

May 14, 2026



OS Therapies Appoints Industry Leader Dr. Craig Eagle as Chief Medical Advisor

- *Appointment strengthens medical, regulatory, and commercial leadership as Company prepares to complete early market access regulatory filings in the U.S., U.K, Europe and Australia in anticipation of OST-HER2 approval decisions expected by year-end 2026*
- *Upcoming FDA Pre-BLA meeting will focus on the use of recent seroconversion biomarker data as a key surrogate clinical efficacy endpoint to support a BLA for OST-HER2 under the Accelerated Approval Program*
- *Commercialization and reimbursement preparations well underway for the U.S., U.K., and Europe in parallel with ongoing partnership discussions*

New York, New York and Rockville, Maryland--(Newsfile Corp. - May 14, 2026) **OS Therapies, Inc. (NYSE American: OSTX) ("OS Therapies" or "the Company")**, the world leader in gene-edited, listeria-based cancer immunotherapies, announced Dr. Craig Eagle's appointment as Chief Medical Advisor. His appointment strengthens the Company's medical, regulatory, and commercial leadership team in preparation for potential early market access decisions from regulators at the U.S. Food & Drug Administration (FDA), U.K. Medicines and Healthcare products Regulatory Agency (MHRA), European Medicines Agency (EMA) and Australian Therapeutic Good Administrations (ATGA) for OST-HER2 in the prevention or delay of recurrence in fully-resected, pulmonary metastatic osteosarcoma (the "Metastatic Osteosarcoma Program"). The Company has already completed key regulatory meetings with EMA and ATGA in the first half of Q2 2026 and has upcoming key regulatory meetings with FDA and MHRA in the second half of Q2 2026.

"Having become significantly more acquainted with the OST-HER2 asset in recent weeks, the potential pivotal nature of the clinical and biomarker data generated from the Phase 2b Metastatic Osteosarcoma Program that is now in the long-term follow-up phase, as well as OS Therapies' broader *listeria monocytogenes* cancer immunotherapy ("Listeria") platform, I have strong conviction that this technology has found its initial commercial niche from which it can expand into treating not only other settings in osteosarcoma, but many other metastatic and primary solid tumors," said Dr. Craig Eagle, Chief Medical Advisor at OS Therapies. "With Advanced Therapy Medicinal Products (ATMP) designation already granted in Europe and the U.K., I am working closely and rapidly with our regulatory team on U.K. and European commercialization and reimbursement preparations. We have upcoming meetings with FDA and MHRA to align upon the confirmatory Phase 3 protocol required to commence prior to the granting of early market access decisions in the U.S., U.K., and Europe. We have already aligned with EMA and ATGA on the key components of the confirmatory Phase 3 protocol design."

Dr. Eagle continued, "We are also preparing for the upcoming FDA Pre-BLA meeting to align on primary and surrogate clinical efficacy endpoints to provide the basis for a positive BLA decision under the Accelerated Approval program. This alignment will provide the basis to

decide on our outstanding Regenerative Medicine Advanced Therapy (RMAT) designation request. It is encouraging that FDA has already aligned that OST-HER2 meets the biological definition of a gene-edited product that is required for RMAT."

Dr. Eagle most recently served as Guardant Health's Chief Medical Officer. Prior to joining Guardant Health, Dr. Eagle served as Vice President of Medical Affairs Oncology for Genentech, where he oversaw the medical programs across the oncology portfolio and developed innovative cancer trials and strategies in personalized health care. Prior to Genentech, Dr. Eagle held several leadership roles at Pfizer, including oncology business lead for the United Kingdom and Canada, global lead for Oncology Strategic Alliances and Partnerships, and global head of the Oncology Therapeutic Area Global Medical and Outcomes Group, where he oversaw the U.S. oncology business. Dr. Eagle attended medical school at the University of New South Wales in Sydney, Australia and received his general internist training at Royal North Shore Hospital in Sydney.

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 receives a BLA in the United States, it will become eligible to receive a Priority Review Voucher (PRV) that it intends to sell. The Company is seeking to obtain a BLA under the Accelerated Approval Program for OST-HER2 in osteosarcoma in the second half of 2026, in addition to CMAs in Europe, the U.K. 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 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 ATMP from the European Medicines Agency.

The Company reported positive data in its Phase 2b clinical trial of OST-HER2 in recurrent, fully resected, lung 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 anticipates receiving 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 Authorisations 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 has been conditionally approved by the U.S. Department of Agriculture for the treatment of canines with osteosarcoma. The Company also anticipates reading out data from a Phase 1b study of OST-504 in castration resistant prostate cancer in the first half of

2026.

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 silicone 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 about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute forward-looking statements within the meaning of the federal securities laws. These forward-looking statements and terms such as "anticipate," "expect," "intend," "may," "will," "should" or other comparable terms involve risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. Those statements include statements regarding the intent, belief or current expectations of OS Therapies and members of its management, as well as the assumptions on which such statements are based. OS Therapies cautions readers that forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to certain risks and uncertainties that could cause actual results to differ materially, including, but not limited to our expected to provide cash runway into 2027, the intended use of net proceeds from the offering, the potential approval of OST-HER2 by the U.S. FDA and other risks and uncertainties described in "Risk Factors" in the Company's most recent Annual Report on Form 10-K and other subsequent documents the Company files with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and, except as required by the federal securities laws, OS Therapies specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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