April 30, 2026

# OS Therapies Announces EMA Initiates Rolling Review of Conditional Marketing Authorization Application for OST-HER2 in the Prevention or Delay of Recurrence in Fully Resected Pulmonary Metastatic Osteosarcoma

*Conference call scheduled for Thursday, April 30, 2026, at 8:30 am ET to review new OST-HER2 immune pharmacodynamic biomarker response (seroconversion) data and review regulatory successes validating the OST-HER2 approach. Participants will include strategic advisors Dr. Craig Eagle and Dr. Bob Langer, and Osteosarcoma key opinion leader Dr. Peter Anderson from Cleveland Clinic.*

- *EMA and Australia TGA (ATGA) align on 3-year overall survival as the approvable clinical efficacy endpoint for Conditional Marketing Authorizations (CMAs), with alignment also achieved on confirmatory Phase 3 initiation, initially only in Australia, planned for Q3 2026 to meet regulatory requirement to support early approvals in the U.S., U.K., Europe and Australia*
- *Alignment achieved with EMA and ATGA on Seroconversion data serving as surrogate clinical efficacy data to support CMAs for early market access and eligibility for a Priority Review Voucher (PRV) under Rare Pediatric Disease Designation (RPDD)*
- *Alignment achieved with EMA and ATGA on non-clinical, CMC and safety data*
- *Alignment achieved with ATGA on existing drug product being used to initiate Phase 3*
- *EMA selects Company into Raw Data Pilot Program*
- *OST-HER2 granted ATMP designation by U.K. MHRA*
- *Company forecasts European peak OST-HER2 osteosarcoma sales exceeding $300 million following ATMP designation grant, with over $50 million in sales expected in 2027*
- *Upcoming U.S. FDA and U.K MHRA meetings scheduled in 2nd quarter of 2026*
- *OST-504 Phase 1b castrate resistant prostate cancer trial biomarker analysis to mirror OST-HER2 Phase 2b osteosarcoma biomarker analysis*
- *OST-503 Phase 2 non-small cell lung cancer candidate indications expanded to include pancreatic cancer following review of target vector antigens include all KRAS G12 position mutations, which represents 76% of all KRAS mutations in cancer*

New York, New York--(Newsfile Corp. - April 30, 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 the European Medicines Agency (EMA)'s Committee for Advanced Therapy (CAT), in conjunction with the Committee for Medicinal Products for Human Use (CHMP) and Pharmacovigilance Risk Assessment

Committee (PRAC), has initiated Continuous Evaluation ("Rolling Review") of the OST-HER2 Conditional Marketing Authorisation (CMA) request regulatory dossier for the prevention of recurrence in fully resected, pulmonary metastatic osteosarcoma.[1] The Company also announced that it was selected into EMA's Raw Data Pilot programme.

Concurrent with this announcement, the effort will be done in concert with the EMA Scientific Advice Working Party (SAWP). TGA has also invited OS Therapies to make an application for Provisional Determination; the Australian equivalent of a Conditional Marketing Authorisation of the OST-HER2 regulatory dossier. The TGA is expected to make a decision on rolling review following the receipt of the Clinical Trial Notification (CTN) for the confirmatory Phase 3 trial later this quarter that will position OS Therapies to initiate the confirmatory Phase 3 in the third quarter of 2026.

"I am delighted with the regulatory interactions OS Therapies has had to date, and I look forward to supporting OS Therapies in upcoming meetings with U.S. and U.K regulators," said Dr. Craig Eagle, strategic advisor for OS Therapies.

***OST-HER2 Immune Pharmacodynamic Biomarkers Conference Call Details***

Title: OS Therapies (NYSE: OSTX) | Conference Call: OST-HER2 immune pharmacodynamic response biomarkers
Date: April 30th, 2026
Time: 8:30 AM Eastern Time
Registration Link: https://zoom.us/webinar/register/WN_Xlmj7kdNTH6C0MA_xdwiiQ

***EMA OST-HER2 Rolling Review Status***

OS Therapies and EMA have agreed that 3-year overall survival data will serve as the basis to complete evaluation of the CMA request. The Company's recently submitted clinical efficacy data includes 2-year overall survival data, with EMA requesting updated 2.5-year overall survival data that will be available by the middle of the second quarter of 2026, and 3-year overall survival data that will become available early in the fourth quarter of 2026, which will complete the CMA submission. The Company anticipates a potential CMA decision by EMA in the fourth quarter of 2026. Market access interactions related to reimbursement with the UK's NICE and EMA Health Technology Assessment (HTA) processes have commenced simultaneously to minimize the time between regulatory approval(s) and patient access to treatment. International regulatory coordination has also commenced under the EMA FDA Information Sharing programme[2].

