September 2, 2025

OS Therapies Provides OST-HER2 Recurrent, Fully Resected, Pulmonary Metastatic Osteosarcoma Program Update Following FDA End of Phase 2 Meeting

- *Company on track to begin submission of a rolling Biologics Licensing Application (BLA) request for OST-HER2 to U.S. Food & Drug Administration in September 2025*

New York, New York--(Newsfile Corp. - September 2, 2025) -**OS Therapies Inc. (NYSE American: OSTX)** ("OS Therapies" or "the Company"), a clinical-stage cancer immunotherapy and antibody drug conjugate biotechnology company, today provided stakeholders with a detailed update regarding the Company's OST-HER2 recurrent, fully resected, pulmonary metastatic osteosarcoma program (the "Metastatic Osteosarcoma Program") following a highly productive End of Phase 2 Meeting with the US Food & Drug Administration ("FDA"). The Company remains on track to begin rolling submission of a Biologics Licensing Application ("BLA") request to FDA for the Metastatic Osteosarcoma Program in September 2025.

Key Metastatic Osteosarcoma Program updates following FDA End of Phase 2 Meeting

FDA and the Company achieved alignment in a number of areas crucial for a successful BLA:

- No significant safety concerns with OST-HER2 in the targeted indication were identified based on the excellent safety profile from clinical data to date
- Non-clinical related matters were agreed to with minimal follow-up required
- Chemistry, Manufacturing, and Controls ("CMC")-related matters were agreed to, with clear guidance on final steps needed to support a BLA approval. The Company expected the feedback it received from FDA, based on prior feedback from the OST-AXAL (previously ADXS-AXAL) program. In February 2025, the Company began generating the necessary data and expects to have it ready for submission to FDA as part of the rolling BLA submission in Q4/25, ahead of an expected pre-BLA meeting

FDA continues to evaluate the appropriateness of various potential amended clinical trial efficacy endpoints, statistical analysis plans, and other protocol amendments that would support a BLA, whether via the Accelerated Approval Program ("Accelerated Approval") or full marketing authorization. As part of the effort to understand the unique challenges presented by osteosarcoma, FDA, together with patient advocacy group the Osteosarcoma Institute ("OSI"), is holding a public meeting with key osteosarcoma stakeholders on October 10, 2025, entitled "Advancing Osteosarcoma Drug Development – Connecting Research and Regulatory Pathways for Improved Outcomes" to gain alignment on the best path(s) forward to rapidly bring new therapies to market. FDA committed to working closely with the Company by prioritizing formal and informal meetings, with the first informal meeting

scheduled for mid-September 2025

- Current single arm, open-label Phase 2b study design, originally recommended by FDA in 2020 as a proof-of-concept study, compares OST-HER2-treated patients with historical clinical outcomes data published by the Children's Oncology Group ("COG") consortium. The Company continues to seek direction on which FDA guidance to rely upon with respect to clinical efficacy for the pending BLA submission
- New FDA Draft Guidance entitled 'Approaches to Assessment of Overall Survival in Oncology Clinical Trials' made public on August 18, 2025 (the "Draft FDA Overall Survival Guidance"), provides potential pathways to evaluate osteosarcoma clinical trial efficacy data. The Company has achieved statistically significant positive final 12-month Event Free Survival (EFS) data (p = 0.0197)and interim 2-year overall survival data (p = 0.0046) from its 40 patient Phase 2b trial
- Final FDA guidance made public in December 2023 entitled 'Rare Diseases: Considerations for the Development of Drugs and Biological Products,' provides additional potential pathways to evaluate osteosarcoma clinical trial efficacy data. From 2015 to 2022, single arm Phase 1 or Phase 2 trials supported 45 out of 84 molecular targeted marketing authorizations in oncology

The Company is continuing to support the expansion of natural history database OST-400, "Recurrent Osteosarcoma after Resection in Children and Young Adults: A Retrospective Longitudinal Study". Data is being sourced from multiple leading US and international oncology research institutions, in addition to real world data sources. OST-400 database is being assembled in order to be able to develop a synthetic control arm suitable to support a randomization process that could serve as comparator arm in the event FDA relies upon its 2023 Rare Diseases guidance. Various FDA-accepted statistical analysis methods reviewed in this Guidance allow for randomization after treatment in single-arm trials. Final decisions on acceptable efficacy outcome measures are needed to support Regenerative Medicine Advanced Therapy ("RMAT") designation, Breakthrough Therapy designation ("BTD") and Accelerated Approval or full approval, and the Company expects significant progress to be made towards that end at the October 10, 2025 FDA/OSI osteosarcoma workshop.

Additionally, the Company received confirmation from FDA that it is eligible for a Prescription Drug User Fee Act (“PDUFA”) small business fee waiver, with a final decision on the PDUFA fee waiver anticipated by the end of the third quarter of 2025. FDA has also accepted the Company’s Expression of Interest for the Commissioner’s National Priority Voucher (CNPV).

"It is clear from the End of Phase 2 Meeting that FDA is committed to finding paths forward to bring new therapies forward for osteosarcoma given the continued high mortality rates in this rare pediatric cancer," said Paul Romness, MHP, Chair & CEO of OS Therapies. "We have already begun the work of preparing responses to FDA's comments stemming from the meeting and look forward to beginning the rolling BLA submission later this quarter. We will continue the highly productive ongoing dialogue we have with FDA as it relates to OST-HER2's potential to improve both Event Free Survival and Overall Survival in the fully resected, pulmonary metastatic osteosarcoma setting. We expect that the October 10th, 2025 workshop FDA and OSI are holding will provide the opportunity for stakeholders to coalesce around the key outcome measures that are clinically meaningful for the brave patients, their families and clinicians who help manage this difficult to treat patient population."

Concurrent with today's announcement, the Company announced that Luis Rojas, PhD (CEO of InCSD, an independent biostatistics firm managing the Metastatic Osteosarcoma Program and compiling data for the OST-400 natural history database) has accepted an invitation to present at the Rare Trials Summit being held in Boston on September 9, 2025 Dr. Rojas' presentation entitled "Accelerating Rare Disease Therapies: Strategies for Efficient Clinical Development" will review the key challenges in developing new treatments for ultra-rare diseases and clinical subsets thereof, such as recurrent, fully resected, pulmonary metastatic osteosarcoma and how to efficiently overcome them. Dr. Rojas will highlight how the data generated from the OST-HER2 Phase 2b clinical trial can be used in a manner compliant with FDA guidance to support Accelerated Approval or full approval for OST-HER2.

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 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 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 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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