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OS Therapies Provides Global Regulatory Update for OST-HER2 in Recurrent, Fully Resected, Pulmonary Metstatic Osteosarcoma

- Additional forthcoming biomarker data from human trial expected to further characterize immune pathway activation and its relationship to clinical outcomes
- U.S., U.K. and European osteosarcoma key opinion leaders assembling to review clinical & biomarker trial data, and comment on proposed confirmatory trial design
- Ayala Pharmaceuticals announces dissolution following liquidation of assets

New York, New York--(Newsfile Corp. - February 17, 2026) -**OS Therapies Inc. (NYSE American: OSTX)** ("OS Therapies" or "the Company"), the world leader in listeria-based cancer immunotherapies, today provided a global regulatory update for OST-HER2 in the prevention or delay of recurrent, fully resected, pulmonary metastatic osteosarcoma (the "Human Metastatic Osteosarcoma Program").

Following the submission of the Non-Clinical and Chemistry, Manufacturing & Controls (CMC) modules of its Biologics License Application (BLA) to U.S. Food & Drug Administration (FDA) at the end of January 2026, the Company anticipates releasing additional biomarker data from its Human Metastatic Osteosarcoma Program in the first quarter of 2026. These analyses are intended to further characterize immune pathway activation and evaluate the relationship between biomarker expression and observed clinical outcomes.

The Company expects to complete conditional Marketing Authorisation Application (MAA) submissions to both the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) by the end of the first quarter of 2026. The Company remains on track to submit the Clinical BLA module to the FDA following an anticipated Type D meeting expected to occur in March 2026.

"We continue to advance our global regulatory strategy following previously reported pre-specified biomarker analyses demonstrating concordant immune pathway activation signatures and clinical outcomes in both human and canine elite responders (long term survivors) when compared with patients who showed no clinical benefit," said Paul Romness, MPH, CEO of OS Therapies. "We have now nearly completed additional follow-on biomarker analyses designed to further elucidate the drug's treatment effect and its relationship to clinical outcomes. We are hopeful the data will provide further support for the use of these biomarkers as surrogate endpoints of clinical efficacy. We expect to share this data in the coming weeks."

Concurrent with this announcement, the Company disclosed that it is assembling a meeting of U.S., U.K. and European osteosarcoma key opinion leaders to review the clinical and

biomarker data from the Human Metastatic Osteosarcoma Program and provide input on proposed confirmatory trial designs for the Company's confirmatory clinical development program. The Company is seeking a BLA under the Accelerated Approval Program ('Accelerated Approval') in the U.S. and conditional MAAs in the U.K. and Europe, which all require confirmatory studies to be initiated prior to approval. The Company anticipates initiating the confirmatory trial in the third quarter of 2026 with the opening of a single site that allows it to meet the Accelerated Approval statutory requirement, with broader site activation expected following regulatory approval.

OST-HER2 has received FDA Orphan Drug Designation (ODD) and Fast Track Designation from the FDA & EMA and has received Rare Pediatric Disease Designation (RPDD) from the FDA. Under the RPDD program, if the Company receives Accelerated Approval 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 January 2026 at a reported value of $200 million.

Additionally, the Company announced that it has been informed that Ayala Pharmaceuticals, Inc. ('Ayala') has informed its shareholders that Ayala is dissolving. The Company acquired all listeria-based clinical, pre-clinical and intellectual property assets from Ayala in April 2025, issuing to Ayala the equivalent of 4.8 million shares of OS Therapies common stock that became eligible for trading on October 9, 2025. The Company was informed by Ayala representatives that Ayala completed the liquidation of its OS Therapies common stock on February 9, 2026, and no longer holds any securities in the Company.

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 receiving a Biologics Licensing 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 European Medicines Agency 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.

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