Oyster Point Pharma Reports Fourth Quarter and Full Year 2020 Financial Results and Recent Business Highlights

February 18, 2021

- **OC-01 (Varenicline) Nasal Spray New Drug Application (NDA) Submitted to the U.S. Food and Drug Administration (FDA) for the Treatment of Signs and Symptoms of Dry Eye Disease on December 17, 2020**
- **Phase 2 Clinical Trial Protocol of OC-01 (Varenicline) Nasal Spray in Patients with Neurotrophic Keratopathy (NK) Submitted to the FDA on November 30, 2020**
- **OLYMPIA Phase 2 Study of OC-01 (Varenicline) Nasal Spray in NK on Track for Enrollment of the First Patient in the First Half of 2021**
- **Announced Positive IMPERIAL Phase 2 Study Results**
- **Advancement of Commercialization Preparations and Strengthening of the Executive Leadership Team**
- **Cash Position of $192.6 million as of December 31, 2020**

PRINCETON, N.J., Feb. 18, 2021 (GLOBE NEWSWIRE) -- Oyster Point Pharma, Inc. (Nasdaq: OYST), ("Oyster Point Pharma", or "the Company"), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class pharmaceutical therapies to treat ocular surface diseases, announced its financial results for the fourth quarter of 2020, and provided an overview of recent business highlights.

“The submission of our NDA to the FDA for OC-01 (varenicline) nasal spray represents an important milestone for Oyster Point Pharma and progresses the development of what we believe will be an important first in class nasal spray for the treatment of the signs and symptoms of dry eye disease." said Jeffrey Nau, Ph.D., MMS president and chief executive officer of Oyster Point Pharma. Dr. Nau continued, "We believe that the strength of our clinical data in mild, moderate and severe dry eye patients, and OC-01's novel mechanism of action as shown in pre-clinical and clinical studies to stimulate natural tear film production and re-establish tear film homeostasis, will support eye care practitioners’ use of a new tool in their dry eye disease treatment armamentarium, if approved by the FDA.”

Recent Business Highlights

- **Submission of the NDA for OC-01 for Signs and Symptoms of Dry Eye Disease to the FDA:** On December 17, 2020, the Company submitted a 505(b)(2) NDA to the FDA for OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease.

- **Phase 2 Clinical Trial Protocol Submission to the FDA:** On November 30, 2020, the Company submitted to the FDA a protocol to initiate a clinical study in adult patients with NK. The submission was made to the Company’s IND application for OC-01 (varenicline) nasal spray in dry eye disease. NK is the second of a number of important potential indications the Company is evaluating for studying OC-01 (varenicline) nasal spray, illustrating the Company's commitment to treating unmet needs related to ocular surface diseases.

- **OLYMPIA Phase 2 Study on Track**: Enrollment of the first patient in the OLYMPIA Phase 2 study of OC-01 (varenicline) nasal spray in NK remains on track, planned for the first half of 2021.

- **Announced IMPERIAL Phase 2 Study Results:** Results from the Phase 2 IMPERIAL study illustrated OC-01 (varenicline) nasal spray caused a statistically significant decrease in goblet cell size, indicating goblet cell degranulation and release of mucin, as compared to placebo after a single administration. Topline data was presented at the American Academy of Ophthalmology 2020 (AAO 2020) virtual meeting and judged to be one of the top 10% best papers at AAO 2020.

- **Advancement of Commercialization Preparations:** The Company has made meaningful progression toward its planned U.S. launch of OC-01 (varenicline) nasal spray in the fourth quarter of 2021, if approved by the FDA, including the addition of key talent in the areas of commercial operations, medical affairs, and manufacturing.

- **Strengthened Executive Leadership Team:** On December 7, 2020, the Company announced the appointment of Marian Macsai, M.D., as chief medical officer, and Eric Carlson, Ph.D., as chief scientific officer, both of whom joined the executive leadership team.

Overview of Financial and Operating Results

Fourth Quarter 2020 Financial Results

- **Cash Position:** As of December 31, 2020, cash and cash equivalents were $192.6 million, compared to $139.1 million as of December 31, 2019. The increase in cash and cash equivalents in the amount of $53.4 million was primarily due to proceeds from a follow-on equity offering in the amount of $112.6 million, partially offset by cash used in operations in the amount of $58.4 million and capital expenditures in the amount of $0.7 million.

- **R&D Expenses:** Total research and development expenses for the fourth quarter of 2020 were $11.7 million compared to $15.0 million for the same period in 2019. The Company's expenditures for preclinical and clinical programs were $4.6 million lower during the fourth quarter of 2020 compared to the same period in 2019 primarily due to the completion of the ONSET-2 Phase 3 clinical trial in May 2020. The Company incurred a higher chemistry, manufacturing, and controls (CMC) expense of $2.9 million primarily due to the continued advancement of OC-01 (varenicline) nasal spray. The Company's expenditures in other research and development expense were $1.6 million lower during the fourth quarter of 2020 compared to the same period in 2019. The decrease in other research and development costs was primarily a result of the NDA submission fee to the FDA in the amount of $2.9 million made in December 2020, as compared to the $5.0 million license payment to Pfizer in December 2019. This decrease was partially offset by higher costs in the amount of $0.5 million primarily related to data management and regulatory costs in connection with the advancement of the OC-01 (varenicline) nasal spray and NDA submission.

