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OS Therapies Initiates U.K. MHRA Conditional Marketing Authorisation Application for Herlystic (OST-HER2) in the Prevention or Delay of Recurrence in Fully Resected, Pulmonary Metastatic Osteosarcoma

US Based Clinical Stage Oncology Company Begins Critical Step Following Successful September 2026 Scientific Advice Meeting

- *Submission expected to be accepted in the fourth quarter of 2026*
- *Potential early market access decision expected from MHRA in the first quarter of 2027*

Grasonville, Maryland--(Newsfile Corp. - November 10, 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 initiated a Conditional Marketing Authorisation Application (CMAA) process with the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) for Herlystic™ (OST-HER2) in the prevention or delay of recurrence in fully resected, pulmonary metastatic osteosarcoma. The Company expects to complete the CMAA process later in the fourth quarter of 2026.

"The initiation of regulatory submissions to bring Herlystic to patients in 2027 has now begun," said Paul Romness, Chairman and CEO of OS Therapies. "With the very productive interactions we have had with MHRA, this filing sets the stage for our international regulatory early market access strategy. We expect that progress with MHRA will help facilitate international regulatory coordination under Project Orbis."

Herlystic has received Orphan Drug Designation (ODD), Fast Track Designation (FTD) and Rare Pediatric Disease Designation (RPDD) from the U.S. Food Drug Administration (FDA), as well as ODD and Advanced Therapeutic Medicinal Product (ATMP) designation from the European Medicines Agency (EMA). Herlystic 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 engaging with FDA towards alignment on a suitable comparator (OST-400 osteosarcoma natural history study) to achieve interpretability of Herystic's Phase 2b clinical trial results such that biomarker data generated

from that trial can be accepted as a surrogate clinical endpoint of treatment efficacy. 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 CMAA submissions in the U.K. and Europe for Herlystic in metastatic osteosarcoma in the fourth quarter of 2026, and align with FDA in the near future on the suitability of OST-400 as comparator such that the Company can complete its ongoing BLA submission. MHRA has granted OS Therapies access to the U.K.'s Clinical Practice Research Datalink (CPRD) to increase patient data included in OST-400.

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, 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) . 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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