October 6, 2026

OS Therapies Achieves Statistically Significant Final Three-Year Overall Survival Benefit for Herlystic(TM)-Treated Patients in Phase 2b Pulmonary Metastatic Osteosarcoma Trial

Leading Clinical Stage Oncology Company Releases Significant Findings from OST-HER2-Treated Patients

- *72.7 percent three-year overall survival vs. 45.8 percent comparable combined historical control (p = 0.0006)*
- *Company preparing to complete submissions for early market access in the U.S., U.K., Europe and Australia*
- *WHO recently accepted the proprietary brand name Herlystic™ for OST-HER2 (daznelimgene lisbac).*

Grasonville, Maryland--(Newsfile Corp. - October 6, 2026) -**OS Therapies, Inc. (NYSE American: OSTX) ("OS Therapies" or the "Company")**, the world leader in gene-edited, Listeria-based cancer immunotherapies, today announced statistically significant final 3-year overall survival benefit for OST-HER2-treated patients in its Phase 2b trial in pulmonary metastatic osteosarcoma, when compared with a combined published historical control. The analysis is from the Company's Phase 2b trial for the prevention or delay of recurrence in patients with fully resected, pulmonary metastatic osteosarcoma (the "Metastatic Osteosarcoma Program"). The final 3-year overall survival rate among OST-HER2 treated patients was 72.7 percent, compared with 45.8 percent of patients in the comparable combined historical control group (*p = 0.0006, 41 total enrolled patients, and four patients lost to follow-up*).

"I am encouraged by the 3-year overall survival results in this trial and am hopeful this could become a potential option for future patients," said Peter Anderson, MD, pediatric oncologist at Cleveland Clinic Children's and member of the scientific advisory board for OS Therapies.

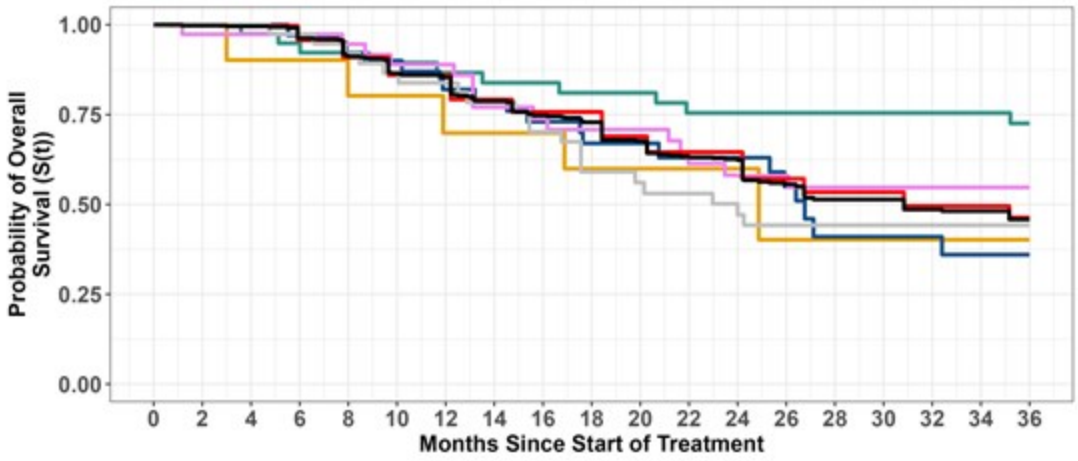
Data Table

Study	Estimate (SE)	90% Confidence Interval	p-value	0 25 50 75 100
OST31-164-01	72.7% (7.4%)	(58.3%, 82.8%)		
Amdt	36.0% (-%)	(-%, -%)		
Chen	40.1% (-%)	(-%, -%)		
Hingorani	54.7% (-%)	(-%, -%)		
Janeway	44.2% (-%)	(-%, -%)		
Kempf-Bielack	46.3% (-%)	(-%, -%)		
Pooled Control	45.8% (2.6%)	(41.6%, 50.0%)		
OST - Control	**26.9% (7.8%)**	**(14.0%, 39.7%)**	**0.0006**	

0 25 50 75 100

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Kaplan-Meier Curve



Study	Population	Number of patients
OST31-164-01	Recurrent, Completely Resected, Pulmonary	41
CHEN	Recurrent, Completely Resected, Pulmonary	10
ARNDT	Recurrent, Completely Resected, Pulmonary	41
HINGORANI	Recurrent, Completely Resected, Pulmonary	39
KEMPF-BIELACK	Recurrent, Completely Resected	339
JANEWAY	Recurrent, Completely Resected	38
Weighted Combined	Recurrent, Completely Resected	467

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"With final three-year overall survival data now in hand, we are working diligently to complete regulatory submissions in the U.S., U.K., Europe and Australia to enable early market access to the therapy," said Dr. Craig Eagle, Chief Medical Advisor and Director of

OS Therapies. "Given that we have full alignment on the clinical trial design of the confirmatory Phase three trial across international regulatory agencies, we are preparing to submit a Clinical Trial Authorisation (CTA) to the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) as the precursor to trial initiation. Commencing the Phase 3 study is a prerequisite to being granted Accelerated Approval of a Biologics License Application (BLA) by the U.S. Food & Drug Administration (FDA), and Conditional Marketing Authorisation Applications (CMAAs) by MHRA, the European Medicines Agency (EMA) and the Australian Therapeutic Goods Administration (TGA)."

"The gene-edited *Listeria monocytogenes* cancer immunotherapy platform represents a potentially very powerful new tool in humanity's fight against cancer," said Dr. Robert Langer, Institute Professor at the Massachusetts Institute of Technology (MIT). "While I am very excited about the prospects of adding a new tool for oncologists in the arsenal against HER2 presenting cancers, I am heartened to know that this platform extends to cancers that present many other antigens, including PSA/PSMA and KRAS mutations. The potential to add this new tool in settings where there is no standard of care is quite significant, in addition to its potential to be added to antigen-targeted antibody therapy as well as checkpoint inhibitors where early evidence suggests there may be synergistic activity."

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, PRIME (European FTD equivalent) 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 Voucher (CNPV) letter of intent has been accepted by FDA. OS Therapies intends to complete its BLA submission under the Accelerated Approval 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 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 intends to submit a Biologics License Application (BLA) request to 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 requesting Conditional Marketing Authorisation Applications from the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) the European Medicines Agency (EMA) and the Australian Therapeutic Goods Administration (TGA) for OST-HER2 in the fourth 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, the Company's; 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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