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OS Therapies Announces Brand Name 'Herlystic' Approved by World Health Organization for OST-HER2 (daznelimgene lisbac)

New York, New York and Rockville, Maryland--(Newsfile Corp. - September 24, 2026) - **OS Therapies, Inc. (NYSE American: OSTX) ("OS Therapies" or the "Company")**, the world leader in gene-edited, Listeria-based cancer immunotherapies, today announce that the World Health Organization has approved the proprietary name 'Herlystic'™ was approved by the World Health Organization (WHO) as the brand name for OST-HER2. The nonproprietary name *daznelimgene lisbac* for the ingredients in OST-HER2 was previously approved WHO. With both the branded proprietary name and the nonproprietary name now approved by WHO, the Company is positioned to initiate regulatory submissions seeking early market access for OST-HER2 worldwide.

The Company intends to initiate international regulatory submissions initially in the U.K. at the invitation of the Medicines and Healthcare products Regulatory Agency (MHRA), and immediately thereafter expand submissions to include the U.S. Food & Drug Administration (FDA), the European Medicines Agency (EMA) and the Australian Therapeutic Goods Administration (TGA). The Company accepted MHRA's request to become the lead international regulatory agency to coordinate early market access approval processes under, Project Orbis, the FDA's Oncology Center of Excellence (OCE)initiative started in May 2019 to provide a framework for concurrent submission and review of oncology products among international partners. Since 2021, 29 MHRA-led oncology products have been approved by the FDA under Project Orbis.

"Herlystic is an inspiring name looking to bring hope to patients that they will have improved likelihood of recovering from pulmonary metastatic osteosarcoma and the opportunity to live a more full life, especially for the kids afflicted by this terrible disease," said Paul Romness, MPH, Chairman & CEO of OS Therapies. "With this final administrative step now in place, we are moving ahead with early market access regulatory filings, with MHRA's slated in the coming weeks based on the 2.5-year and interim 3-year Overall Survival (OS) reviewed in our most recent Scientific Advice Meeting, and thereafter with FDA, EMA and TGA once the final 3-year OS data is available."

Mr. Romness continued "We appreciate MHRA taking the lead under Project Orbis, and the access they have given the Company to the U.K.'s Clinical Practice Research Datalink (CPRD). While MHRA, EMA and TGA have aligned on the use of non-concurrent historical control to evaluate the efficacy of OST-HER2's pending Conditional Marketing Authorization Application (CMAA) submissions, we know the FDA approves Biologics License Applications (BLAs) under the Accelerated Approval Program using surrogate clinical endpoints, such as biomarkers, to make approval decisions. To this end, the Company is waiting for the 3-year OS data to be complete for its pending meeting with the Center for Drug Research

Evaluation (CDER) to review the correlation between previously announced pharmacodynamic response biomarkers and overall survival as part of the Biomarker Qualification Program. The previously announced Type B Pre-BLA Meeting will occur once the full data package is complete, while BLA submission continues that was initiated in January 2026. The Company expects that it will have sufficient additional concurrent external historical control comparator data via the CPRD to further buttress its BLA package as part of its BLA filing. This is a very exciting period for OS Therapies."

OST-HER2 has received Orphan Drug Designation (ODD), Fast Track Designation (FTD) and Rare Pediatric Disease Designation (RPDD) from the FDA. OST-HER2 has received ODD, FTD and ATMP from the EMA. OST-HER2 has received ODD and ATMP from MHRA, who also recruited the Company into Project Orbis. 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. A 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 a Conditional Marketing Authorization Application from MHRA in the U.K. under Project Orbis for OST-HER2 in metastatic osteosarcoma in the fourth quarter of 2026, and immediately thereafter is seeking to obtain a BLA under the Accelerated Approval Program in the U.S., followed by CMAAs in Europe, and Australia.

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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