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OS Therapies Initiates Commercial-ready Manufacturing of OST-HER2 to Support Anticipated Biologics Licensing Authorization (BLA) Filing

NEW YORK--(BUSINESS WIRE)-- OS Therapies, Inc. (NYSE-A: OSTX), a clinical-stage biotechnology company advancing immunotherapies and targeted drug conjugates for cancer treatment, today announced that it has entered into agreements for the commercial manufacture of OST-HER2. The Company is currently organizing additional data in relation to the recently-completed treatment phase of its Phase 2b trial of OST-HER2 in the prevention of recurrence of lung metastatic osteosarcoma in preparation for a Type B or Type C meeting with the US Food & Drug Administration ("FDA"). Following the FDA meeting, the Company anticipates that it will be submitting a Biologics Licensing Authorization (BLA) application to the FDA for accelerated or conditional approval consideration.

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, fast-track and orphan drug designations from the US FDA. The Company has completed enrollment for a 41-patient Phase 2b clinical trial of OST-HER2 in recurrent, fully resected, lung metastatic osteosarcoma, with positive results released in the first quarter of 2025. 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) platform, known as *tunable ADC* (tADC), which features tunable, tailored antibody-linker-payload candidates. This platform leverages the Company's proprietary silicone linker 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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