Oyster Point Pharma Announces FDA Clearance of Investigational New Drug Application for the Treatment of Dry Eye Disease

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Second Product Candidate to Receive an IND Clearance in Less Than 12 Months

PRINCETON, New Jersey – June 27, 2018 – Oyster Point Pharma, Inc., a clinical-stage pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company’s Investigational New Drug (IND) application to proceed with clinical development of OC-01, an investigational compound intended to stimulate natural tear film production in people with Dry Eye Disease that is administered with a nasal spray.

This regulatory milestone will support the company’s ongoing Phase 2 clinical trials evaluating the safety and efficacy of two different nicotine acetylcholine receptor (nAChR) agonists – OC-01 and OC-02 – as potential treatments for the signs and symptoms of Dry Eye Disease. A Phase 2 trial of OC-02, which received IND clearance in October of 2017, was recently completed and data will be presented at an upcoming medical meeting.

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 which 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 massive prevalence of dry eye and the burden of the disease, there remains a significant unmet need for effective therapies.

“Our innovative pharmaceutical approach leverages the parasympathetic nervous system by stimulating the glands responsible for producing natural tear film. Delivered through a nasal spray, as opposed to traditional eye drops, this therapy has the potential to immediately reduce the symptoms of dry eye. Clearance of our IND application for OC-01 allows us to quickly advance this therapy into Phase 2 clinical trials,” said Dr. Jeffrey Nau, CEO of Oyster Point. “We look forward to continuing Phase 2 clinical trials for both drug candidates, OC-01 and OC-02, and sharing the results of multiple studies over the course of the year.”

OC-01 and OC-02 come from a class of drugs called nicotine acetylcholine receptor (nAChR) agonists that are known to affect the parasympathetic nervous system. The trigeminal nerve provides parasympathetic control of the glands that produce the eye’s natural tear film. Oyster Point is the only company developing a pharmaceutical approach to treating Dry Eye Disease by stimulating the trigeminal parasympathetic pathway to promote natural tear film production. These compounds are being developed in a nasal spray to deliver them directly to the trigeminal nerve, which is accessible within the nose.

About Oyster Point Pharma

Based in Princeton, New Jersey, Oyster Point Pharma, Inc. is a clinical-stage pharmaceutical company leveraging neuroscience to discover, develop, and commercialize novel therapies to treat diseases with high unmet needs. The company’s initial focus is on developing innovative therapeutics to treat the signs and symptoms of Dry Eye Disease by stimulating the trigeminal parasympathetic pathway to activate the glands responsible for tear film production. Oyster Point is leveraging a class of receptors called nicotinic acetylcholine receptors (nAChRs) which are located on the trigeminal nerve, accessible within the nose, to stimulate natural tear film production. The two lead product candidates, OC-01 and OC-02, are delivered via nasal spray and are currently in Phase 2 trials for the treatment of Dry Eye Disease.

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