September 12, 2025

OS Therapies Announces Last Patient Enrolled in OST-504 (previously ADXS-504) Phase 1b Prostate Cancer Clinical Trial Completes Last Visit

- Clinical data from Phase 1b prostate cancer trial to be released in Q4/25
- *Additionally, updated 2-year overall survival data from all 40 patients in the Phase 2b clinical trial of OST-HER2 in the prevention of delay of recurrent, fully resected, pulmonary metastatic osteosarcoma to be released on October 10, 2025*

New York, New York--(Newsfile Corp. - September 12, 2025) -**OS Therapies Inc. (NYSE American: OSTX)** ("OS Therapies" or "the Company"), a clinical-stage cancer immunotherapy and antibody drug conjugate biotechnology company, today announced that the last patient enrolled in its OST-504 (previously ADXS-504) Phase 1b clinical trial in subjects with biochemically recurrent prostate cancer previously treated with radical prostatectomy (RP) or radiation therapy (external beam or brachytherapy) who are not currently receiving androgen ablation therapy has completed their last patient visit (NCT05077098). A total of 7 patients enrolled in the study.

"We were pleasantly surprised by the level of enthusiasm around the OST-504 program from the clinical investigators at Columbia University after we took over the program as part of the acquisition of assets from Ayala," said Robert Petit, PhD, Chief Medical & Scientific Officer at OS Therapies. "We were especially excited that there was significant demand for expanded access following treatment. We believe the OST-504 construct has significant potential to be used in various prostate cancer settings and look forward to reporting on the study results in the fourth quarter of 2025."

"While we remain extremely focused on the regulatory pathway for OST-HER2 in osteosarcoma where we are preparing to initiate a rolling submission for a Biologics Licensing Application (BLA) in the next several weeks, we are in the fortunate position of being able to read out on an important initial proof of concept study in a major clinical indication without having to spend any money treating patients," said Paul Romness, MHP, Chairman & CEO of OS Therapies. "Prostate cancer represents a huge market opportunity with significant unmet medical need. 1 in 8 men are diagnosed at some point in their lives, with 1 in 44 men dying of prostate cancer, second among male cancer deaths only to lung cancer. If we are successful in our regulatory efforts with OST-HER2, we believe that OST-504 would become eligible for the FDA's new Platform Designation that could significantly accelerate OST-504's path to market."

Concurrent with this announcement, the Company announced that updated 2-year overall survival data from all 40 patients in the Company's Phase 2b clinical trial of OST-HER2 in the prevention of delay of recurrent, fully resected, pulmonary metastatic osteosarcoma (NCT04974008) to be released on October 10, 2025.

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.

OS Therapies Contact Information:

Investor Relations
Harrison Seidner, PhD

WaterSeid Partners
OSTX@waterseid.com

Public Relations
Stephanie Chen
Elev8 New Media
stephanie@elev8newmedia.com

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

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