June 2, 2026

OS Therapies Achieves Statistically Significant 2.5-Year Overall Survival in Phase 2b Trial of OST-HER2 in Fully Resected Pulmonary Metastatic Osteosarcoma

- *75% 2.5-year overall survival for OST-HER2 vs. 47% pooled historical control (p = 0.003), with no new patient deaths reported since the 2-year overall survival data (75% vs. 60%, p = 0.034)*
- *Updated clinical efficacy data being added to regulatory dossiers as Company seeks early market authorizations in U.S., U.K., Europe and Australia in 2nd half of 2026*
- *EMA and Australia TGA (TGA) alignment achieved on early Q4-2026 3-year overall survival data, supported by biomarker data, as key approvable clinical efficacy endpoint*
- *Upcoming U.S. FDA and U.K. MHRA meetings seek alignment with EMA and TGA on Phase 2b 3-year overall survival and biomarker data to support early market access*
- *Confirmatory Phase 3 study, required to have commenced prior to grant of early market access in U.S., U.K., Europe or Australia, expected to initiate in late Q3-2026 in Australia*

New York and Rockville, Maryland--(Newsfile Corp. - June 2, 2026) -**OS Therapies, Inc. (NYSE American: OSTX) ("OS Therapies" or "the Company")**, the world leader in gene-edited, Listeria-based cancer immunotherapies, today announced that its Phase 2b trial of OST-HER2 in the prevention or delay of recurrence in fully resected, pulmonary metastatic osteosarcoma (the "Metastatic Osteosarcoma") achieved statistically significant benefit for OST-HER2 treated patients in overall survival at the 2.5-year timepoint (75% vs. 47%, p = 0.003, Figure 1 OST-HER2 vs. pooled historical control). The topline data shows improving OST-HER2 survival benefit when compared with the 2-year data (2-year overall survival was 75% vs. 60%, p = 0.034). No new patient deaths were reported between the 2 and 2.5-year timepoints in the OST-HER2 treated group. OST-HER2 data is supported by a unique, patent pending pharmacodynamic immune response biomarker signature (Antigen Presentation, NK Cell Activation, T Cell Activation, etc.) that was developed as a surrogate clinical efficacy endpoint. The Company intends to present detailed data results during the MIB Agents Factor 2026 Osteosarcoma Conference being held June 25-27, 2026 in Columbus, OH.

"The osteosarcoma community is eagerly awaiting its first approved immunotherapy that has a strong safety profile and activates the immune system to surveil against pulmonary recurrence," said Dr. Peter Anderson, pediatric oncologist at Cleveland Clinic Children's and member of the scientific advisory board for OS Therapies. "New treatments are needed for metastatic osteosarcoma, so I am hopeful OST-HER2 could become an option in the near

future."

