March 31, 2025

OS Therapies Provides Regulatory Update on Rare Pediatric Cancer Immunotherapy Candidate OST-HER2 for Human Osteosarcoma

- *Dialogue open with FDA in preparation for End of Phase 2 Meeting request*
- *New canine elite responder biomarkers added to human biomarker strategy*

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 provided a regulatory update for its OST-HER2 listeria monocytogenes (*Lm*) immunotherapeutic cancer biologic drug candidate in the prevention or delay of fully-resected, recurrent, lung metastatic osteosarcoma.

"We are making rapid progress in putting together an appropriate data package to achieve accelerated approval for OST-HER2 given the feedback we've received to date from the FDA," said Paul Romness, MHP, Chairman & CEO of OS Therapies. "We know one of the US government's stated priorities is to treat deadly childhood cancers, and we believe that OST-HER2 for osteosarcoma aligns well with that mission."

Regulatory Timelines

The Company initiated regulatory correspondence with the US Food & Drug Administration (FDA) and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) in the first quarter of 2025. The Company intends to initiate regulatory interaction with the European Medicines Agency (EMA) and EMA National Competent Authorities in the second quarter of 2025.

FDA

- Q1/25: Regulatory communication regarding endpoints for accelerated approval
- Q2/25: End of Phase 2 Meeting
- Q3/25: Initiation of rolling BLA submission
- Q4/25: Conditional BLA via Accelerated Approval Program

MHRA

- Q1/25: Scientific Advice Meeting requested and granted
- Q3/25: Scientific Advice Meeting with MHRA and ILAP application submission
- Q4/25: Application for joint Scientific Advice Meeting with MHRA and National Institute for Health and Care Excellence (NICE)
- Q4 25: MHRA Conditional Marketing Authorisation application.

EMA

- Q2/25: EMA National Competent Authority Scientific Advice Meeting Request (Medicines Evaluation Board, Netherlands)
- Q3/25: EMA PRIME and EMA Orphan Designation applications
- Q4/25: EMA-FDA Parallel Scientific Advice application
- Q1 26: EMA Conditional Marketing Authorisation application.

The Company has recently buttressed its regulatory and clinical strategy & operations infrastructure with the addition of key consulting agencies with significant track records in rare pediatric cancer, Priority Review Voucher (PRV) program approvals, and worldwide Conditional Market Access Applications including in the EU and UK.

The Company reiterates its commitment to seeking to obtain FDA approval for OST-HER2 in the rare pediatric cancer osteosarcoma in 2025. The Company is eligible to receive a Priority Review Voucher (PRV) if OST-HER2 is approved under its Rare Pediatric Disease Designation (RPDD) by September 30, 2026.

The Company has sufficient cash on hand to operate into 2026.

Potential Treatment Response Biomarkers from Canine Osteosarcoma Program

The Company's canine osteosarcoma program recently made significant progress in understanding which biomarkers likely drive anti-tumor activity in prevention of recurrence of metastases, metastasis treatment (lung resection is not standard of care in canines) and primary tumor treatment to achieve limb sparing in dogs. The data generated creates the potential for the eventual expansion of the uses of OST-HER2 in osteosarcoma into treatment of unresectable lung metastases and limb sparing prior to surgical resection.

The Company intends to evaluate these biomarkers as potentially predictive of treatment response in humans in preparation for regulatory discussions with FDA, MHRA and EMA. Canine equivalent biomarkers have previously been used as surrogate endpoints for rare diseases in Comparative Oncology, which is the study of diseases that occur in humans and animals and have significant genetic homology. Human and Canine osteosarcoma have 96% genetic homology.

The Company is preparing to initiate regulatory correspondence with the United States Department of Agriculture (USDA) with the Company's updated manufacturing process which incorporates key improvements covered under a patent that was recently granted a notice of allowance by the United States Patent & Trademark Office (USPTO).

Shelter Me is a film that was produced to highlight the important role of human and canine Comparative Oncology disease research. The movie will premiere on April 3, 2025 at AMC Century City in Los Angeles and will later be available to stream through the PBS app and on PBS.org.

About Shelter Me

Shelter Me: The Cancer Pioneers also features leading scientists at the National Cancer Institute/National Institutes of Health, the University of Pennsylvania, the University of Illinois, the University of Wisconsin, and Colorado State University. It is part of an Emmy

Award-winning PBS series, *Shelter Me,* that celebrates the life-changing relationships between people and animals.

A trailer of the movie can be viewed here.

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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OS Therapies Contact Information:
Jack Doll
571.243.9455
lrpr@ostherapies.com

https://x.com/OSTherapies
https://www.instagram.com/ostherapies/
https://www.facebook.com/OSTherapies/
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