July 10, 2025

OS Therapies Provides Clinical & Global Regulatory Updates

- *End of Phase 2 Meeting with FDA scheduled for August 27, 2025 to review OST-HER2 recurrent, pulmonary metastatic osteosarcoma program*
- *Scientific Advice Meetings confirmed with global regulators in major markets - including the United Kingdom and European Union*
- *All patients enrolled in its Phase 1 clinical study of OST-504 in second line prostate cancer have completed treatment, with data expected to be announced later in 2025*

New York, New York--(Newsfile Corp. - July 10, 2025) - OS Therapies (NYSE American: OSTX) ("OS Therapies" or "the Company"), a clinical-stage immunotherapy and Antibody Drug Conjugate (ADC) biopharmaceutical company, today provided a clinical and global regulatory update on its currently active clinical-stage oncology programs. The Company announced that the End of Phase 2 Meeting granted by the US Food & Drug Administration ("FDA") to review the clinical data from its OST-HER2 recurrent, pulmonary metastatic osteosarcoma program is scheduled for August 27, 2025, during which the Company expects to seek alignment with FDA to begin a rolling review Biologics Licensing Application ("BLA") submission to FDA under its Accelerated Approval Program ("Accelerated Approval").

Further, the Company announced that it has a confirmed a Scientific Advice Meeting ("SAM") with a European Medicines Agency ("EMA") rapporteur with respect to the OST-HER2 osteosarcoma program. This milestone is a critical step in the EMA's Centralized Procedure, providing a single Marketing Authorization valid across all European Member States. The Company also announced that it intends to pursue a Conditional Marketing Authorization ("CMA") in the United Kingdom via the Medicines and Health products Regulatory Agency's ("MHRA") Innovative Licensing and Access Pathway ("ILAP") in the event of a successful previously disclosed July 31st, 2025 UK SAM Meeting. Biolacuna has been appointed by OS Therapies as advisors for all global regulatory affairs efforts.

In addition, the Company reported that all patients enrolled in thePhase 1 clinical study of OST-504 (previously ADXS-504) have completed treatment, with updated clinical data expected to be reported in the second half of 2025.

"We are making significant progress towards our primary objective of obtaining regulatory approval for OST-HER2 in recurrent, pulmonary metastatic osteosarcoma prior to the sunsetting of the rare pediatric disease priority review voucher ("PRV") program," said Paul Romness, MPH, Chairman & CEO of OS Therapies. "If successful, we expect to receive significant non-dilutive funding from the sale of the PRV which we would then be able to deploy in commercializing OST-HER2 osteosarcoma and other HER2 expressing cancers, as well as advance the other clinical candidates in our pipeline, including OST-504 in prostate cancer. We strongly believe in the promise of the listeria immunotherapy platform to help prevent and treat cancer, and intend to judiciously deploy our capital to focus on the

OST-HER2 approval while advancing our other clinical programs without deploying significant capital or running other clinical studies while we wait for the OST-HER2 approval and related PRV sale."

OST-HER2, an immunotherapy for osteosarcoma that uses a HER2-bioengineered form of the bacterium *Listeria monocytogenes* to trigger a strong immune response against HER2-expressing cancer cells, is featured in the movie *Shelter Me: The Cancer Pioneers*. The movie offers a look into canine comparative oncology, a field that compares treatment of cancers in dogs to those in people and covers developing treatments for rare forms of cancer. The movie is available via streaming on PBS' website.

The most recent data updated regarding the OST-HER2 canine osteosarcoma program is available at this link. The Company has formed the subsidiary OS Animal Health to advance the canine osteosarcoma program.

OST-504 is a prostate cancer-specific listeria-based immunotherapy targeting multiple common prostate cancer-specific antigens such as PSA, certain cancer-testis antigens and certain standard-of-care treatment resistance mutations.

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 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 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 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 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.

OS Therapies Contact Information:

Jack Doll
410.297.7793
lrpr@ostherapies.com

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