Additionally, the Company has been granted Advanced Therapy Medicinal Product designation from the U.K. Medicines and Healthcare products Regulatory Agency (MHRA)[3] by virtue of its reciprocal designation agreement with EMA.

"We are grateful for EMA and ATGA's strong support of our OST-HER2 program as we urgently work to improve outcomes for patients facing this rare and deadly pediatric cancer," said Paul Romness, Chair and Chief Executive Officer of OS Therapies. "With all currently available data submitted and key regulatory alignment achieved, we are advancing toward early market access via Conditional Marketing Authorizations in Europe, the U.K., and Australia, as well as a U.S. Biologics License Application (BLA) under Accelerated Approval.

Following our recent ATMP designation in Europe, we believe peak European sales could exceed $300 million annually, with the potential to generate more than $50 million in sales beginning in 2027." Mr. Romness continued: "We have aligned with EMA and ATGA on the provisional design of our global confirmatory Phase 3 trial that is required to be initiated prior to being granted early market access, including 3-year overall survival as the primary efficacy endpoint. 3-year overall survival will also be the efficacy endpoint that will serve as the basis for potential early market access in the U.S., U.K., Europe, and Australia. This gives us strong confidence as we head into upcoming FDA and MHRA meetings, while reinforcing the growing recognition of our pharmacodynamic biomarker response seroconversion data as a meaningful surrogate for the key overall survival efficacy endpoint, further supporting our global regulatory pathway. We are delighted that immunotherapies are becoming more central in the approach to treating cancers globally, which bolsters OST-HER2 and the rest of our attenuated *listeria monocytogenes* platform candidates."

"With the significant momentum we now have surrounding OST-HER2 in osteosarcoma, we are actively working to be prepared for the time when resources become available to advance our exciting listeria monocytogenes platform pipeline," said Robert Petit, PhD, Chief Medical and Scientific Officer at OS Therapies. "Based upon the extensive biomarker work we have done to date on the OST-HER2 osteosarcoma program, we are now positioned to generate congruent data for the OST-504 castration-resistant prostate cancer program. Additionally, following significant advancement in the exciting KRAS-targeted antibody pancreatic cancer field with important clinical data showing significant survival benefit, we have identified that our promising Phase 2 non-small cell lung cancer (NSCLC) candidate OST-503 was constructed to target all KRAS G12 position-related antigen mutations, which represents 76% of all KRAS mutations in cancer. As a result, we believe OST-503 could represent a highly complementary approach to KRAS-target antibodies currently in development."

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.

### *Upcoming 2$^{nd}$ Quarter Milestones*

- 2.5-year overall survival data
- FDA Pre-BLA Type B meeting to gain alignment on surrogate clinical efficacy endpoints based on most up-to-date Phase 2b clinical, biomarker and CMC, following the December 2025 alignment achieved non-clinical and safety data
- Regenerative Medicine Advanced Therapy designation ("RMAT" - FDA equivalent to EMA ATMP designation) decision to be based upon preliminary evidence of efficacy supported by clinical and biomarker data metrics aligned upon
- FDA rolling review decision based upon pre-BLA meeting outcome
- FDA Type C meeting to gain alignment on the design of the confirmatory Phase 3 study
- Submission of the Accelerated Approval BLA request to FDA

- MHRA meeting to gain alignment on the design of the confirmatory Phase 3 study
- Submission of CMA request to MHRA
- MHRA rolling review decision based on Phase 3 confirmatory study design alignment
- Submission of CMA request to Australia in conjunction with Clinical Trial Notification (CTN) request for confirmatory Phase 3 study
- Receipt of approximately 1.45 million GBP in non-dilutive cash VAT tax refund

**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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[1] https://www.ema.europa.eu/en/about-us/how-we-work/data-regulation-big-data-other-sources/use-clinical-study-data-medicine-evaluation
[2] https://www.fda.gov/drugs/cder-international-program/international-agreements-information-sharing
[3] https://www.gov.uk/guidance/advanced-therapy-medicinal-products-regulation-and-licensing

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