April 22, 2025

OS Therapies FDA Meeting Request Granted

- *Written response-only meeting to align analysis plan of surrogate endpoint to support Breakthrough Therapy Designation & Accelerated Approval of OST-HER2 in the Prevention of Recurrence of Fully Resected, Lung Metastatic Osteosarcoma*
- *Analysis to be featured at keynote presentation closing out major osteosarcoma conference MIB Factor on June 28, 2025 at 3:30pm MDT*

NEW YORK--(BUSINESS WIRE)-- OS Therapies (NYSE-A: OSTX) ("OS Therapies" or "the Company"), a clinical-stage immunotherapy and Antibody Drug Conjugate (ADC) biopharmaceutical company, today announced that the US Food & Drug Administration ("FDA") granted the Company's meeting request to gain alignment on the surrogate endpoint to support Breakthrough Therapy Designation & Accelerated Approval of OST-HER2 in the Prevention of Recurrence of Fully Resected, Lung Metastatic Osteosarcoma. FDA granted a written response-only meeting and confirmed that its response would be received by mid-June 2025, in time for the Company to present the statistical analysis as part of the keynote presentation closing out major osteosarcoma conference MIB Factor on June 28, 2025 at 3:30pm MDT.

"We are pleased that FDA agreed to the requested meeting forward and work within the timelines of the meeting type requested so that we would be able to share our analysis with the patient and physician communities that will be represented at MIB Factor in late June," said Robert Petit, Chief Medical & Scientific Officer of OS Therapies.

"We remain on track for an early third quarter submission and are hopeful to receive approval by year-end 2025 in order to bring this life saving treatment to patients in early 2026," said Paul Romness, CEO of OS Therapies.

OST-HER2 has received Rare Pediatric Disease Designation (RPDD) for osteosarcoma from the US FDA, and if it receives a conditional BLA via Accelerated Review prior to September 30, 2026, it will become eligible to receive a Priority Review Voucher (PRV) that it intends to immediately sell. The most recent PRV sale, valued at $150 million, occurred in February 2025.

The osteosarcoma treatment market was estimated at $1.2 billion in 2022 according to Data Bridge Market Research. Approximately 50% of patients are diagnosed with a lung metastasis at some point following surgical resection and chemotherapy. 3-year survival rates in patients who were not diagnosed with a metastasis are 59%. 3-year survival rates in patients who were diagnosed with pulmonary metastasis were 30%. The Company believes the market opportunity for OST-HER2 in the prevention of lung metastases is over $500 million.

OST-HER2, an immunotherapy for osteosarcoma using a HER2 bioengineered form of the bacteria Listeria monocytogenes to trigger a strong immune response against cancer cells

expressing HER2, is being featured in the upcoming movie Shelter Me: The Cancer Pioneers. The movie offers a look into canine comparative oncology, a field that compares treatment of cancers in dogs to those in people and covers developing treatments for rare forms of cancer. A trailer for the movie is available here. The movie will air live nationally on PBS and be available via streaming on PBS' website in early May 2025.

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 US Food & Drug Administration and Fast-Track and Orphan Drug designations from the US FDA and European Medicines Agency. The Company 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 US 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 US FDA and grant of a priority review voucher 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 registration statement on Form S-1 filed with the Securities and Exchange Commission (the "SEC") on November 12, 2024, as amended on November 27, 2024, and other subsequent documents we file with the SEC, including but not limited to our Quarterly Reports on Form 10-Q. 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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