- **SG&A Expenses:** Total selling, general and administrative expenses for the fourth quarter of 2020 were $10.5 million compared to $5.1 million for the same period in 2019. The increase was due to higher employee headcount and reflects an increase in payroll-related expense, including stock-based compensation, of $3.0 million. The Company incurred higher commercialization planning expenses of $1.5 million in anticipation of an expected U.S. launch of OC-01 (varenicline) nasal spray, if approved by the FDA, in the fourth quarter of 2021. Additionally, there was an increase in other general and administrative expenses of $0.9 million due to expansion of the Company's organization and operating as a publicly traded company.

- **Net Loss:** For the fourth quarter of 2020, the Company had a net loss of $22.2 million, or $(0.86) per share, compared to a net loss of $19.7 million, or $(1.41) per share, for the same period in 2019.

Conference Call Details and Webcast

Oyster Point Pharma will host a live conference call and webcast today at 4:30 pm Eastern Time to discuss the fourth quarter 2020 financial results and provide a business update. To access the live call by phone, please dial (855) 548-1220 (US/Canada) or (602) 563-8619 (International). The conference ID number is 2066335. The webcast will be made available on the company's website at www.oysterpointrx.com under the "Events & Presentations" section of the company's website at https://edge.media-server.com/mmc/p/7mdvsfdb.

A telephone replay will be available for approximately 7 days following the live conference call. To access the telephone replay, please dial (855) 859-2056 (US/Canada) or (404) 537-3406 (International). The conference ID number is 2066335. A replay of the webcast will be available for approximately 30 days following the live audio webcast.

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 (varenicline) nasal spray, a highly selective cholinergic agonist, is being developed as a nasal spray to treat the signs and symptoms of dry eye disease. In preclinical and clinical studies, OC-01 (varenicline) nasal spray was shown to have a novel mechanism of action via activation of the trigeminal parasympathetic pathway to stimulate the glands and cells responsible for natural tear film production, known as the lacrimal functional unit. 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 previously been established.

About Dry Eye Disease

Dry eye disease is a chronic, progressive condition that impacts more than 30 million people in the United States (U.S.) 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 Neurotrophic Keratopathy

Neurotrophic keratopathy (NK), is a disease characterized by decreased corneal sensitivity and poor corneal healing. The most common causes of loss of corneal sensation are viral infection (herpes simplex and herpes zoster keratoconjunctivitis) followed by chemical burns, physical injuries, and corneal surgery. In addition, systemic diseases such as diabetes and multiple sclerosis may decrease sensory nerve function or damage sensory fibers. NK can be classified broadly into three stages: Stage 1 (mild) consists of ocular surface irregularities and reduced vision, Stage 2 (moderate)

exhibits a non-healing persistent defect of the corneal epithelium, and Stage 3 (severe) exhibits corneal ulceration, which may progress to corneal melting and perforation. If not adequately addressed, the progression of NK can lead to the loss of the cornea and the need for transplantation.

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 future results of operations and financial position, business strategy, product candidates, regulatory approvals, expected research and development costs, planned preclinical studies and clinical trials, expected results of clinical trials, and their timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. The words "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 our product candidates; our ability to obtain and maintain regulatory approvals of our product candidates; our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy; the success of competing therapies that are or may become available; the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates; our plans relating to the further development and manufacturing of our product candidates, including the size, number and additional indications or disease areas to be evaluated and pursued; the impact of the COVID-19 pandemic on our business, operations, and regulatory and clinical development timelines, plans and expectations; the size of the market opportunities and prevalence of dry eye disease and Neurotrophic Keratopathy (NK) for our product candidates, the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates, and other positive results; the timing of initiation of our future clinical trials, and the reporting of data from our current and future trials; the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory and commercialization expertise; existing regulations and regulatory developments in the United States and other jurisdictions; our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available; our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials, and potentially for commercial supply; 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; our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; 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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Oyster Point Pharma, Inc.
Select Balance Sheet Data
(in thousands)

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 192,585	$ 139,147
Working capital*	$ 185,385	$ 136,781
Total assets	$ 197,910	$ 143,209
Stockholders' equity	$ 186,659	$ 137,298

* Working capital is defined as current assets less current liabilities.

Oyster Point Pharma, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Three months ended December 31,		Year ended December 31,	
	2020	2019	2020	2019
Research and development:	*(unaudited)*			
Clinical, preclinical	$ 2,124	$ 6,712	$ 12,265	$ 13,550
Chemistry, manufacturing and controls	5,240	2,376	19,476	13,145

Other	4,343	5,946	8,070	6,933
Total research and development	11,707	15,034	39,811	33,628
Selling, general and administrative	10,537	5,127	31,178	13,673
Loss from operations	(22,244)	(20,161)	(70,989)	(47,301)
Other income, net	12	437	469	1,590
Net loss and comprehensive loss	$ (22,232)	$ (19,724)	$ (70,520)	$ (45,711)
Net loss per share basic and diluted	$ (0.86)	$ (1.41)	$ (2.92)	$ (9.97)
Weighted average shares outstanding, basic and diluted	25,869,601	13,993,730	24,128,603	4,585,146