were no reports of serious TEAE in the study and no serious adverse events related to study drug administration. The most common adverse events in the nasal spray groups were blurry vision, sneezing, and headache. All events were mild in the OC-01 nasal spray groups and resolved by the next visit.

"We are excited to further validate the ability of OC-01 nasal spray to stimulate an increase in tear film production that is sustained over the course of twice daily dosing for 84 days in subjects with Dry Eye Disease from the MYSTIC study," said Dr. Jeffrey Nau, CEO of Oyster Point Pharma. "We look forward to discussing top-line data from our Phase 3 ONSET-2 study in Dry Eye Disease in mid-2020."

The MYSTIC Study

The MYSTIC study was a randomized, single-masked, vehicle-controlled Phase 2 clinical trial that evaluated the safety and efficacy of OC-01 in 123 subjects with Dry Eye Disease at the Asociación para Evitar la Ceguera (APEC) in Mexico City. APEC is the largest specialized ophthalmology hospital in North America by patient volume. The study compared two different doses of OC-01 nasal spray to vehicle control nasal spray (1:1:1 randomization). The goal of this study was to assess the safety and efficacy of twice daily dosing of OC-01 nasal spray administered for 84 days. The pre-specified primary endpoint was the assessment of tear production as measured by mean change in Schirmer's score at Day 84 as compared to vehicle control.

Conference Call and Webcast

Oyster Point will host a conference call and webcast to discuss the results of the MYSTIC Phase 2 clinical study tomorrow, January 13 at 8:30 a.m. ET. To access the live call by phone please dial (855) 548-1220 (US/Canada) or (602) 563-8619 (international); the conference ID is 9569009.

A live audio webcast of the event and accompanying slides may also be accessed through the “News and Events” page of the “Investors and News” section of the company’s website at https://investors.oysterpointrx.com/news-and-events/events-and-presentations.

In addition, the direct webcast registration link is: https://edge.media-server.com/mmc/p/s256m6pe. A replay of the webcast will be available for 7 days following the event.

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 our plans for the anticipated benefits of and safety of our product candidates, the timing, objectives and results of the clinical studies and anticipated regulatory and development milestones. 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 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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