Oyster Point Pharma Announces Enrollment of First Subject in Phase 3 Clinical Trial of Nasal Spray for Dry Eye Disease

July 24, 2019

PRINCETON, N.J. – July 24, 2019 – Oyster Point Pharma, Inc., 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 enrollment of the first subject in the Phase 3 ONSET-2 clinical trial of OC-01 Nasal Spray for the treatment of the signs and symptoms of dry eye disease.

“After successfully completing our registrational Phase 2b clinical trial, ONSET-1, we are excited to announce the initiation of our second registrational trial, ONSET-2,” said Jeffrey Nau, Ph.D., M.M.S., President and CEO of Oyster Point Pharma. “We believe OC-01 has the potential to change the way that eye care practitioners treat patients with dry eye disease due to the rapid onset of action in increasing natural tear film production, the ability to significantly improve both signs and symptoms of dry eye disease, and 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, providing eye care practitioners and patients unique benefits.”

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. The study, which will enroll approximately 750 subjects at approximately 20 U.S. centers, will 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 will be 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 will be the assessment of patient-reported symptoms of dry eye disease as measured by the Eye Dryness Scale (EDS) at Week 4.

In October 2018, Oyster Point reported results from the Phase 2b ONSET-1 clinical trial in which OC-01 demonstrated statistically significant improvements in both the pre-specified primary sign endpoint and multiple pre-specified secondary symptom endpoints as compared to placebo (vehicle). OC-01 was well-tolerated with no significant ocular adverse events or serious drug-related adverse events. The most common adverse events included sneeze, cough, and nose and throat irritation. These events were mild, self-limiting, and resolved immediately following administration.

“It’s encouraging to see the progress Oyster Point is making in the development of OC-01,” said Elizabeth Yeu, M.D., an ophthalmologist at Virginia Eye Consultants, and member of Oyster Point Pharma’s medical advisory board. “There is a significant need for more therapeutic options that can successfully benefit a broad population of patients with dry eye disease. OC-01 addresses a fundamental aspect of the disease, and I believe it has the potential to become a new standard of care.”

About Dry Eye Disease
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 antimicrobials 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. Our lead product candidate, OC-01, 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. Dry eye disease is a chronic, progressive condition that impacts more than 30 million Americans and is growing in prevalence. OC-01’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. For more information, visit oysterpointrx.com and follow on Twitter at @OysterPointRx.

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