

March 13, 2025



OS Therapies Awarded OST-HER2 Clinical Trial Data Presentation at MIB Agents FACTOR Osteosarcoma Conference

NEW YORK--(BUSINESS WIRE)-- **OS Therapies, Inc. (NYSE-A: OSTX)**, a clinical-stage biotechnology company advancing immunotherapies and targeted drug conjugates for cancer treatment, today announced that it has been awarded a presentation slot at the [MIB Agents Factor Osteosarcoma Conference](#) to be held June 26-28, 2025 in Salt Lake City, Utah. Key data will be presented from the Company's Phase 2b clinical trial of OST-HER2 in the prevention of recurrent, fully resected, lung metastatic osteosarcoma. This data will be compared with a newly created regulatorily compliant synthetic control group comprised of case matched controls that will be used for the Company's US Food & Drug Administration (FDA) OST-HER2 Biologics License Application (BLA) submission. Equivalent submissions with international regulatory authorities will be made in order to gain commercial marketing authorization. MIB Agents FACTOR is the most important annual osteosarcoma conference bringing together the leading osteosarcoma researchers, clinicians, patient families, osteosarcoma survivors, patients, and bereaved parents to "Make It Better" (MIB) for those battling this deadly cancer.

The Company reiterates its intention to submit a BLA with FDA for OST-HER2 in osteosarcoma in the second quarter of 2025, positioning it to receive approval in the fourth quarter of 2025. OST-HER2 has received Rare & Pediatric Disease Designation (RPDD) from the FDA and Fast Track and Orphan Drug Designations from the FDA and European Medicines Agency (EMA). If OST-HER2's BLA submission is approved by the FDA before September 30, 2026, the Company will be granted a Priority Review Voucher (PRV) that it will be able to sell to a third party. The most recent PRV transaction occurred last month when Zevra sold its PRV to an undisclosed third party for \$150 million.

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. 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 US Food & Drug Administration and Fast-Track and Orphan Drug designations from the US FDA and European Medicines Agency. The Company announced that its Phase 2b clinical trial of OST-HER2 in recurrent, fully resected, lung metastatic osteosarcoma achieved the primary endpoint of the study of 12-month event free survival (EFS). The Company anticipates submitting a Biologics Licensing Application (BLA) to the US FDA for OST-HER2 in osteosarcoma in 2025 and, if approved, would become eligible to receive a Priority Review Voucher that it could then sell. 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.

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 news 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 US FDA and grant of a priority review voucher and other risks and uncertainties described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's registration statement on Form S-1 filed with the Securities and Exchange Commission (the "SEC") on November 12, 2024, as amended on November 27, 2024, and other subsequent documents we file with the SEC, including but not limited to our Quarterly Reports on Form 10-Q. 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.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20250313374522/en/>

OS Therapies Contact Information:

Jack Doll
571.243.9455
lrpr@ostherapies.com

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

Source: OS Therapies, Inc.