December 5, 2025

# OS Therapies Announces FDA PDUFA Waiver & EMA Grants Union Marketing Authorisation Eligibility

- U.S. FDA grants waiver of application fee for BLA Filing of OST-HER2
- Scheduled pre-Marketing Authorisation Application meeting with United Kingdom's Medicines and Healthcare products Regulatory Agency on December 8, 2025
- Scheduled Type C Meeting with United States Food & Drug Administration on December 11, 2025

New York, New York--(Newsfile Corp. - December 5, 2025) -**OS Therapies Inc. (NYSE American: OSTX)** ("OS Therapies" or "the Company"), the world leader in listeria-based cancer immunotherapies, today announced the United States Food & Drug Administration (FDA) granted the Company waiver of the application fee for BLA 125867 for OST-HER2.

Additionally, the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use ('CHMP') granted Union Marketing Authorisation eligibility for OST-HERs in the prevention or delay of recurrent, fully-resected, pulmonary metastatic osteosarcoma (the 'Metastatic Osteosarcoma Program'). EMA CHMP requested an accelerated Marketing Authorisation Application ('MAA') submission for the Metastatic Osteosarcoma Program by February 28, 2026. The intent of the European Union-wide Centralised Procedure is to support the marketing authorization of medicines, where there is a single application, a single evaluation and a single authorization for all EU Member States.

Concurrent with this announcement, the Company has completed pre-meeting submissions to the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) for its pre-MAA meeting on December 8, 2025 and its Type C Meeting with the FDA on December 11, 2025. The Company intends to review final commercial CMC and non-clinical considerations, as well as propose the global confirmatory study design to support an MAA Conditional Approval from MHRA, and a Biologics Licensing Application (BLA) under the Accelerated Approval Program ('Accelerated Approval') from FDA, respectively.

**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 early 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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