

OS Therapies Schedules OST-HER2 Pharmacodynamic Response Biomarker Conference Call on April 30, 2026 at 8:30am ET

- *Regulatory feedback recent from April 2026 EU EMA and Australian TGA meetings*
- *Remaining Q2-2026 regulatory meetings include two U.S. FDA meetings and one UK MHRA meeting, in addition to follow-up meetings with EU EMA and Australian TGA*

New York, New York--(Newsfile Corp. - April 27, 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 it will be hosting a conference call on Thursday April 30, 2026 at 8:30am ET to review the data that supported the recent Patent Cooperation Treaty (PCT) international application for a [OST-HER2 pharmacodynamic biomarker](#)¹ (the "OST-HER2 Immune Signature") as a surrogate clinical efficacy endpoint. The OST-HER2 Immune Signature is expected to be used to support early market access in the second half of 2026 in the U.S via a Biologics License Application ("BLA") under the [Accelerated Approval Program](#)² (Accelerated Approval), in addition to Europe, the UK and Australia via [Conditional Marketing Authorisations](#)³ (CMAs).

Conference Call Details

Title: OS Therapies (NYSE American: 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

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 most recent publicly disclosed PRV transaction occurred in February 2026 at a reported value of \\$205 million.](#) 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 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.ncbi.nlm.nih.gov/books/NBK338448/>
² <https://www.fda.gov/drugs/nda-and-bla-approvals/accelerated-approval-program>
³ <https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/conditional-marketing-authorisation>



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