June 30, 2026

OS Therapies Provides U.S. Regulatory Update

- *Type B Meeting requested to follow up on September 2025 End of Phase 2 FDA Meeting guidance on statistical methods to be used for BLA Submission*
- *Seeking to align FDA with MHRA & EMA on 3-year overall survival as approval endpoint*
- *Biomarker data submitted to FDA BEST program as surrogate clinical efficacy data*
- *Synthetic historical control arm OST-400 recruitment potentially adds comparator for BLA submission under the Accelerated Approval*
- *Review of Rolling Review, RMAT & Breakthrough Therapy designation requests sought*

New York, New York and Rockville, Maryland--(Newsfile Corp. - June 30, 2026) - **OS Therapies, Inc. (NYSE American: OSTX) ("OS Therapies" or "the Company")**, the world leader in gene-edited, Listeria-based cancer immunotherapies, today provided regulatory update on the Company's interactions with the U.S. Food and Drug Administration (FDA) in its pursuit of a Biologics License Application (BLA) under the Accelerated Approval Program (Accelerated Approval) for OST-HER2 in the prevention or delay of recurrence in fully resected, pulmonary metastatic osteosarcoma (the "Metastatic Osteosarcoma Program"). OS Therapies has requested a Type B Meeting to review the Company's 2.5-year overall survival data and to confirm alignment that 3-year overall survival data is an approvable clinical efficacy endpoint. The Company recently aligned with the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency on 3-year overall survival as the proposed approvable clinical endpoint to support Conditional Marketing Authorisations. The Company has also submitted its pharmacodynamic response biomarker data to the FDA's Biomarkers, Endpoints, and other Tools (BEST) program for evaluation as a surrogate clinical efficacy data. FDA and EMA have begun joint coordination on the OST-HER2 regulatory dossier to evaluate early market access.

OS Therapies intends to review with FDA the potential inclusion of concurrent natural history control database OST-400, "Recurrent Osteosarcoma after Resection in Children and Young Adults: A Retrospective Longitudinal Study," as an added synthetic control comparator arm at the meeting. The Company recently made significant progress with recruitment for OST-400 that now allows the Company to respond to June 2025 Breakthrough Therapy Designation (BTD) request feedback and September 2025 End of Phase 2 Meeting guidance provided by FDA on OST-400's development. OS Therapies also expects to review outstanding Rolling Review, Regenerative Medicine Advanced Therapy (RMAT) designation and BTD requests with FDA at the meeting. The potential suitability of OST-400 as a second supportive comparator arm for Accelerated Approval is in addition to the suitability of pooled historical control data already shared with FDA to support Accelerated Approval.

"We look forward to reviewing our overall survival data with FDA as we seek to gain the same alignment we now have with MHRA and EMA on the use of 3-year overall survival clinical efficacy data together with pharmacodynamic biomarker surrogate clinical efficacy

data to support early market access of OST-HER2 for patients in the U.S.," said Paul Romness, MHP, Chairman and CEO of OS Therapies. "With significant progress having now been made with recruitment for OST-400, we believe we are in a strong position to gain alignment on the proposed statistical analysis methods to be used to confirm clinical results in the upcoming 3-year overall survival data readout early in the fall. We are hopeful that this upcoming meeting will allow us to align FDA with the EMA and MHRA on rolling review and regenerative medicine status now that joint dossier coordination has begun between the three agencies."

About OST-400

OST-400 is a natural history study entitled "Recurrent Osteosarcoma after Resection in Children and Young Adults: A Retrospective Longitudinal Study". Data is being sourced primarily from US and international oncology research institutions. OST-400 database is being assembled in order to be able to develop a synthetic control arm suitable to support a randomization process that could serve as comparator arm in the event FDA relies upon its 2023 Rare Diseases guidance. Various FDA-accepted statistical analysis methods reviewed in this Guidance allow for randomization after treatment in single-arm trials.

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 Authorisation Applications 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.

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 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 as a result of new information, future events or otherwise.

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