

OS Therapies Receives Non-Proprietary Name 'daznelimgene lisbac' for OST-HER2 from World Health Organization

New York, New York--(Newsfile Corp. - November 25, 2025) -**OS Therapies Inc. (NYSE American: OSTX)** ("OS Therapies" or "the Company"), the world leader in listeria-based cancer immunotherapies, today announced that the International Nonproprietary Names (INN) Expert Committee of the World Health Organization (WHO) approved 'daznelimgene lisbac' for the non-proprietary name for the Company's HER2 targeted *Listeria monocytogenes*-based cancer immunotherapy product candidate OST-HER2. OST-HER2 is currently being developed for the prevention or delay of recurrent, fully resected, pulmonary metastatic osteosarcoma.

Each INN name is unique and is used to identify active pharmaceutical ingredients. Each active substance that is to be marketed as a pharmaceutical must be granted a unique name of worldwide acceptability to ensure clear identification, safe prescription and dispensing of medicines. OS Therapies will begin to transition towards the use of diznalimgene lisbac alongside the OST-HER2 in future communications.

"We are pleased to have completed this milestone on our path towards gaining regulatory approval for OST-HER2, now called diznalimgene lisbac" said Paul Romness, MPH, Chairman & CEO of OS Therapies. "We remain on track to get regulatory feedback from the US, UK and European regulatory authorities in December 2025 and file for regulatory approvals beginning 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 early 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.

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