December 9, 2025

OS Therapies Announces Successful pre-Marketing Authorisation Application Meeting with UK MHRA Regarding the Phase 2b Clinical Trial of OST-HER2 in the Prevention or Delay of Recurrent, Fully Resected, Pulmonary Metastatic Osteosarcoma

- Alignment achieved on all key points surrounding non-clinical, CMC and post-market authorization confirmatory study design
- Biomarker data advanced as key pre-specified surrogate clinical efficacy endpoint, with pending analysis awaiting alignment with US FDA on biomarker statistical analysis plan to be discussed at upcoming December 11, 2025 FDA Type C Meeting
- Company reiterates end of January 2026 timeline for MAA submission

New York, New York--(Newsfile Corp. - December 9, 2025) -**OS Therapies Inc. (NYSE American: OSTX)** ("OS Therapies" or "the Company"), the world leader in listeria-based cancer immunotherapies, today announced that it held a successful pre-Marketing Authorisation Application (MAA) with the United Kingdom (UK) Medicines and Healthcare Products Regulatory Agency (MHRA) regarding the Phase 2b human clinical trial of OST-HER2 in the prevention or delay of recurrent, fully-resected, pulmonary metastatic osteosarcoma (the 'Metastatic Osteosarcoma Program'). The Company achieved full alignment with its pre-meeting objectives related to non-clinical, CMC (chemistry, manufacturing, and controls) and post-market authorization confirmatory study design.

Additionally, the Company advanced the correlation ofupregulated immune response biomarkers shown to be activated in OST-HER2 treated canine patients who achieved long term survival with 2-year overall survival data from the OST-HER2 Phase 2b human clinical trial as a surrogate clinical efficacy endpoint to further support the approval of a conditional MAA in the United Kingdom. The Company is awaiting feedback from its upcoming December 11, 2025 meeting with United States Food & Drug Administration (FDA) before initiating the proposed biomarker data analysis to ensure that the analysis is pre-specified, thereby making the resulting data suitable to support a Biologics Licensing Application (BLA) under the Accelerated Approval Program ('Accelerated Approval') in the United States.

"We were pleased with the insightful feedback from our colleagues at UK MHRA during yesterday's pre-MAA meeting," said Paul Romness, Chairman & CEO of OS Therapies. "Their perspective will be very helpful as we finalize preparations for our upcoming Type C Meeting with US FDA on Thursday."

The Company reiterated that it expects to submit a conditional MAA for the Metastatic Osteosarcoma Program to MHRA by the end of January 2026.

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. The Company is the world leader in listeria-based cancer immunotherapies. 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 U.S. Food & Drug Administration and Fast-Track and Orphan Drug designations from the U.S. FDA and European Medicines Agency. The Company reported 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 U.S. FDA for OST-HER2 in osteosarcoma in the First Quarter of 2026 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 press 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 U.S. FDA and other risks and uncertainties described in "Risk Factors" in the Company's most recent Annual Report on Form 10-K, most recent Quarterly Report on Form 10-Q 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.

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