October 3, 2024

OS Therapies Announces Last Patient Enrolled in OST-HER2 Osteosarcoma Phase 2b Clinical Trial Completes Last Patient Visit

Company to ring Closing Bell at NYSE on Thursday, October 3, 2024
Interviews scheduled with Fintech.TV and Schwab Network

NEW YORK--(BUSINESS WIRE)-- OS Therapies (NYSE American: OSTX) ("OS Therapies" or "the Company"), a clinical-stage immunotherapy and Antibody Drug Conjugate biopharmaceutical company, today announces that the last patient (Patient #41) enrolled in the AOST-2121 clinical trial (NCT04974008) of OST-HER2 in recurred, resected Osteosarcoma (OS) has completed their final radiographical evaluation at 52 weeks and the treatment period for the clinical trial has now ended. The Company is preparing to request a Type C Meeting with the U.S. Food & Drug Administration (FDA) and to make any protocol adjustments based on FDA's recommendations. Following those adjustments, the Company will lock the clinical trial database in preparation for data analysis and topline data readout, expected to be announced in the fourth quarter of 2024.

Concurrent with this announcement the Company announces that it will be ringing the closing bell at the New York Stock Exchange today. Company President and CEO Paul Romness is scheduled to give two interviews live on national television networks:

- "B" Block in Market Movers on Fintech.TV at 9:10am on Thursday, October 3, 2024
- Trading 360 on the Schwab Network at 11:30am on Thursday, October 3, 2024

OST-HER2, a biologic therapeutic candidate, is a Lm (Listeria monocytogenes) vector-based off-the-shelf immunotherapeutic vaccine designed to prevent metastasis, delay recurrence, and increase overall survival in patients with Osteosarcoma. The AOST-2121 Phase 2b clinical trial of 41 patients treated with OST-HER2 at 21 clinical trial sites across the United States is designed to demonstrate efficacy in patients who have already had recurrent metastatic disease to the lungs and are highly likely to continue to recur. A total of 16 OST-HER2 doses were administered once every three weeks, with a follow-up approximately four weeks after the final dose was administered, for a total of 52 weeks on study. Radiographic evaluation of recurrence occurred throughout the treatment period. The primary endpoints for the AOST-2121 study are Event Free Survival ("EFS"), defined as absence of recurrence of primary tumor or metastasis) at 12 months and Overall Survival (OS) at 36 months, with interim OS endpoints at 12 months, 18 months and 24 months. Topline EFS data, interim OS data, as well as additional secondary data analyses are expected to be reported in the fourth quarter of 2024.

The proposed OST-HER2 mechanism of action is based on innate and adaptive immune stimulating responses activated by the Lm vector. This treatment generates T-cells that can

eliminate or slow potential micro-metastases that can grow into recurrent Osteosarcoma. T-cell responses target HER2 expressed by the tumor and then kill the cell, releasing additional tumor targets. There are currently no approved adjuvant treatments for recurrent Osteosarcoma in the United States. There have not been any novel therapeutic interventions approved by the FDA in over 40 years.

About OS Therapies

OS Therapies is a clinical stage oncology company focused on the identification, development and commercialization of treatments for Osteosarcoma (OS) and other solid tumors. OST-HER2, the Company's lead asset, is an immunotherapy leveraging the immune-stimulatory effects of Listeria bacteria to initiate a strong immune response targeting the HER2 protein. The Company has completed enrollment for a 41-patient Phase 2b clinical trial of OST-HER2 in resected, recurrent osteosarcoma, with results expected in the fourth quarter of 2024. OST-HER2 has completed a Phase 1 clinical study primarily in breast cancer patients, in addition to showing strong preclinical efficacy data in various models of breast cancer. OST-HER2 has been conditionally approved by the U.S. Department of Agriculture for the treatment of canines with osteosarcoma. In addition, OS Therapies is advancing its next generation Antibody Drug Conjugate (ADC) platform, known as *tunable ADC* (tADC), which features tunable, tailored antibody-linker-payload candidates. This platform leverages the Company's proprietary silicone linker technology, enabling the delivery of multiple payloads per linker. For more information, please visit www.ostherapies.com.

Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute forward-looking statements within the meaning of the federal securities laws. These forward-looking statements and terms such as "anticipate," "expect," "intend," "may," "will," "should" or other comparable terms involve risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. Those statements include statements regarding the intent, belief or current expectations of OS Therapies and members of its management, as well as the assumptions on which such statements are based. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, including those described under the section entitled "Risk Factors" of our Registration Statement on Form S-1 declared effective by the Securities and Exchange Commission (the "SEC") on July 31, 2024, as well as any of our periodic reports filed with the SEC, and that actual results may differ materially from those indicated by such forward-looking statements. Any forward-looking statements contained in this press release speak only as of the date hereof, and, except as required by the federal securities laws, OS Therapies specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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Source: OS Therapies