October 22, 2025

OS Therapies Announces Overall and Event Free Survival Key Subgroup Data for OST-HER2 in Recurrent, Fully Resected, Pulmonary Metastatic Osteosarcoma

New York, New York--(Newsfile Corp. - October 22, 2025) -**OS Therapies Inc. (NYSE American: OSTX)** ("OS Therapies" or "the Company"), a clinical-stage cancer immunotherapy and antibody drug conjugate biotechnology company, today announced additional overall and event free survival data generated from the Company's 41-patient Phase 2b clinical trial of its off-the-shelf immunotherapeutic candidate OST-HER2 in recurrent, fully resected, pulmonary metastatic osteosarcoma (the "Phase 2b Osteosarcoma Trial"). The Company previously announced statistically significant positive final 2-year overall survival data from its Phase 2b Osteosarcoma Trial on October 10, 2025. The Company performed these subgroup analyses following its participation in the October 10, 2025 FDA/The Osteosarcoma Institute (OSI) Workshop: Advancing Osteosarcoma Drug Development - Connecting Research and Regulatory Pathways for Improved Outcomes.

- Patients with a lung-only second or greater metastatic event:
  - 2-year Overall Survival: 80.0% (8/10, 2 lost to follow-up)
  - 1-year Event Free Survival: 50% (6/12, 0 lost to follow-up)
- Patients with a lung-only first metastatic event:
  - 2-year Overall Survival: 73.8% (19/26, 3 lost to follow-up) vs. 30% Natural History Comparator ($p < 0.0001$)[1]
  - 1-year Event Free Survival: 28.6% (8/28, 1 Lost to follow-up)

"There was significant interest in the different patient subgroups that made up our study given the challenges typically seen in recruiting for clinical trials in osteosarcoma, especially with patients' first metastatic event for which we have sufficient data to perform this subgroup analysis," said Paul Romness, MPH, Chairman & CEO of OS Therapies. "We believe the favorable safety profile when compared with alternative institutional standards of care that rely primarily on chemotherapeutic agents played a significant role in that. The recruitment of patients into our study seems representative of the overall annual patient population and the overall survival efficacy signal appears broadly across the different subgroups of patients in our trial."

Mr. Romness continued, "We are looking forward to upcoming regulatory meetings with the U.S. Food & Drug Administration ('FDA'), the U.K. Medicines and Healthcare products Regulatory Agency ('MHRA') and the European Medicines Agency ('EMA') to review our overall survival data, pending biomarker data and post-market confirmatory OST-HER2 metastatic osteosarcoma trial design as we prepare to file a Biologics License Authorization (BLA) under the FDA's Accelerated Approval Program and Marketing Authorization Applications (MAAs) utilizing MHRA and EMA's Conditional Approval pathway."

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. OST-HER2 has received Rare Pediatric Disease Designation (RPDD) from the U.S. Food & Drug Administration and Fast-Track and Orphan Drug designations from the U.S. FDA and European Medicines Agency. The Company reported positive data in its Phase 2b clinical trial of OST-HER2 in recurrent, fully resected, lung metastatic osteosarcoma, demonstrating statistically significant benefit in the 12-month event free survival (EFS) primary endpoint of the study. The Company anticipates submitting a Biologics Licensing Application (BLA) to the U.S. FDA for OST-HER2 in osteosarcoma in 2025 and, if approved, would become eligible to receive a Priority Review Voucher that it could then sell. OST-HER2 has completed a Phase 1 clinical study primarily in breast cancer patients, in addition to showing 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) and Drug Conjugates (DC), known as tunable ADC (tADC), which features tunable, tailored antibody-linker-payload candidates. This platform leverages the Company's proprietary silicone Si-Linker and Conditionally Active Payload (CAP) 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. OS Therapies cautions readers that forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to certain risks and uncertainties that could cause actual results to differ materially, including, but not limited to the approval of OST-HER2 by the U.S. FDA and other risks and uncertainties described in "Risk Factors" in the Company's most recent Annual Report on Form 10-K, most recent Quarterly Report on Form 10-Q and other subsequent documents the Company files with the Securities and Exchange Commission. 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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[1] A.H. Aljubran, A. Griffin, M. Pintilie, M. Blackstein; Osteosarcoma in adolescents and adults: survival analysis with and without lung metastases; Annals of Oncology; Volume 20, Issue 6; 2009;1136-41

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