April 16, 2026

OS Therapies Files New Patent Application Covering Biomarkers of the Immune Response to Listeria Monocytogenes

- *New patent application covers treatment-emergent immune signature related to 'turning cold tumors hot' and the activation of targeted cytotoxic cellular immune responses*
- *Company to host conference call later in April 2026 to review new biomarker signature*
- *Biomarker signature meets pharmacodynamic/response criteria established by FDA's Biomarkers, EndpointS and other Tools (BEST) program for use as a surrogate clinical endpoint of 1-year event free survival and 2-year overall survival in OST-HER2's Phase 2b trial in the prevention of delay of recurrent, fully-resected, pulmonary metastatic osteosarcoma to support a BLA submission under FDA's Accelerated Approval Program*

New York, New York--(Newsfile Corp. - April 16, 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 has filed a new patent application covering a unique immune signature in response to treatment with therapeutic candidates developed from the Company's proprietary *Listeria monocytogenes* platform ('Listeria') based on new biomarker data from the Company's Phase 2b trial of OST-HER2 in the prevention or delay of recurrent, fully-resected, pulmonary metastatic osteosarcoma. Filed claims include treatment with Listeria leading to the downregulation of genes associated with tumor and circulating tumor cell immune evasion in combination with the upregulation of genes associated with cytotoxic cellular immune activation leads to improved anti-tumor cellular immunity activation. The Company will host a conference call later in April 2026 to review OST-HER2 Phase 2b's new treatment response biomarker signature data showing correlation with clinical outcomes, and its regulatory implications in upcoming Q2-2026 meetings and regulatory submissions with the U.S. Food & Drug Administration (FDA), the European Medicines Agency (EMA), the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) and the Australian Therapeutic Goods Administration (TGA). The Company will complete the first complete OST-HER2 regulatory market access filing in the world to the EMA, at its request, on April 30, 2026.

"The biomarker data from patients who responded to OST-HER2 treatment shows tremendous innate and adaptive immune responses that result in a significantly improved ability to fight cancer," said Paul Romness, MPH, Chair & CEO of OS Therapies. "While not all metastatic osteosarcoma is HER2 positive, a recently published study reported that over 80% of the patients who were screened for enrollment were found to have HER2 positive metastatic lesions[1]. In our Phase 2b trial, 100% of the patients that did achieve 1-year event free survival (EFS) exhibited the distinct immune signature covered in our patent application and went of to achieve 2-year overall survival. We believe this meets the pharmacodynamic/response biomarker criteria outlined in the U.S. Food & Drug

Administration's (FDA)'s Biomarkers, EndpointS, and other Tools (BEST)[2] glossary as a surrogate clinical endpoint to support a Biologics License Application under the Accelerated Approval Program[3]. This pharmacodynamic/response biomarker also provides us with a strong basis to think about additional clinical applications of OST-HER2 beyond osteosarcoma, such as in HER2 positive breast cancer and bladder cancer.

Mr. Romness continued, "Notwithstanding the potential for future indication expansion, we are now laser focused on our packed Q2-2026 regulatory meeting schedule with FDA, EMA, MHRA and TGA in preparation for gaining accelerated market access for OST-HER2 in the fully-resected pulmonary metastatic setting later this year in the U.S., Europe and the U.K. with the potential to expand beyond these jurisdictions in 2027."

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 Biologics License Application (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.

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 statistically 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://ascopubs.org/doi/10.1200/OA-25-00094

[2] https://www.fda.gov/drugs/biomarker-qualification-program/about-biomarkers-and-qualification

[3] https://www.fda.gov/drugs/nda-and-bla-approvals/accelerated-approval-program



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