Oyster Point Pharma Announces Positive Top-Line Results From the Phase 1 “ZEN” Study of Its Lead Nicotinic Agonist Nasal Spray in Development for the Treatment of Dry Eye Disease

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PRINCETON, N.J., Nov. 22, 2019 (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 1 “ZEN” study in healthy volunteers. The ZEN Study was an open-label, single-center, randomized, 2-way crossover study to evaluate the relative bioavailability of varenicline administered as a preservative-free nasal spray (OC-01 nasal spray) as compared to varenicline administered orally as a single oral dose of Chantix®.

The ZEN study was designed to assess the relative bioavailability of varenicline administered intranasally at its highest intended clinical strength (1.2 mg/ml in a 50 microliter nasal spray) compared to varenicline administered as a single oral dose at its commercially available maintenance oral tablet strength (1 mg). The treatment cohort consisted of 22 healthy volunteers who were administered study medication under fasted conditions.

Top-line results indicate that the relative bioavailability (systemic exposure as defined by adjusted geometric mean $AUC_{0\text{-}inf}$) was 13 times lower for a single dose of the highest strength of OC-01 nasal spray as compared to a single dose of the highest strength Chantix® tablet (7.46 vs 99.67 h*ng/ml). Maximal concentration (as defined by adjusted geometric mean C_{max}) was 14 times lower for a single dose of the highest strength of OC-01 nasal spray as compared to a single dose of the highest strength Chantix® tablet (0.32 vs 4.55 ng/ml).

The study demonstrated that OC-01 nasal spray was safe and well-tolerated at the doses tested. The number of subjects reporting any treatment-emergent adverse event (TEAE) was 13 out of 21 (61.9 percent) after nasal spray administration and 9 out of 22 (22.9 percent) after oral tablet administration but there were no reports of serious TEAE noted with either oral or nasal administration. The most common adverse events in the nasal spray group were sneeze in 7 volunteers (33.3 percent) and cough in 6 volunteers (28.6 percent). All events were mild. There were no events of sneeze or cough in the oral tablet administration group. The most common adverse events in the oral tablet administration group were nausea in 5 volunteers (22.7 percent) and vomiting in 4 volunteers (18.1 percent). All events were mild or moderate in severity. There were no events of nausea or vomiting in the nasal spray administration group.

"We are pleased by the positive results of the ZEN study as they confirm and validate the pharmacokinetic profile and the fundamental science of our OC-01 nasal spray. OC-01 nasal spray is designed to deliver a concentrated local dose of drug to the nasal mucosa, stimulating the trigeminal nerve to produce natural tear film, while limiting the systemic exposure," stated Jeffrey Nau, PhD, MMS, Oyster Point’s President and CEO.

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 and the anticipated benefits 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

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