September 17, 2026

OS Therapies Achieves Incremental Alignment With FDA and Accepts Project Orbis Invitation From MHRA on OST-HER2 Metastatic Osteosarcoma Program

- *FDA aligns with MHRA and EMA on adaptive design for Phase 3 trial*
- *After successful Scientific Advice Meeting, OS Therapies accepts MHRA request to become the Company's sponsor into Project Orbis to harmonize regulatory review with FDA and EMA*
- *CBER recently re-opened Project Orbis to foreign-sponsored U.S. companies only*

New York, New York and Rockville, Maryland--(Newsfile Corp. - September 17, 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 achieved incremental alignment with the U.S. Food & Drug Administration (FDA) in the Company's pursuit of a Biologics License Application (BLA) for OST-HER2 in the prevention or delay of recurrence in fully-resected, pulmonary metastatic osteosarcoma (the "Metastatic Osteosarcoma Program"). The Company aligned with the FDA on the use of the proposed adaptive design agreed upon with the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) for the pending Phase 3 clinical trial that is expected to commence in the fourth quarter of 2026. The Company expects to hold its previously disclosed invited Type B Pre-BLA meeting with FDA in the fourth quarter of 2026 following the submission of the clinical section, inclusive of 3-year overall survival data, thereby completing the ongoing BLA filing that was initiated in January 2026.

Concurrent with this announcement, OS Therapies announced that it has accepted a request from MHRA to become the Company's representative to Project Orbis following the recent successful Statistical Methods Scientific Advice Meeting (SAM). Project Orbis is an innovative reciprocal global initiative designed to facilitate international regulatory collaboration in the field of oncology. Launched by the FDA, this program seeks to streamline the process of drug approval for cancer treatments by partnering with regulatory agencies from other countries. The goal of Project Orbis is to provide patients with faster access to promising therapies through simultaneous submission and review of oncology products across multiple nations. By sharing critical insights and harmonizing standards, participating countries aim to enhance the development of effective cancer treatments and improve patient outcomes worldwide. FDA's Center for Biologics Evaluation and Research (CBER) recently re-opened Project Orbis.

"With alignment in hand with FDA on the most recent updates to the proposed adaptive design for the Phase 3 trial design reviewed with MHRA and EMA, we have overcome the key hurdle to initiating the Phase 3 in the U.K. and beyond." said Paul Romness, MPH, Chairman & CEO of OS Therapies. "More importantly, now that MHRA has stepped up and

volunteered to take the international lead with Project Orbis, we expect to be able to move expeditiously through the regulatory process in the U.K., U.S. and Europe."

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 is granted a BLA in the United States, it will become eligible to receive a Priority Review Voucher (PRV) that it intends to sell. The most recent PRV sale occurred in August 2026 for $220 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 the Company's Commissioner's National Priority Review Voucher (CNPV) letter of intent has been accepted by FDA. OS Therapies is seeking to obtain a BLA under the Accelerated Approval Program in the U.S. and Conditional Marketing Authorization Applications (CMAAs) in Europe, the U.K. and Australia 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 (OS) 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, FTD 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 is seeking 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 Authorisation Applications 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 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, the Company's expectations regarding its cash runway; the timing, amount and receipt of VAT refunds and R&D tax credits; the Company's ability to obtain additional financing on acceptable terms or at all; 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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