March 25, 2026

OS Therapies Granted EMA's Advanced Therapy Medicinal Product (ATMP) Designation for OST-HER2 in the Treatment of Pulmonary Recurrence in Resected Osteosarcoma

- *ATMP benefits include access to the Conditional Marketing Authorisation accelerated market access pathway in Europe, significantly reduced user fees for small and medium-sized enterprises (SMEs), tailored regulatory assessment via Committee for Advanced Therapies (CAT) and increased pricing power*

New York, New York--(Newsfile Corp. - March 25, 2026) -OS Therapies, Inc. (NYSE American: OSTX) ("OS Therapies" or "the Company"), the world leader in listeria-based cancer immunotherapies, today announced that the European Medicines Agency's (EMA) Committee for Advanced Therapies (CAT) granted OST-HER2 Advanced Therapy Medicinal Product designation (ATMP) for the treatment of pulmonary recurrence in resected osteosarcoma in the European Union (EU) at CAT's 18-20th March 2026 meeting.

ATMP benefits include opening of the Conditional Marketing Authorisation (CMA) accelerated market access pathway in Europe, significantly reduced user fees for small and medium-sized enterprises (SMEs), tailored regulatory assessment via Committee for Advanced Therapies (CAT) and increased reimbursement pathways & reimbursement codes. The Company is finalizing the preparation of a CMA submission to EMA for OST-HER2 in the prevention or delay of recurrent, fully-resected, pulmonary metastatic osteosarcoma. ATMP designation is the European equivalent of the Regenerative Medicine Advanced Therapy (RMAT) designation with the U.S. Food & Drug Administration.

"ATMP designation marks a significant milestone along OST-HER2's path toward becoming the standard of care in Europe," said Paul Romness, MPH, Chairman & CEO of OS Therapies. "We believe this increases the likelihood that we will receive conditional marketing authorisation later this year, which would help us establish a significant revenue stream for the Company projected to begin in 2027. We look forward to continued engagement with the EMA in the months ahead and are pleased that EMA has begun coordinating with the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) and U.S. Food & Drug Administration (FDA) on the product candidate evaluation process. We will deliver regulatory dossiers to each of these agencies in the weeks ahead and look forward to upcoming meetings where we will review the clinical data, biomarker data, manufacturing data, non-clinical data and proposed confirmatory study designs that would position OST-HER2 for market access in the U.S., U.K. and Europe later this year."

OST-HER2 has received Orphan Drug Designation (ODD), Fast Track Designation (FTD) and Rare Pediatric Disease Designation (RPDD) from the FDA, and ODD, FTD and ATMP

from the EMA. Under the RPDD program, if the Company receives a Biologics License Application (BLA) in the United States, it will become eligible to receive a Priority Review Voucher (PRV) that it intends to sell. The most recent publicly disclosed PRV transaction occurred in February 2026 at a reported value of $205 million. The Company is seeking to obtain a BLA under the Accelerated Approval Program for OST-HER2 in osteosarcoma in the second half of 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 Orphan Drug Designation (ODD), Fast Track Designation (FTD) and Rare Pediatric Disease Designation (RPDD) from the U.S. Food & Drug Administration and has received ODD, FTD and ATMP from the 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 and the overall survival (OS) secondary endpoint. The Company anticipates receiving a Biologics License Application (BLA) from the U.S. FDA for OST-HER2 in osteosarcoma in 2026 and, if approved, would become eligible to receive a Priority Review Voucher that it could then sell. The Company also anticipates receiving Conditional Marketing Authorisations from the U.K.'s Medicines and Healthcare products Regulatory Agency and the EMA for OST-HER2 in 2026. 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. The Company also anticipates reading out data from a Phase 1b study of OST-504 in castration resistant prostate cancer in the first half of 2026.

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.

OS Therapies Contact Information:

Investor Relations
Harrison Seidner, PhD
WaterSeid Partners
OSTX@waterseid.com

Public Relations
Stephanie Chen
Elev8 New Media
media@ostherapies.com

https://x.com/OSTherapies
https://www.instagram.com/ostherapies/
https://www.facebook.com/OSTherapies/
https://www.linkedin.com/company/os-therapies/

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