October 10, 2025

OS Therapies Announces Statistically Significant Positive Final 2-Year Overall Survival Data from Phase 2b Trial of OST-HER2 in the Prevention or Delay of Recurrent, Fully-Resected, Pulmonary Metastatic Osteosarcoma

- *75% of OST-HER2 treated patients achieved 2-year overall survival compared with 40% in the historical control group ($p < 0.0001$)*
- *100% of patients who achieved 12 month event free survival achieved 2 year overall survival*

New York, New York--(Newsfile Corp. - October 10, 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 statistically significant positive final 2-year overall survival data from the Company's Phase 2b trial of off-the-shelf immunotherapy candidate OST-HER2 in the prevention or delay of recurrent, fully-resected, pulmonary metastatic osteosarcoma (the "Fully Resected Metastatic Osteosarcoma Trial"). 75% (27 out of 36 evaluable patients; 5 patients were lost to follow-up) of OST-HER2 treated patients achieved 2-year overall survival as measured from most recent pulmonary resection, compared with 40% of historical control patients[1] (*$p < 0.0001$*) Subgroup analyses showed that 100% of patients who achieved 12-month Event Free Survival (EFS) achieved 2-year overall survival, whereas 59% of patients who did not achieve EFS achieved 2-year overall survival.

"The overall survival data in this non-randomized OST-HER2 study is encouraging as the results show it was safe and well-tolerated," said Dr. Peter Anderson, pediatric oncologist at Cleveland Clinic Children's. "New treatments are needed for treating metastatic osteosarcoma, so I am hopeful this could become an option in the near future." Dr. Anderson is a scientific advisor for OS Therapies.

"The continued outperformance in overall survival of OST-HER2 when compared with historical control is exactly what we were hoping for when we started the Company in 2018," said Paul Romness, MPH, Chairman & CEO of OS Therapies. "We have had highly productive regulatory meetings with the United Kingdom's (UK) Medicines and Healthcare products Regulatory Agency (MHRA), the United States (US) Food & Drug Administration (FDA) and the European Medicines Agency's (EMA) Dutch rapporteur. Representatives of all three regulatory agencies, in various ways, indicated that overall survival may be an appropriate clinical endpoint to support a conditional marketing authorization, especially when supported with biomarker data. The rationale for overall survival combined with

biomarkers is largely a result of the compelling data recently published in canine osteosarcoma by researchers at the University of Pennsylvania."

Dr. Robert Petit, Chief Medical & Scientific Officer for OS Therapies: "We are now prospectively analyzing patient samples from the clinical trial to confirm that clinical outcomes are indeed correlated with immune system biomarker activation. We expect that data to be available to us in November 2025, in time for our meetings we expect to hold with each of these regulatory agencies in December 2025. We remain on track to file a conditional Marketing Authorization Application (MAA) to MHRA in December 2025, a Biologics Licensing Application (BLA) under the Accelerated Approval Program to FDA in January 2026, and a MAA to EMA in the first quarter of 2026."

The Company will host an investor conference call on Monday, October 13, 2025 at 8:30am ET to discuss the data collected to date from the ongoing Fully Resected Metastatic Osteosarcoma Trial and the regulatory path to conditional marketing authorization(s) for OST-HER2 in the United Kingdom, the United States and the European Union. Dial-in details for the conference call / webcast will be available on the News/Investors page of the Company's website by 6am ET on the morning of the conference call.

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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