October 9, 2025

OS Therapies Provides Positive EMA Regulatory Update Following Positive Rapporteur Meeting

- *Overall survival recognized as key efficacy endpoint in osteosarcoma, where no standard of care exists*
- *Rapporteur highlights potential broader benefits of OST-HER2 in pulmonary and primary osteosarcoma settings, supported by translational canine data from the University of Pennsylvania*

New York, New York--(Newsfile Corp. - October 9, 2025) -**OS Therapies Inc. (NYSE American: OSTX)** ("OS Therapies" or "the Company"), a clinical-stage cancer immunotherapy and antibody drug conjugate biotechnology company, today announced a positive regulatory update following an October 6, 2025 meeting with its European Medicines Agency (EMA) rapporteur, the Dutch Medicines Evaluation Board (MEB).

During the meeting, OS Therapies and the Dutch Rapporteur aligned on key areas, including safety, non-clinical and chemistry, manufacturing, and controls (CMC) data in support of the Company's ongoing OST-HER2 Phase 2b clinical trial in the prevention or delay of recurrent, fully-resected, pulmonary metastatic osteosarcoma. The Rapporteur advised that the overall survival results, demonstrating statistically significant, final two-year data, may serve as an appropriate primary endpoint for consideration of conditional marketing authorization (CMA).

The meeting represented an important milestone toward formal EMA Scientific Advice, anticipated in December 2025. A potential pathway was also established to support a confirmatory, randomized clinical development program, which could explore additional osteosarcoma settings and potentially expand the product label upon full marketing authorization.

Meeting outcomes

- The safety profile from the Fully Resected Osteosarcoma clinical study was confirmed as positive. In addition, data from other Listeria monocytogenes candidates, representing more than 500 patients treated across four other therapeutic indications, may be sufficient to support a conditional marketing authorization (CMA).
- Non-clinical data is sufficient to support a CMA submission.
- The chemistry, manufacturing, and controls (CMC) data package was also viewed as sufficient to support a CMA.
- Efficacy data available as of July 2025 from the Fully Resected Osteosarcoma Trial were viewed as encouraging. The Rapporteur noted that 12-month Event-Free Survival (EFS) may not be the most appropriate endpoint and that overall survival (OS) could provide a stronger measure of clinical benefit, particularly if ongoing biomarker analyses confirm differential immune activation among patients showing favorable

outcomes.
- The Rapporteur also indicated that efficacy data generated outside the Fully Resected Osteosarcoma Trial, such as in recurrent, unresectable, pulmonary metastatic osteosarcoma setting, could be incorporated into a post-market confirmatory clinical development program.

Additionally, the company is pleased to report that following the recently announced commencement of the Marketing Authorisation Application (MAA) submissions process with the UK MHRA, that the Agency has kindly granted OS Therapies an expedited Market Access Scientific Advice Meeting. This is an important milestone in the MAA submission and approval process. The meeting is intended to ensure alignment between Sponsors and the Agency on issues that will be evaluated during the MAA review process, with the intent of accelerating patient access.

"We are pleased that the Dutch Rapporteur's evaluation of the data submitted aligns closely with UK MHRA and US FDA so far on safety, non-clinical and CMC," said Paul Romness, MPH, Chairman & CEO of OS Therapies. "Importantly the feedback on clinical efficacy provides a clear regulatory pathway. We believe this will enable us to pursue a conditional marketing authorization while advancing a confirmatory, global randomized clinical study in parallel. This next trial may evaluate OST-HER2 in one or more osteosarcoma clinical settings that could determine the full breadth of OST-HER2 clinical utility, given its immunotherapy mechanism of action in light of the exciting data generated in highly translational canine studies generated at the University of Pennsylvania."

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 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 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 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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