September 15, 2026

OS Therapies Announces Full Alignment with UK MHRA and EU EMA for Conditional Marketing Authorisation Application Filing

- *Overall Survival (OS) historical-control data gains HMRA and EMA support for pending CMAA submissions*
- *Full alignment achieved on confirmatory Phase 3 trial design*
- *Complete CMAA submission expected in coming weeks*

New York, New York and Rockville, Maryland--(Newsfile Corp. - September 15, 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 full alignment with the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) on its pending Conditional Marketing Authorisation Application (CMAA). MHRA agreed that the use of comparable historical control data – derived from a systematic evaluation of all suitable available peer-reviewed literature by independent biostatistics advisors presented in its most recent Scientific Advice Meeting (SAM) - was appropriate in the orphan indication Prevention or Delay of Recurrence in Fully Resected, Pulmonary Metastatic Osteosarcoma. Further, the Company achieved full alignment on the proposed design of its upcoming confirmatory Phase 3 trial design – including the proportion of patients to be dosed with remaining Phase 2 drug product versus forthcoming Phase 3 material. The Phase 3 trial is required to have commenced prior to being granted a CMAA. OS Therapies expects to complete the CMAA submission in the coming weeks. The Company also intends to commence the confirmatory Phase 3 as soon as possible in the fourth quarter of 2026 and site outreach has commenced accordingly.

The MHRA's supportive advice aligns with the Agency's recently published Rare Disease Regulatory Framework (https://www.gov.uk/government/consultations/draft-rare-disease-therapies-regulatory-framework/draft-rare-disease-therapies-regulatory-framework); and advice from the European Medicines Agency (EMA) pertaining to a forthcoming CMAA via the pan-European Centralised Procedure.

"Achieving full alignment with MHRA and EMA, which paves the way for our upcoming CMAA submissions, and the initiation of our confirmatory Phase 3 trial is a major achievement," said Paul Romness, MPH, Chairman & CEO of OS Therapies. "With this full alignment now in hand, and with it the recognition from international regulators that the standard of care in Osteosarcoma has not meaningfully changed in the last forty years, we are bringing this to the U.S. Food & Drug Administration (FDA). The FDA is part of the Orbis Project that coordinates approvals between international regulators, including the UK. The FDA is considering the ongoing Biologics License Application (BLA) submission that began in January 2026, with potential early market access under the Accelerated Approval Program. Additionally, the EMA recently informed the Company that a previously requested

SAWP meeting was no longer required prior to submission of the CMAA to EMA."

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 Advanced Therapy Medicinal Products (ATMP – RMAT equivalent in the EU and UK) from the EMA and MHRA. 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. The Company intends to request Rolling Review of the ongoing BLA submission that began in January 2026 following its upcoming mid-September 2026 FDA Type C Statistical Methods Meeting. 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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