February 4, 2026

OS Therapies Applauds Reauthorization of Pediatric Priority Review Voucher Program to Advance Breakthrough Osteosarcoma Immunotherapies

New York, New York--(Newsfile Corp. - February 4, 2026) - **OS Therapies Inc. (NYSE American: OSTX)** ("OS Therapies" or "the Company"), the world leader in listeria-based cancer immunotherapies, is honored to celebrate the passage of the *Mikaela Naylon Give Kids A Chance Act*. Mikaela, like so many other children, courageously battled pediatric cancer - specifically Osteosarcoma. Her legacy through this legislation will accelerate critical opportunities for research and therapeutic access for other children and teens currently living with pediatric cancers.

Innovation is urgent and direly needed as pediatric cancers remain the leading disease-based cause of pediatric death in the United States. OS Therapies is empowered to continue its groundbreaking work combating osteosarcoma, where there is still significant unmet need for patients - primarily children and teens.

Through the reauthorization of the Rare Pediatric Disease Designation (RPDD) Priority Review Voucher (PRV) program, OS Therapies can continue their dedicated efforts with an extended deadline for the Company to receive a Biologics License Application (BLA) for OST-HER2 in the prevention or delay of recurrent, fully resected, pulmonary metastatic osteosarcoma. The Company will now remain eligible to receive a PRV from September 30, 2026, to September 30, 2029.

The reauthorization of the program also incentivizes OS Therapies to re-evaluate the development of other pipeline products across its listeria-based cancer immunotherapy platform in the context of potential additional PRV opportunities, and benefits afforded by the FDA Platform Technology Designation Program for Drug Development. The Company will provide further details regarding the outcome of this evaluation process after the current sequence of marketing authorization submissions for its lead osteosarcoma candidate is completed.

OS Therapies is grateful for the positive impact of Mikaela's and some many other patients' legacy, and the Company is committed to building upon it to transform the lives of children and teens living with osteosarcoma and other rare cancers.

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, 2029, it will become eligible to receive a Priority Review Voucher (PRV).

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 is submitting a Biologics Licensing Application (BLA) to the U.S. FDA for OST-HER2 in osteosarcoma 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

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

To view the source version of this press release, please visit
https://www.newsfilecorp.com/release/282703

SOURCE OS Therapies