# Oyster Point Pharma Announces Clinical Data Presentations on OC-01 Nasal Spray for Dry Eye Disease at the American Academy of Ophthalmology 2020 Virtual Annual Meeting

November 13, 2020

**Results from the Phase 2 IMPERIAL study illustrate OC-01 nasal spray caused a decrease in goblet cell size, as compared to placebo, indicating mucin secretion after a single administration**

PRINCETON, N.J., Nov. 13, 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 new data from its Phase 2 IMPERIAL clinical trial evaluating OC-01 (varenicline) nasal spray in the treatment of the signs and symptoms of dry eye disease in adults at the American Academy of Ophthalmology (AAO) 2020 Virtual Annual Meeting, being held on November 13-15.

A single administration of OC-01 nasal spray significantly reduced goblet cell area and perimeter as measured by *in vivo* confocal microscopy as compared to placebo in subjects with dry eye disease. Goblet cells in the conjunctiva are responsible for releasing mucus and, based on clinical data, may help re-establish tear film homeostasis. OC-01 nasal spray was found to be safe and well-tolerated in the study, with the most commonly reported treatment-related event being sneeze.

“The positive results from IMPERIAL add to the growing body of evidence around the safety and efficacy of OC-01 in addressing the signs and symptoms of dry eye disease, a condition that impacts the day-to-day lives of millions of adults in the United States despite current treatments,” said Pedram Hamrah, M.D., principal investigator for the IMPERIAL study and an ophthalmologist and cornea specialist at Tufts Medical Center, and professor of ophthalmology at Tufts University School of Medicine. “The data from this clinical study show how parasympathetic activation may stimulate mucin production at the ocular surface.”

The single-center, randomized, double-masked, placebo-controlled trial included 18 patients with dry eye disease. The objective of the study was to assess the effect of OC-01 nasal spray on goblet cell alterations by *in vivo* confocal microscopy (IVCM). IVCM images of the bulbar conjunctiva, the membrane covering the outer surface of the eye, taken prior to and 10 minutes after administration showed that OC-01 significantly reduced goblet cell area and perimeter in dry eye disease, indicating goblet cell degranulation, which releases lubricating mucus.

**Details of the Poster Presentation**

**Title**: OC-01 (Varenicline) Nasal Spray Induces Goblet Cell Alterations in Patients with Dry Eye Disease

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In addition to the poster presentation, Oyster Point Pharma president and CEO, Jeffrey Nau Ph.D., M.M.S., will present at the AAO Industry Showcase on Friday, Nov. 13 from 12:50 to 1:20 p.m. EST.

Presentations will be available to view during the event for those registered through the following link: https://www.aao.org/annual-meeting.

**About OC-01 Nasal Spray**

OC-01 is a highly selective nicotinic cholinergic agonist, being developed as a 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, 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 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**

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. 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.

**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, including our plans for and 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, including potential timing of NDA submission and potential commercialization. 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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