Oyster Point Pharma Provides Key Supply Chain Insight For OC-01 (varenicline) Nasal Spray

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PRINCETON, N.J., June 29, 2021 (GLOBE NEWSWIRE) -- Oyster Point Pharma, Inc. (Nasdaq: OYST), today announced information regarding a key supply chain insight for OC-01 (varenicline) nasal spray following the announcement that an unrelated manufacturer of varenicline oral tablets has suspended distribution due to impurities discovered in one or more lots of its product. Oyster Point Pharma has not observed any measurable impurities in its OC-01 (varenicline) nasal spray.

Oyster Point Pharma is developing OC-01 (varenicline) nasal spray to treat the signs and symptoms of dry eye disease. Oyster Point Pharma currently sources OC-01 (varenicline) nasal spray active pharmaceutical ingredient (API), varenicline tartrate, from a supplier unrelated to the manufacturer that has suspended distribution due to nitrosamine being above acceptable levels.

Oyster Point Pharma takes seriously the quality of products in development and patient safety. To date, Oyster Point Pharma has tested samples of varenicline tartrate API intermediate, multiple lots of varenicline tartrate drug substance used in OC-01 (varenicline) nasal spray finished product, and multiple lots of OC-01 (varenicline) nasal spray finished product with no evidence of nitrosamine levels being above the lower limit of detection from the assay used for measuring presence.

The Prescription Drug User Fee Act (PDUFA) target action date for OC-01 (varenicline) nasal spray is October 17, 2021, with a planned U.S. launch in the fourth quarter of 2021, if approved by the U.S. Food and Drug Administration (FDA).

OC-01 (varenicline) nasal spray is an investigational new drug and has not been approved for any use in any country. The safety and efficacy of OC-01 (varenicline) nasal spray have not been established.

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 and biologic therapies to treat ophthalmic diseases.

About OC-01 (varenicline) Nasal Spray
OC-01 (varenicline) nasal spray is a highly selective cholinergic agonist being developed as a multidose preservative-free nasal spray to treat the signs and symptoms of dry eye disease and neurotrophic keratopathy. 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, in pre-clinical and clinical studies, OC-01 (varenicline) nasal spray was shown to have a novel mechanism of action with activation of the trigeminal parasympathetic pathway in the nasal cavity to activate natural tear film production. The 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 is responsible for forming the primary refracting surface of the eye, as well as protecting and moisturizing the cornea. In December 2020, Oyster Point submitted to the U.S. Food and Drug Administration (FDA) a New Drug Application (NDA) for OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease. The Prescription Drug User Fee Act (PDUFA) target action date is October 17, 2021, with a planned U.S. launch of OC-01 (varenicline) nasal spray in this indication in the fourth quarter of 2021, if approved by the FDA. OC-01 (varenicline) nasal spray is an investigational new drug and has not been approved for any use in any country. The safety and efficacy of OC-01 (varenicline) nasal spray have not been established.

Forward-Looking Statements
This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 that reflect the current beliefs, expectations and assumptions of the “Company regarding the future of the Company’s business, our future plans and strategies, regulatory approvals, clinical results, future financial condition and other future conditions. All statements other than statements of historical facts contained in this press release, including express or implied statements regarding product candidates, regulatory approvals, planned preclinical studies and clinical trials, expected results of preclinical or clinical trials, and their timing and likelihood of success, expected research and development costs, as well as plans and objectives of management for future operations, are forward-looking statements. The words “if approved,” “may,” “will,” “should,” “would,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: the timing or likelihood of regulatory filings and approvals for OC-01; the beneficial characteristics, safety, efficacy and therapeutic effects of OC-01; our plans relating to the further development and manufacturing of OC-01, including potential additional indications or disease areas to be evaluated and pursued; the timing of initiation of our future clinical trials; the uncertainties inherent in pharmaceutical research and development, including preclinical study and clinical trial results and additional analysis of existing data; the likelihood of our clinical trials demonstrating safety and efficacy of OC-01, and other positive results; our plans and potential for success relating to commercializing OC-01; our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available; our ability to recruit and retain key personnel needed to develop and commercialize our product candidates, if approved, and to grow our company; existing regulations and regulatory developments in the United States and other jurisdictions; our continued reliance on third parties to conduct additional preclinical studies and clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials; the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; our financial performance; market conditions; the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements; and other risks

described in the “Risk Factors” section included in our public filings that we have made and will make with the Securities and Exchange Commission (SEC). The Company is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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