April 7, 2025

OS Therapies Requests Meeting with FDA to Gain Agreement on Surrogate Endpoint(s) for Breakthrough Therapy Designation & Accelerated Approval of OST-HER2 in the Prevention of Recurrence of Fully Resected, Lung Metastatic Osteosarcoma

- *OS Therapies applies for meeting per FDA suggestion received on April 2, 2025*
- *Based on prior FDA guidance, greater than 200 suitable matched lung metastatic osteosarcoma patient records identified from leading oncology centers in the US, UK and France for inclusion in OST-400, a Retrospective Longitudinal Study of Recurrent Osteosarcoma after Resection in Children and Young Adults*

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 it has submitted a request for a formal meeting with the Center for Biologics Evaluation and Research (CBER) of the United States Food & Drug Administration (FDA) to gain alignment on the clinical endpoints required to support Breakthrough Therapy Designation (BTD) and Accelerated Approval via a conditional BLA of investigational off-the-shelf immunotherapy candidate OST-HER2 in the prevention or delay of recurrence of fully resected, lung metastatic osteosarcoma. The meeting is expected to occur in the second quarter of 2025, and thereafter the Company intends to initiate a rolling BLA submission with the potential to receive Accelerated Approval as early as year-end 2025. The Company has sufficient cash on hand to operate into mid-2026.

"We are excited to meet with the FDA – and commence market access discussions - the goal of receiving Accelerated Approval for a Biologics License Application of OST-HER2 in the prevention or delay of recurrence lung metastatic osteosarcoma by year-end 2025," said Dr. Robert Petit, Chief Medical & Scientific Officer of OS Therapies. "We believe that we have identified the comparator data necessary to address the comments from FDA regarding our prior BTD request. We expect this data will also be able support our application for Accelerated Approval. Our clinical and regulatory teams are diligently preparing for the meeting and the subsequent BLA submission that is targeted to begin after the public release of additional clinical trial data at MIB Factor in June."

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.

“We congratulate the new Acting Director at CBER, Dr. Scott Steele, who comes from a translational medicine background and understands the importance of Comparative Oncology in the development of new cancer immunotherapies and note that President Trump cited deadly rare pediatric cancers as a priority for continued product development for the administration,” said Paul Romness, CEO of OS Therapies. “We believe OST-HER2 will make a significant difference in the treatment of osteosarcoma and welcome the opportunity to engage with FDA to get this investigational treatment to patients as quickly as possible.”

The Company announced positive Phase 2b clinical trial results from its US-based, 21 site, single-arm, open-label clinical study of 39 patients in recurrent, fully resected, lung metastatic osteosarcoma that demonstrated a statistically significant improvement in the proportion of patients that achieved the primary endpoint of 12-month event free survival (EFS) when compared with historical control (33% vs. 20%, *p=0.0158*), as recommended by FDA prior to the initiation of the study. Due to the aggressive nature of osteosarcoma metastatic to the lung, an aggressive form of rare pediatric bone cancer that requires resections to sequentially remove tumors from the lung given the very poor clinical responses and survival rates to current treatments, placebo-controlled trials are generally disfavored.

Following feedback from FDA, the Company designed OST-400, a Retrospective Longitudinal Study of Recurrent Osteosarcoma after Resection in Children and Young Adults being conducted with clinicians from leading oncology centers in the United States, the United Kingdom and France to obtain potentially over 200 suitable de-identified patient records from which the appropriate matched, external historic control is being developed. At the invitation of FDA on April 2, 2025, the requested meeting is to get agreement with respect to the methods the Company is using to finish collecting OST-400 so that the appropriate matched, external, historic control is used to complete the statistical analysis that will be used to support BTD and Accelerated Approval.

The Company intends to present the data from the Phase 2b clinical trial of OST-HER2 compared with the matched, external, historic control comparator agreed upon with FDA derived from OST-400 at MIB Factor in June 2025. Thereafter, the Company intends to file a BLA for OST-HER2 in the prevention or delay of recurrence of fully resected, lung metastatic osteosarcoma, with the aim of receiving approval by the end of 2025.

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 be aired live nationally on PBS and will 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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