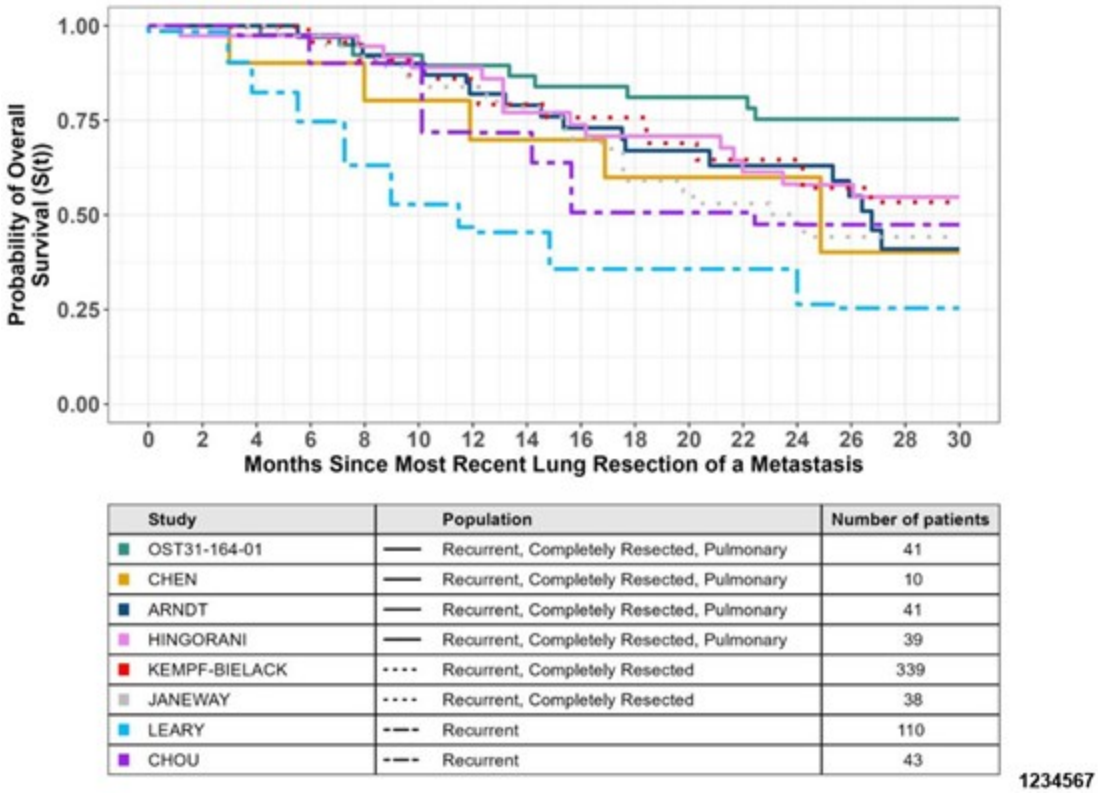

Figure 1 - Overall Survival Kaplan-Meier Curve

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OS Therapies is now updating its ongoing U.S. and international regulatory market authorization submissions for OST-HER2 in Metastatic Osteosarcoma with this new clinical efficacy data. The European Medicines Agency (EMA) and the Australian Therapeutic Goods Administration (TGA) have already aligned on the use of 3-year overall survival data that will be available in early Q4-2026 as the key clinical efficacy data to support the Company's conditional Marketing Authorisation Applications (cMAAs), with rolling review already underway in Europe. The Company has an upcoming Type B Pre-BLA Meeting with the U.S. Food & Drug Administration (FDA) to gain alignment on use of the forthcoming 3-year overall survival to support a Biologics Licensing Application (BLA) under the Accelerated Approval Program.

"The sustained survival benefit for patients treated with our immunotherapy, with no new deaths reported between the 2-year and 2.5-year timepoints, demonstrates potential durability of OST-HER2's clinical benefit for metastatic osteosarcoma patients," said Dr. Craig Eagle, Chief Medical Advisor of OS Therapies. "As we engage further with regulators on the risk-benefit of OST-HER2 treatment for patients likely to experience metastatic osteosarcoma recurrence, we believe that sustained overall survival benefit, when coupled with the biomarker data, will support early market access authorizations in late 2026. With 3-year survival data on the horizon in early Q4-2026 to support our FDA, EMA, MHRA and TGA filings for early market access, we anticipate receiving authorizations in late Q4-2026."

OS Therapies also has an upcoming Type C Meeting with FDA, and a separate Scientific Advice Meeting (SAM) with the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA), both being held in early June 2026, to confirm each agency's alignment with the key design parameters already agreed upon with EMA and TGA for the confirmatory Phase 3 protocol.

OST-HER2 has received Orphan Drug Designation (ODD), Fast Track Designation (FTD) and Rare Pediatric Disease Designation (RPDD) from the FDA, and ODD, FTD and ATMP from the EMA. Under the RPDD program, if the Company is granted a BLA in the United States, it will become eligible to receive a Priority Review Voucher (PRV) which it intends to sell. The Company has begun filing a BLA for OST-HER2 in pulmonary metastatic osteosarcoma with FDA under the Accelerated Approval Program for OST-HER2 and has received rolling review from the EMA. The Company also anticipates CMA decisions in Europe, the U.K. and Australia in late 2026.

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. The Company is the world leader in gene-edited, Listeria-based cancer immunotherapies. 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 is designed to target two mutated extracellular epitopes and one mutated intracellular epitope of the HER2 oncogene, requiring only one of these three epitopes to be present in a tumor (or micro-metastasis) to trigger the desired immune response. OST-HER2 has received Orphan Drug Designation (ODD), Fast Track Designation (FTD) and Rare Pediatric Disease Designation (RPDD) from the U.S. Food & Drug Administration and has received ODD, FTD and ATMP from the 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 clinically significant benefit in the 12-month event free survival (EFS) primary endpoint of the study and the overall survival (OS) secondary endpoint. The Company is seeking a Biologics License Application (BLA) from the U.S. FDA for OST-HER2 in osteosarcoma in 2026 and, if approved, would become eligible to receive a Priority Review Voucher that it could then sell. The Company also anticipates receiving Conditional Marketing Authorisations from the U.K.'s Medicines and Healthcare products Regulatory Agency and the EMA for OST-HER2 in 2026. 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. The Company also anticipates reading out data from a Phase 1b study of OST-504 in castration resistant prostate cancer in the first half of 2026.

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 our expectations regarding cash runway into 2027, the potential 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 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 because of new information, future events or otherwise.

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