September 8, 2026

OS Therapies Achieves Statistically Significant Benefit for OST-HER2-Treated Patients in Interim 3-Year Overall Survival Analysis of Phase 2b Pulmonary Metastatic Osteosarcoma Trial

- *71.2% 3-year overall survival for OST-HER2-treated patients vs. 45.8% comparable combined historical control (p = 0.002)*
- *The two remaining patients who have not yet reached the 3-year timepoint from enrollment have trial monitoring visits scheduled for September 2026 and early October 2026*
- *Company receives $3.15 million in VAT refunds into OS Therapies UK, Ltd. subsidiary, with an additional $7.2 million in refundable VAT and R&D Tax Credits pending*

New York, New York and Rockville, Maryland--(Newsfile Corp. - September 8, 2026) - **OS Therapies, Inc. (NYSE American: OSTX) ("OS Therapies" or the "Company")**, the world leader in gene-edited, Listeria-based cancer immunotherapies, today announced a statistically significant benefit for OST-HER2-treated patients in an interim 3-year overall survival data analysis when compared with a combined published historical control arm being used for regulatory interactions. 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").

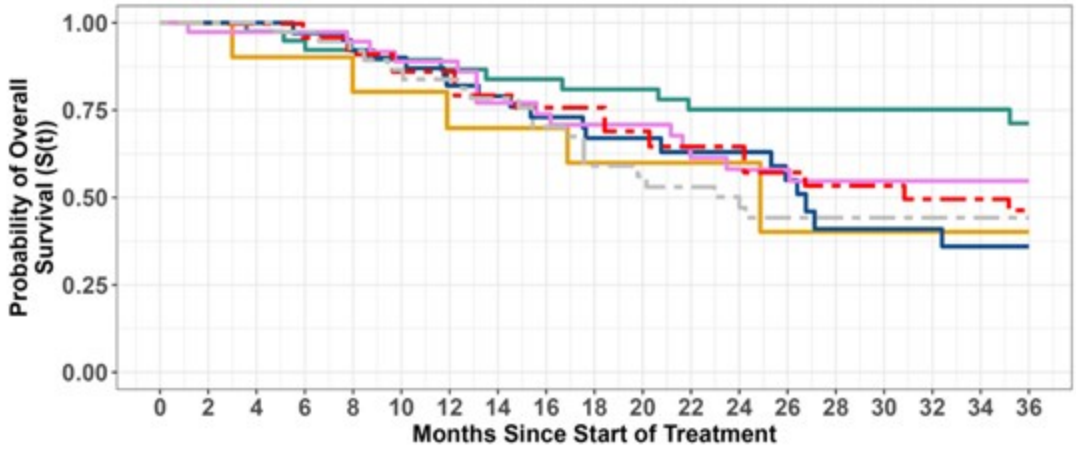
The interim 3-year overall survival rate among OST-HER2 treated patients was 71.2%, compared with 45.8% of patients in the comparable combined historical control group (*p = 0.002, 41 total enrolled patients, with visits for the two remaining patients who have not reached 3-years from enrollment scheduled for September 2026 and early October 2026, respectively, and 6 patients lost to follow-up*).

Data Table and Kaplan-Meier Curve

Study	N	Estimate (SE)	90% Confidence Interval	p-value	0 25 50 75 100
OST31-164-01	16/41	71.2% (7.8%)	(56.1%, 81.9%)		
Arndt	15/41	36.0% (-%)	(-%, -%)		
Chen	4/10	40.1% (-%)	(-%, -%)		
Hingorani	21/39	54.7% (-%)	(-%, -%)		
Janeway	17/38	44.2% (-%)	(-%, -%)		
Kempf-Bielack	157/339	46.3% (-%)	(-%, -%)		
Weighted-Combined Control	214/467	45.8% (2.6%)	(41.6%, 50.0%)		
OST - Control		**25.4% (8.2%)**	**(11.9%, 38.9%)**	**0.0020**	

0 25 50 75 100

To view an enhanced version of this graphic, please visit:
https://images.newsfilecorp.com/files/11596/313297_cc2f88a0547aaa52_001full.jpg



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

To view an enhanced version of this graphic, please visit:
https://images.newsfilecorp.com/files/11596/313297_cc2f88a0547aaa52_002full.jpg

"We believe the increasing survival benefit as time goes on for OST-HER2 treated patients when compared with any and all available published literature in fully resected metastatic osteosarcoma patients, including data published as recently as 2026, presents a compelling case for early market access for osteosarcoma patients who have not seen a new drug approved in the last forty years," said Dr. Craig Eagle, Chief Medical Advisor and Director of OS Therapies.

"Persistence of therapeutic benefit on extended follow-up is typical of the "tail-effect" characteristic of cancer immunotherapies. As we prepare to complete the final data analysis in the next month while we continue our ongoing engagement with regulators worldwide, we believe that the 3-year survival endpoint that the European Medicines Agency (EMA) and the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) have accepted as suitable for early market access decisions will also be acceptable to the U.S. Food & Drug Administration (FDA) to support a Biologics License Application (BLA) under the Accelerated Approval Program. We intend to complete regulatory approval submissions to FDA, MHRA, EMA and Australia's Therapeutic Goods Administration (TGA) in months ahead with a view towards making the drug commercially available for patients in 2027," continued Dr. Eagle.

Concurrent with this announcement, the Company announced that it has received $3.15 million in Value Added Tax (VAT) refunds into its wholly-owned subsidiary OS Therapies UK, Ltd. that also now confirms its eligibility to receive at least an additional $7.2 million in VAT and R&D Tax Credits. Those funds are earmarked for the initiation of the confirmatory Phase 3 clinical trial that is set to commence in the U.K. in order for the Company to become eligible to be granted a BLA under the Accelerated Approval Program in the U.S., as well as Conditional Marketing Authorization Applications (CMAAs) in the U.K., Europe and Australia.

"Following receipt of the first $3.15 million VAT refund through OS Therapies UK, Ltd, we now have resources earmarked to fund the commencement of the confirmatory Metastatic Osteosarcoma Program Phase 3 trial that is required to be initiated prior to an FDA decision on a BLA under the Accelerated Approval Program, as well as MHRA, EMA and TGA decisions on CMAAs," said Paul Romness, MPH, Chair and CEO of OS Therapies. "The opening of that confirmatory trial following the upcoming MHRA meeting will initially be limited to the U.K. because of MHRA allowing the Company to use existing Phase 2 drug product to open that confirmatory Phase 3 trial. Based upon the positive VAT outcome, we have now confirmed our refundable research & development tax credits (Refundable R&D Tax Credits) eligibility and expect a decision on our outstanding $7.2 million refund requests. With our U.K. tax strategy now firmly in place, we expect those funds to fully support the commencement of the U.K. portion of the Phase 3 trial while we wait for early market access regulatory decisions from FDA MHRA, EMA and TGA."

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. 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.

OS Therapies Contact Information:

Investor Relations
Harrison Seidner, PhD
WaterSeid Partners
OSTX@waterseid.com

Public Relations
Stephanie Chen
Elev8 New Media
media@ostherapies.com

https://x.com/OSTherapies
https://www.instagram.com/ostherapies/
https://www.facebook.com/OSTherapies/
https://www.linkedin.com/company/os-therapies/

To view the source version of this press release, please visit
https://www.newsfilecorp.com/release/313297

SOURCE OS Therapies