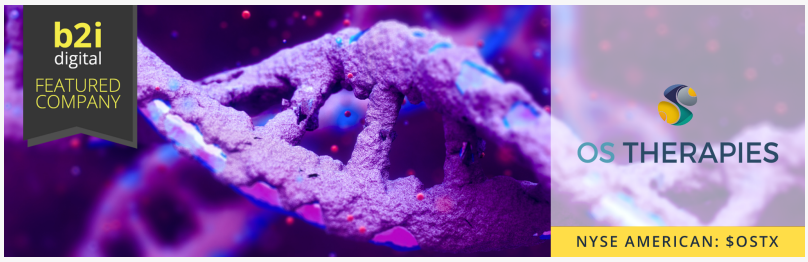
OS Therapies Announces Positive Biomarker Data from Phase 2b Clinical Trial of OST-HER2

Activation of immune blood biomarkers from interferon gamma pathway distinguished long-term survivors (>=2 years) from short-term survivors (<1year)



Pre-specified pathway analysis strategy developed as a result of immune biomarker pathway data generated from 118-patient canine metastatic osteosarcoma study published in February 2025 demonstrates translational power of Comparative Oncology to identify

NEW YORK, NY, UNITED STATES, January 16, 2026 /EINPresswire.com/ -- OS Therapies Inc. (NYSE American: OSTX) ("OS Therapies" or "the Company"), the world leader in listeria-based cancer immunotherapies, today announced positive biomarker data from its Phase 2b clinical trial of OST-HER2 in the prevention or delay of recurrent, fully resected, pulmonary metastatic osteosarcoma (the "Human Metastatic Osteosarcoma Trial"). Activation of immune blood biomarkers in the interferon gamma pathway was predictive of overall survival, distinguishing long-term survivors (>=2 years) from short-term survivors (<1year). The Company's pre-specified pathway analysis strategy that was developed as a result of immune biomarker pathway data generated from 118-patient canine metastatic osteosarcoma study published in February 2025 (the "Canine Metastatic Osteosarcoma Trial") demonstrates the translational power of Comparative Oncology in identifying surrogate markers of clinical efficacy for human osteosarcoma clinical development programs.

> “Leveraging the power of Comparative Oncology, we were able to train and test potentially predictive biomarkers from the Canine Metastatic Osteosarcoma Trial.”
>
> *Paul Romness, MHP, Chairman & CEO of OS Therapies*

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

"Leveraging the power of Comparative Oncology, we were able to train and test potentially predictive biomarkers from the Canine Metastatic Osteosarcoma Trial in order to form a hypothesis to test in a pre-specified way in the Human Metastatic Osteosarcoma Trial," said Paul

Romness, MHP, Chairman & CEO of OS Therapies. "We believe the confirmation of this pre-specified pathway analysis in humans adds significant resolution to our clinical data, increasing the clinical interpretability of the 2-year overall survival data for regulatory agencies. The confirmation of a pre-specified canine biomarker pathway being upregulated in a comparable human clinical study population leveraged canine biomarker data to a generate hypothesis that was tested in a pre-specified way and confirmed as a surrogate marker of clinical efficacy. This biomarker data strengthens our pending Biologics License Application (BLA) submission."

This biomarker data strengthens our pending Biologics License Application (BLA) submission.

The Company is focused on completing the drafting of its planned BLA submission along with its pending Marketing Authorisation Application submissions in the U.K. and Europe. The Company is targeting gaining regulatory approval for OST-HER2 in the United Kingdom by the end of the second quarter of 2026, the United States by the end of the third quarter of 2026 and Europe by year end 2026."

OST-HER2 has received FDA Orphan Disease Designation (ODD) and Fast Track Designation from FDA & EMA and has received Rare Pediatric Disease Designation (RPDD) from FDA. Under the RPDD program, if the Company receives Accelerated Approval prior to September 30, 2026, it will become eligible to receive a Priority Review Voucher (PRV) that it intends to sell. The most recent PRV sale, valued at $200 million, occurred in January 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 submitting a Biologics Licensing Application (BLA) to 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. 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 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.

OS Therapies Contact Information:

Investor Relations
Harrison Seidner, PhD
WaterSeid Partners
OSTX@waterseid.com

Public Relations
Stephanie Chen
Elev8 New Media
media@ostherapies.com

Additional Contact

David Shapiro
B2i Digital, Inc.
+1 212-579-4844
david@b2idigital.com
Visit us on social media:
LinkedIn
Instagram
Facebook
X
