June 30, 2025

OS Therapies Presents Statistically Significantly Positive 1-Year Event Free Survival, Overall Survival and Safety Clinical Data Updates for OST-HER2 at the MIB Agents Factor Osteosarcoma Conference

- *The primary endpoint of 12-month Event Free Survival (EFS) for OST-HER2- treated patients (35%) was statistically significant (p= 0.0194) when compared with peer-reviewed comparable historical control (20%)*
- *Company also provides regulatory update on comparator for OST-HER2 Phase 2b Trial in the Prevention or Delay of Recurrence in Fully Resected, Lung Metastatic Osteosarcoma*
- *Responses to recent FDA Type D Meeting follow-up questions submitted by OS Therapies*

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 positive 1-year event free survival (EFS), overall survival and safety clinical trial data updates from the 40 patient treatment arm of its Phase 2b clinical trial of immunotherapy candidate OST-HER2 in the prevention or delay of recurrence in fully resected, lung metastatic osteosarcoma. In data presented by Principal Investigator Dr. Damon Reed at the MIB Factor Osteosarcoma Conference held in Salt Lake City, Utah on Saturday June 28, 2025 the following data updates were released:

- 35% (14 out of 40) of OST-HER2-treated patients achieved 1-year event free survival (EFS) compared with 20% of patients from peer-reviewed publication selected by Children's Oncology Group (COG)[1] as equivalent to osteosarcoma patient subpopulation enrolled (p = 0.0194);
- A total of 13 out of 40 patients were reported to have experienced severe adverse events (SAEs) during the trial, of which 7 patients' adverse events were treatment-associated adverse events (TSAEs). All of the 7 patients' TSAEs were grade 3 TSAEs; 0 patients experienced grade 4 or grade 5 TSAEs. None of the patients for whom TSAEs were reported discontinued the study.

"The updated OST-HER2 data presented at MIB Factor that showed EFS data statistically significantly favoring OST-HER2 treated patients when compared with the leading peer-reviewed publications on historical event free survival outcomes in this subset of the pulmonary metastatic osteosarcoma patient population," said Dr. Robert Petit, Chief Medical & Scientific Officer of OS Therapies. "The favorable safety profile of OST-HER2 compared

with standard of care is also an important quality of life factor when assessing potential new treatment options for this difficult to treat patient population."

Additionally, the Company today announced a regulatory update regarding the submission of preliminary external control data and comprehensive plans for the finalization of this data package to the US Food & Drug Administration's ("FDA"). In accordance with the provisions of prevailing Guidance to Industry – including *ICH E10 Choice of Control Group in Clinical Trials; Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products 2019; and Rare Diseases – Natural History Studies for Drug Development 2019* - to support a Biologics Licensing Application (BLA) marketing authorization under the US Food & Drug Administration's ("FDA") Accelerated Approval Program ("Accelerated Approval").

Based on guidance from FDA from its recent Type D Meeting and the submission of subsequent responses to FDA arising from the Meeting, the Company is providing updated superiority peer-reviewed historical external control data, matched external control data and/or real-world external control data. This data, individually or collectively at FDA's discretion, may be sufficient for FDA to support a marketing authorization in a setting where randomization may not be feasible. Such an approach is common in rare diseases – such as Prevention or Delay of Recurrence in Fully Resected, Lung Metastatic Osteosarcoma - for which the company holds US FDA Orphan Disease Designation (ODD), Fast Track and Rare Pediatric Disease Designation (RPDD).

The Company has submitted clarifying information to FDA Type D Meeting feedback requests regarding proposed statistical methods to be used in FDA's assessment of external control arm(s) suitable to support Accelerated Approval. The Company is awaiting response from FDA to its End of Phase 2 meeting request where, if granted, the Company will seek full alignment on the individual and/or collective data sets necessary to support Accelerated Approval. The Company has collected multiple sources of potential case matched external control and real-world data potentially suitable, individually or together with historical external control data at FDA's discretion, to support Accelerated Approval.

"The feedback received from FDA regarding the use of external control comparators in settings where placebo-controlled randomization trials are not feasible increases the avenues available for OST-HER to gain Accelerated Approval," said Paul Romness, Chairman & CEO of OS Therapies. "We have now responded to the follow-up questions from our recent positive Type D Meeting with FDA positioning us to soon be granted an End of Phase 2 meeting. We were also very pleased with the reception the presentation received from the osteosarcoma community."

Mr. Romness continued: "Recent interactions we have had with FDA are consistent with public statements from FDA leadership prioritizing the safety profile of potential new products under consideration for Accelerated Approval that are intended to treat deadly rare diseases where randomized trials may not be feasible, especially in pediatric cancer where no alternative treatment options are approved."

Concurrent with this announcement, the United Kingdom's (UK) Medicines and Healthcare products Regulatory Agency (MHRA) has agreed to support the Company in utilizing its Clinical Practice Research Datalink (CRPD) to assist the Company in developing data necessary to support potential worldwide marketing authorizations – including in the UK, US

and EU - for OST-HER2. The CPRD collects anonymized patient data from a network of healthcare practitioners and institutions across the UK. Primary care data are linked to a range of other health related data to provide a longitudinal, representative population health dataset. The data encompass 60 million patients, including 18 million currently registered patients. Follow-up from the Company's July 31st, 2025 Scientific Advice Meeting with MHRA is expected by mid-August 2025. (https://www.cprd.com)

OST-HER2 has received Rare Pediatric Disease Designation (RPDD) for osteosarcoma from the US FDA. If the Company receives Accelerated Approval prior to September 30, 2026, it will become eligible to receive a Priority Review Voucher (PRV) that it intends to sell. The most recent PRV sale, valued at $160 million, occurred in June 2025.

OST-HER2, an immunotherapy for osteosarcoma that uses a HER2-bioengineered form of the bacterium *Listeria monocytogenes* to trigger a strong immune response against HER2-expressing cancer cells, is featured in the 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. The movie is available via streaming on PBS' website.

The most recent data updated regarding the OST-HER2 canine osteosarcoma program is available at this link.

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 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.

[1] 1 Lagmay JP, Krailo MD, Dang H, et al: Outcome of patients with recurrent osteosarcoma enrolled in seven Phase II trials through Children's Cancer Group, Pediatric Oncology Group, and Children's Oncology Group: learning from the past to move forward. J Clin Oncol. 2016;34:3031-8

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