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OS Therapies Achieves Global Regulatory Alignment on Design of Phase 3 Trial of OST-HER2 in Fully Resected, Pulmonary Metastatic Osteosarcoma

- *Confirmatory Phase 3 trial to commence prior to BLA grant under Accelerated Approval Program in the U.S. and Conditional MAA in the U.K., Europe and Australia*
- *Patent pending pharmacodynamic response biomarker accepted as surrogate clinical efficacy endpoint*
- *TGA and MHRA agree to allow utilization of remaining Phase 2b drug product for initiation of confirmatory Phase 3*
- *FDA and EMA fully align with Company on Chemistry, Manufacturing and Controls (CMC)*
- *Market access process initiated with UK NICE and EU JCA*

New York, New York and Rockville, Maryland--(Newsfile Corp. - June 8, 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 it achieved alignment on the design of its pending Phase 3 study of OST-HER2 in the prevention or delay of recurrence in fully resected, pulmonary metastatic osteosarcoma with the U.S. Food & Drug Administration (FDA) and the U.K. Medicines and Healthcare products Regulatory Agency (MHRA). A confirmatory Phase 3 study is required to have commenced prior to the grant of a Biologics License Application (BLA) under the Accelerated Approval Program in the U.S. and Conditional Marketing Authorisation Applications (CMAAs) in the U.K., Europe and Australia. The Phase 3 study has received substantial support from international KOLs as part of regulatory meetings and is expected to commence late in the third quarter in Australia making the Company eligible for regulatory decisions in the fourth quarter.

"This alignment amongst each of the four key regulatory agencies where we are seeking early market access allows us to move forward with confidence as we prepare the Clinical Trial Notification (CTN) scheme submission to the Australian Therapeutic Goods Administration (TGA) to gain authorization to initiate the Phase 3 study," said Dr. Craig Eagle, Chief Medical Advisor of OS Therapies. "Australia has a very attractive R&D tax incentive program complementing the company's existing UK R&D tax credit strategy to incentivize the initiation of global clinical trials, allowing us to initiate the Phase 3 with minimal cost. MHRA and TGA are allowing us to initiate the Phase 3 trial with the same drug product used in the Phase 2b trial, positioning the Phase 3 trial to open in the third quarter of 2026. FDA, MHRA, EMA and TGA have now aligned with the Company on the CMC plan and potency assays for commercial drug product. These alignments allow the Company to be positioned for potential year-end regulatory decisions and 2027 patient access."

Dr. Eagle continued, "Both FDA and MHRA also aligned with the EMA and TGA to include

the pharmacodynamic biomarker signature as a surrogate clinical efficacy endpoint in the Phase 3. EMA has already begun rolling review of the regulatory dossier and we expect decisions regarding rolling review and Regenerative Medicine Advanced Therapy (RMAT) designation in the United States following our upcoming Type B Pre-BLA Meeting following the successful Type C Phase 3 Design Meeting last week."

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 Advanced Therapeutic Medicinal Product (ATMP) designation from the EMA and MHRA. 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) that it intends to sell. The Company has begun filing a BLA for osteosarcoma with FDA and has received rolling review from the EMA.

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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