June 6, 2025

OS Therapies Submits Request for Regenerative Medicine Advanced Therapy (RMAT) Designation to U.S. FDA for OST-HER2 in the Prevention of Metastases in Recurrent, Fully-Resected, Lung Metastatic Pediatric Osteosarcoma

- If awarded, OST-HER2 would become the first listeria investigational medicinal product to be awarded the RMAT designation
- RMAT designation reduces BLA application review time and permits augmented interactions with FDA to inform market access

NEW YORK--(BUSINESS WIRE)-- **OS Therapies Inc. (NYSE-A: OSTX)** ("OS Therapies" or "the Company"), a clinical-stage cancer immunotherapy and antibody drug conjugate biotechnology company, today announced it has submitted a request for Regenerative Medicine Advanced Therapy (RMAT) Designation to U.S. FDA for OST-HER2 in the prevention of metastases in recurrent, fully-resected, lung metastatic pediatric osteosarcoma. RMAT designations are granted to sponsors with regenerative medicine therapies for serious or life-threatening conditions and provide sponsors with various benefits, including eligibility for an accelerated Biologics License Application (BLA) review.

OST-HER2 has already received Rare Pediatric Disease Designation (RPDD), Orphan Drug Designation (ODD) and Fast Track Designation (FTD) for osteosarcoma from the U.S. FDA. If OST-HER2 receives a conditional BLA via Accelerated Review prior to September 30, 2026, the Company will become eligible to receive a Priority Review Voucher (PRV) that it intends to immediately sell. The most recent publicly disclosed PRV sale, valued at $155 million, occurred in May 2025.

The Company is awaiting feedback by mid-June 2025 from a Type D meeting with FDA regarding the statistical analysis plan to be used in an End of Phase 2 meeting for OST-HER2 in the prevention of metastases in recurrent, fully-resected, lung metastatic pediatric osteosarcoma. Upon receipt of the Type D Meeting feedback, the Company intends to promptly request the End of Phase 2 meeting with FDA in which it will be seek agreement to allow it to begin a rolling BLA submission in the third quarter of 2025. The grant of the RMAT designation in the third quarter of 2025 complements the company's parallel efforts in other major markets, including Europe and the United Kingdom, where the company plans to seek EMA PRIME Designation and Conditional Market Access (CMA) applications.

In parallel to regulatory engagement and market access planning for OST-HER2, the Company is preparing for the late stage clinical development of other pipeline candidates. As such, the Company is well positioned for sustained growth across multiple therapeutic

modalities.

About OS Therapies

OS Therapies is a clinical stage oncology company focused on the identification, development, and commercialization of treatments for osteosarcoma 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 has demonstrated 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 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 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 U.S. FDA and other risks and uncertainties described in “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” 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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