August 29, 2024

OS Therapies Announces Last Patient Enrolled in OST-HER2 Osteosarcoma Phase 2b Clinical Trial Receives Last Treatment Dose

NEW YORK--(BUSINESS WIRE)-- OS Therapies Incorporated (NYSE American: OSTX) ("OS Therapies" or "the Company"), an ADC and Immunotherapy research and clinical-stage biopharmaceutical company, today announced that the last patient (Patient #41) enrolled in the AOST-2121 clinical trial (NCT04974008) of OST-HER2 in recurred, resected Osteosarcoma (OS) - has received its last treatment dose. This last patient is expected to complete its final radiological imaging evaluation as part of the 12-month Event Free Survival primary endpoint analysis by early in the fourth quarter of 2024. Concurrently, the Company will close all clinical trial sites and lock the database in preparation for data analysis and topline data readout that is expected to be announced in the fourth quarter of 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 study is designed to demonstrate efficacy in patients who have already had recurrent disease and are highly likely to recur. A total of 16 OST-HER2 doses are administered once every three weeks, with a follow-up approximately four weeks after the final dose is administered, for a total of 52 weeks study. Radiographic evaluation of recurrence is evaluated throughout treatment. 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.

AOST-2121 has achieved full enrollment of 41 patients treated with OST-HER2 at 21 clinical trial sites across the United States. 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 at 36 months, with interim Overall Survival endpoints at 12 months and 24 months. Topline EFS data, interim 2-year OS data, as well as additional secondary data analyses are expected to be reported in the fourth quarter of 2024. We believe there have not been any novel therapeutic interventions approved by the FDA that have improved the clinical outcomes for patients with Osteosarcoma in over 40 years.

The addition of the data from this final patient, along with Patient #40, will enhance interim data announced in conjunction with ASCO 2024. This is in addition to previously reported Phase I clinical data in Breast cancer, which the Company plans to target after Osteosarcoma. We thank the patients, families, clinicians, researchers, assistants and the

entire Osteosarcoma community for supporting this important and ground-breaking trial.

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. 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 initially filed with the Securities and Exchange Commission (the "SEC") on May 30, 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.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20240829924878/en/

Corporate and Media Contact:
Jack Doll
410-297-7793
lrpr@ostherapies.com

Investor Relations:
Dave Gentry
RedChip Companies, Inc.

1-407-644-4256
OSTX@redchip.com

Source: OS Therapies