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OS Therapies Completes Requalification of Phase 2b Herlystic (OST-HER2) Drug Substance for Confirmatory Phase 3 Trial

Leading Clinical Stage Oncology Company Now Able to Complete CMMA Submission to U.K's MHRA for Early Commercial Access and Trial Authorisation

Grasonville, Maryland--(Newsfile Corp. - November 5, 2026) -**OS Therapies, Inc. (NYSE American: OSTX) ("OS Therapies" or the "Company")**, the world leader in gene-edited, Listeria-based cancer immunotherapies, today announced that it has completed the requalification of drug substance used in its Phase 2b trial of OST-HER2 (Herlystic™) in the prevention of recurrence in fully resected, pulmonary metastatic osteosarcoma. The requalification is key as the Company is now able to commence the submission of a Conditional Marketing Authorisation Application (CMAA) and complete a Rolling Review Request for Herlystic (Daznelimgene Lisbac) to the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) for early commercial market access and file the Clinical Trial Authorisation (CTA) required to initiate the confirmatory Phase 3 trial.

Additionally, OS Therapies will be using the drug substance requalification data to support CMAA submissions to the European Medicines Agency (EMA), as well as to include in the U.S. Food and Drug Administration (FDA) Biologics License Application (BLA) submissions. The Company has decided to pause regulatory interactions in Australia to focus its resources on the U.S., U.K. and Europe.

"We are very pleased with the stability data generated from the material used in the Phase 2b trial, as it shows our product and its Critical Quality Attributes (CQAs) is stable even after ten years in storage," said Paul Romness, Chairman and CEO of OS Therapies. "With this important chemistry, manufacturing and controls (CMC) milestone now in-hand, we are moving full steam ahead on all regulatory fronts in the U.S., U.K., and Europe. We also note that our recent capital raise and Refundable R&D Tax Credit and VAT programs provides the Company with sufficient resources to fund operations through mid-2027."

Mr. Romness continued, "Due to the delay we experienced in receiving the data from our manufacturing partners to support the drug substance requalification to initiate the confirmatory Phase 3 program, we are updating our previously stated timelines to expect a regulatory decision on the pending MHRA CMAA in the first quarter of 2027, and from EMA in the first half of 2027. With respect to FDA, the Company intends to update the market on the timing of completion BLA activities, and regulatory interactions related thereto, following additional feedback on comparator data being assembled to support a BLA under the Accelerated Approval Program. The Company has identified additional sources of data for OST-400 that are currently being evaluated for inclusion in submissions to the Agency"

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

Advanced Therapeutic Medicinal Product (ATMP) designation from the EMA. OST-HER2 was permitted access to the Centralised Procedure in Europe, allowing a unified, expedited regulatory review process rather than review of individual applications by each European Union (EU) Member State. Under the RPDD program, if the Company is granted a BLA in the United States, it will become eligible to receive a Priority Review Voucher (PRV) that it intends to sell. Two recent PRV sales occurred in October 2026, totaling $413 million (average $206.5 million). However, there can be no assurance that the Company would realize a comparable value, if any, in connection with any future PRV sale. OS Therapies has completed resubmission of a Regenerative Medicine Advanced Therapy (RMAT) request, and is currently awaiting FDA feedback. The Company's Commissioner's National Priority Voucher (CNPV) letter of intent was accepted by FDA in the first quarter of 2026. OS Therapies intends to complete its BLA submission under the Accelerated Approval Program in the U.S. and Conditional Marketing Authorization Applications (CMAAs) in Europe and the U.K for OST-HER2 in metastatic osteosarcoma in the fourth quarter of 2026.

About OS Therapies

OS Therapies is a clinical stage oncology company focused on the identification, development, and commercialization of treatments for Osteosarcoma and other solid tumors. The Company is the world leader in gene-edited, 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 is designed to target two mutated extracellular epitopes and one mutated intracellular epitope of the HER2 oncogene, requiring only one of these three epitopes to be present in a tumor (or micro-metastasis) to trigger the desired immune response. 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, and Advanced Therapy Medicinal Products (ATMP) from the European Medicines Agency.

The Company reported positive data in its Phase 2b clinical trial of OST-HER2 in the prevention or delay of recurrence in fully resected, pulmonary metastatic osteosarcoma, demonstrating clinically significant benefit in the 12-month event free survival (EFS) primary endpoint of the study and the overall survival (OS) secondary endpoint. The Company intends to complete a Biologics License Application (BLA) submission to the U.S. FDA for OST-HER2 in osteosarcoma in the fourth quarter of 2026 and, if approved, would become eligible to receive a Priority Review Voucher that it could then sell. The Company also anticipates requesting Conditional Marketing Authorisation Applications (CMAAs) from the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA)for OST-HER2 in the fourth quarter of 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 was previously conditionally approved by the U.S. Department of Agriculture for the treatment of canines with osteosarcoma. The Company has also completed dosing in a Phase 1 study of OST-504 for castration-resistant prostate cancer.

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

silicon 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 regarding future expectations, plans, prospects or performance, as well as any other statements that are not historical facts, may constitute forward-looking statements within the meaning of the federal securities laws. Forward-looking statements are generally identified by words such as "anticipate," "believe," "could," "expect," "intend," "may," "plan," "potential," "should," "will" and similar expressions, although not all forward-looking statements contain these words. These statements are based on the current expectations and assumptions of OS Therapies and its management and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to chemistry, manufacturing and controls (CMC) of OST-HER; OST-HER2 product stability; Company funding runway and need for additional capital; Commissioner's National Priority Voucher(CNPV) status, priority review voucher value, the timing and outcome of regulatory submissions and potential approval of OST-HER2 by the U.S. Food and Drug Administration and applicable foreign regulatory authorities; and other risks and uncertainties described under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K and in its other filings with the Securities and Exchange Commission. The forward-looking statements contained in this press release speak only as of the date of this press release, and OS Therapies undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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