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OS Therapies Schedules United Kingdom’s Medicines and Healthcare products Regulatory Agency's (MHRA) Scientific Advice Meeting in the Third Quarter of 2025 for Review of its OST-HER2 Immunotherapy Candidate for Osteosarcoma

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 scheduled a Scientific Advice Meeting (SAM) in the third quarter of 2025 to discuss the Innovative Licensing and Access Pathway (ILAP) with the United Kingdom’s (UK) Medicines and Healthcare products Regulatory Agency (MHRA) for OST-HER2, its immunotherapy candidate for the prevention of recurrence of metastases in osteosarcoma. The Company released positive Phase 2b data in January 2025 that demonstrates statistically significant results in the primary endpoint of the study, 12-month event free survival (EFS). The meeting with MHRA has been scheduled to position the Company to bring OST-HER2 to market in the UK in 2025.

“Today’s announcement marks the beginning of the regulatory process required to bring our OST-HER2 immunotherapy to market globally,” stated OS Therapies’ CEO Paul Romness. “As we prepare for regulatory interactions in the UK, US, Europe and other regulatory bodies worldwide, we are now focused on aligning our regulatory strategy to getting our product to patients as quickly as possible.”

The UK is a reference country for multiple national drug approval agencies worldwide, meaning that if the Company receives approval in the UK then it becomes eligible to receive approval in other certain countries including Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Israel, Italy, Netherlands, Spain, and Sweden. OST-HER2 has received Fast Track and Orphan Drug designations from the European Medicines Agency.

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 announced that its Phase

2b clinical trial of OST-HER2 in recurrent, fully resected, lung metastatic osteosarcoma achieved the primary endpoint of the study of 12-month event free survival (EFS). 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 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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