August 7, 2025

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

- *66.6% of OST-HER2 treated patients achieved 2-year overall survival compared with 40% in the historical control group (p = 0.0046)*
- *FDA issues Biologics Licensing Application (BLA) number for OST-HER2 in preparation for anticipated BLA filing for the prevention or delay of recurrent, fully resected, pulmonary metastatic osteosarcoma following August 27, 2025 End of Phase 2 Meeting*
- *Company responds to FDA correspondences seeking to align approval metrics for Regenerative Medicine Advanced Therapy (RMAT) designation, Breakthrough Therapy designation (BTD)* and Biologics Licensing Application via *Accelerated Approval Program*
- *Company's NYSE American listing included in the Russell Microcap, Russell Microcap Value and Russell Microcap Growth indexes*

New York, New York--(Newsfile Corp. - August 7, 2025) - OS Therapies (NYSE American: OSTX) ("OS Therapies" or "the Company"), a clinical-stage immunotherapy and Antibody Drug Conjugate (ADC) biopharmaceutical company, today announced statistically significant positive updated interim 2-year overall survival data from the Company's Phase 2b trial of off-the-shelf immunotherapy candidate OST-HER2 in the prevention of delay of recurrent, fully resected, pulmonary metastatic osteosarcoma. 66.6% (18 out of 27) of OST-HER2 treated patients achieved 2-year overall survival compared with 40% of historical control[1] (p = 0.0046).

Additionally, the US Food & Drug Administration ("FDA") issued a Biologics Licensing Application ("BLA") number for OST-HER2 to receive a BLA submission following the Company's pending August 27, 2025 End of Phase 2 Meeting. The Company has responded to FDA correspondences seeking to align approval metrics for Regenerative Medicine Advanced Therapy (RMAT) designation, Breakthrough Therapy designation (BTD) and BLA via the Accelerated Approval Program.

"We are seeking to bring this novel immunotherapy to market to improve the survival rates in pulmonary metastatic osteosarcoma, and today's updated interim overall survival data continues to show a statistically significant benefit for OST-HER2 treated patients compared with control," said Paul Romness, MPH, Chairman & CEO of OS Therapies. "We believe that

continued statistically significant outperformance in overall survival of OST-HER2 treated patients compared with historical control, together with the statistically significant positive 12-month Event Free Survival data presented at MIB Factor in June 2025, will provide the necessary scientific and medical basis to support a BLA under the FDA's Accelerated Approval Program."

Concurrent with this announcement, the Company today announced that its NYSE American listing is included in the Russell Microcap, Russell Microcap Value and Russell Microcap Growth indexes. FTSE Russell determines membership for its Russell indexes primarily by objective, market-capitalization rankings and style attributes. Russell indexes are widely used by investment managers and institutional investors for index funds and as benchmarks for active investment strategies. Approximately $12 trillion in assets are benchmarked against Russell's US indexes. Russell indexes are part of FTSE Russell, a leading global index provider. For more information on the US Russell Microcap Index and the Russell indexes reconstitution, including Russell 2000 and Russell 3000 reconstitution, please visit the FTSE Russell website.

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. This information concerns product candidates that are under clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA). These product candidates are currently limited by Federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated. OS Therapies cautions readers that forward-looking statements are based on management's expectations and assumptions as of the date of this news 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 FDA and other risks and uncertainties described under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K 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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