OS Therapies Announces FDA OST-HER2 Type D Meeting Elevated to Type B Pre-BLA Meeting

FDA's elevated meeting status signals transition from biomarker data discussions to Accelerated Approval discussions

OS Therapies on track to complete clinical data submission by the end of Q1 2026

The most recent publicly disclosed PRV transaction occurred in February 2026 at a reported value of $205 million.

NEW YORK, NY, UNITED STATES, March 10, 2026 /EINPresswire.com/ -- OS Therapies Inc. (NYSE American: OSTX) ("OS Therapies" or "the Company"), the world leader in listeria-based cancer immunotherapies, today provided an update regarding ongoing conversations with the United States Food & Drug Administration (FDA) with regards to its ongoing Biologics License Application (BLA) submission under the Accelerated Approval Program (Accelerated Approval) for OST-HER2 in the prevention or delay of recurrent, fully resected, pulmonary metastatic osteosarcoma. FDA elevated OS Therapies' Type D Biomarker Meeting to a Type B pre-BLA Meeting, expected to occur shortly after the Company completes submission of its clinical data package to the agency, targeted for the end of the first quarter of 2026.

OS Therapies is a B2i Digital Featured Company. View their comprehensive profile at https://b2idigital.com/os-therapies-1.

"We credit FDA with taking decisive action to help advance Accelerated Approval discussions regarding OST-HER2 for pediatric cancer patients with osteosarcoma," said Paul Romness, MPH, Chairman & CEO of OS Therapies. "With the biomarker analysis complete, and patent filings in

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> *Paul Romness, MPH, Chairman & CEO of OS Therapies*

process, we are poised to deliver data to the agency that we believe represents surrogate clinical efficacy sufficient to enable our ongoing BLA submission. Following key meetings with Key Opinion Leaders over the last few weeks, many of whom treated patients in our clinical trial, we believe we now have a clear path forward to establish confirmatory randomized Phase 3 trial that is required to have a commenced prior to being granted Accelerated Approval in the United States."

OST-HER2 has received FDA Orphan Drug Designation (ODD) and Fast Track Designation from the FDA & EMA and has also received Rare Pediatric Disease Designation (RPDD) from the FDA. Under the RPDD program, if the Company receives Accelerated Approval 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 get Accelerated Approval for OST-HER2 in osteosarcoma in the second half 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 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 Rare Pediatric Disease Designation (RPDD) from the U.S. Food & Drug Administration and Fast-Track and Orphan Drug designations from the U.S. FDA and 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 statistically significant benefit in the 12-month event free survival (EFS) primary endpoint of the study. The Company anticipates receiving a Biologics Licensing 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 European Medicines Agency 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 the 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, most recent Quarterly Report on Form 10-Q 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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