June 24, 2025

OS Therapies Receives Positive FDA Meeting Feedback on Regulatory Pathway for Accelerated Approval of OST-HER2 in the Prevention or Delay of Recurrent, Fully Resected, Pediatric Lung Metastatic Osteosarcoma

- *Company has requested End of Phase 2 Meeting and Breakthrough Therapy Designation (BTD) based upon the positive FDA Meeting feedback*

NEW YORK--(BUSINESS WIRE)-- OS Therapies (NYSE-A: OSTX) ("OS Therapies" or "the Company"), a clinical-stage immunotherapy and Antibody Drug Conjugate (ADC) biopharmaceutical company, today announced that it received positive written feedback from the US Food & Drug Administration ("FDA") Type D Meeting that occurred in mid-June 2025 regarding endpoints required to support an Accelerated Approval Program marketing application for its Phase 2b trial of OST-HER2 in the prevention or delay of recurrence in fully resected, pediatric lung metastatic osteosarcoma. The Company reiterates that additional data from its Phase 2b trial will be presented at the major osteosarcoma conference MIB Factor in Salt Lake City on Saturday June 28, 2025 at 3:30pm MDT.

Concurrent with this announcement, the Company announced that it has submitted End of Phase 2 Meeting and Breakthrough Therapy Designation (BTD) requests to FDA based on the positive Type D Meeting feedback. The End of Phase 2 Meeting is expected to occur in the third quarter of 2025. This is in alignment with the company's overall regulatory strategy and timelines.

"We are pleased with the feedback we received from the FDA regarding the use of external control comparators in settings where placebo-controlled randomization trials are not feasible – particularly in rare pediatric diseases such as the indication treated by OST-HER2 ," said Dr. Robert Petit, Chief Medical & Scientific Officer of OS Therapies. "Moreover, we received additional collaborative input regarding suggested statistical methods as we seek to compare OST-HER2 active treatment with external control arm(s) to support a Biologics Licensing Application (BLA) via the Accelerated Approval Program. Taken together, the feedback gives us insight on the FDA's current position and allows us to be fully prepared for the End of Phase 2 Meeting."

OST-HER2 has received Rare Pediatric Disease Designation (RPDD) for osteosarcoma from the US FDA, and if it receives a conditional BLA via Accelerated Review prior to September 30, 2026, it will become eligible to receive a Priority Review Voucher (PRV) that it intends to immediately sell. The most recent PRV sale occurred in June 2025, valued at $160 million.

The osteosarcoma treatment market was estimated at $1.2 billion in 2022 according to Data Bridge Market Research. Approximately 50% of patients are diagnosed with a lung metastasis at some point following surgical resection and chemotherapy. 3-year survival rates in patients who were not diagnosed with a metastasis are 59%. 3-year survival rates in patients who were diagnosed with pulmonary metastasis were 30%. The Company believes the market opportunity for OST-HER2 in the prevention of lung metastases is over $500 million.

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.

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.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20250624414411/en/

OS Therapies Contact Information:

Jack Doll
410-297-7793
lrpr@ostherapies.com

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

Source: OS Therapies