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OS Therapies Announces Phase 2b Clinical Trial of OST-HER2 Achieves Primary Endpoint with Statistical Significance in the Prevention of Recurrent, Fully Resected, Lung Metastatic Osteosarcoma

- *The primary endpoint of 12-month Event Free Survival (EFS) for OST-HER2- treated patients (33.3%) was statistically significant (p= 0.0158) when compared with peer-reviewed comparable historical control (20%)*
- *Ongoing follow up demonstrates strong trend in favor of OST-HER2 in 1-year and 2-year interim analyses of the secondary endpoint, 3-year overall survival (OS) when compared with comparable peer-reviewed historical control*
- *100% of patients who achieved 12-month EFS remain alive in OS follow-up*
- *OST-HER2 was safe and well tolerated in the Phase 2b study*
- *OS Therapies reiterates clinical and regulatory path in recurrent, fully resected osteosarcoma with lung metastases, an indication with no currently approved treatments*

NEW YORK--(BUSINESS WIRE)-- OS Therapies, Inc. (NYSE-A: OSTX), a clinical-stage biotechnology company advancing immunotherapies and targeted drug conjugates for cancer treatment, today announced positive data from a Phase 2b clinical trial (NCT04974008) of OST-HER2 (OST31-164) - the Company's HER2-targeted immunotherapy candidate in the rare pediatric-designated indication of prevention of recurrent, fully resected, lung metastatic osteosarcoma. The data demonstrate statistically significant results in the primary endpoint of the study, 12-month event free survival ('EFS'), where an event is defined as the recurrence of metastatic osteosarcoma, in OST-HER2-treated patients when compared with the leading published historical comparable control group. Further as of the most recent follow up, the data show a strong trend in favor of OST-HER2-treated patients in overall survival ('OS', remaining alive) at the 1-year and 2-year interim timepoints of the ongoing 3-year overall survival secondary endpoint. Notably, all patients who achieved the primary 12-month EFS endpoint remain alive.

"We are extremely pleased with these results of our Phase 2b clinical trial because they show that OST-HER2-treated patients achieved the primary endpoint of 12-month EFS in a statistically significantly higher ratio than comparable historical controls, in addition to increasing the likelihood of 1-year and 2-year survival as compared with comparable historical controls," commented Dr. Robert Petit, Chief Medical & Scientific Officer of OS Therapies. "The strong safety profile shown in this study also supports the use of OST-HER2 in this incredibly difficult-to-treat population that has no currently approved therapies."

“The achievement of the primary endpoint in the OST-HER2 phase 2b is a tremendous success that opens the possibility, for the first time, of meaningful therapy for patients suffering from osteosarcoma with lung metastases after resection. This is a leap forward in the development of OST-HER2 and we are pleased that our regulatory strategy is consistent with the FDA’s recent draft guidance update for accelerated approvals. With these positive data in hand, we are preparing to engage with U.S. FDA on an accelerated pathway for approval in this extremely challenging indication,” said Paul Romness, MHP, Chair & CEO of OS Therapies. “We do not expect to have to treat additional patients as part of this process with FDA.”

Phase 2b Clinical Trial Data

Enrollment Criteria:

- 12-39 years old
- Recurred, fully resected lung only metastatic (METS) Osteosarcoma
- 39 evaluable patients at 21 centers, single treatment arm
- 52 Weeks on Study: Dosed 16 times every 3 weeks for 48 weeks with 4-week follow-up final visit

Primary Endpoint of 12-month EFS:

- 33% for OST-HER2 vs. 20% for historical control[1] (p = 0.0158)

Interim Analysis of Ongoing Secondary Endpoint, OS:

- 1-year OS: 91% for OST-HER2 vs. 80% for historical control[2] (p = 0.0700)
- 2-year OS: 61% for OST-HER2 vs. 40% for historical control[2] (p = 0.0576)

Post-Hoc Analyses

12-months EFS Subgroup Analysis in the OST-HER2 Treatment Group:

Gender (Males vs Females), n = 39:

- Females (n=19) = 47%
- Males (n= 20) = 20%
  (p= 0.0604)

Number of lung resections (1 Prior Resection vs. 2+ Prior Resections), n= 39:

- 1 Prior Resection (n= 28) = 25%
- 2+ Prior Resections (n= 11) = 55%
  (p = 0.1366)

12-month EFS Responders using a Non-Concurrent Control Group from the only existing US osteosarcoma database with patients qualified for disease-free status following a fully-resected lung-only metastasis of osteosarcoma origin:

- OST-HER2, n=39
  12-month EFS Responders = 13/39 (33%)

- NCCG, n=9
  12-month EFS Responders = 1/9 (11%)
  (p = 0.1848)

Time to recurrence in patients who did not achieve 12-month EFS:

- OST-HER2, n=26 = 5.9 months
- NCCG, n=8 = 4.7 months
  (p = 0.1454)

About OST-HER2

OST-HER2 is an innovative immunotherapy using a HER2 bioengineered form of the bacteria Listeria monocytogenes (Lm) to trigger a strong immune response against cancer cells expressing HER2. This off-the-shelf immunotherapy treatment is designed to prevent metastasis, delay recurrence, kill primary tumors expressing HER2 alone and potentially in combination with existing approved therapies, and increase overall survival. OST-HER2 has received Rare Pediatric Disease Designation (RPDD) from the FDA and Fast Track and Orphan Drug Designations from the FDA and European Medicines Agency (EMA).

The US FDA granted OST-HER2 rare pediatric disease designation for osteosarcoma in 2021. The US FDA rare pediatric disease PRV program aims to incentivize drug development for rare pediatric diseases. Under this voucher program, a sponsor who receives an approval for a drug or biological product for a rare pediatric disease qualifies for a voucher that can be redeemed to receive priority review for a different product. The sponsor may also transfer or sell the voucher to another sponsor. OS Therapies intends to sell the PRV it would earn upon receiving an approval of OST-HER2 for recurrent, fully resected, lung metastatic osteosarcoma. The most recent publicly disclosed sale price of a PRV was on November 27th, 2024 when PTC Therapeutics announced selling its PRV to Kebilidi for $150M. With emerging scarcity in the PRV market, the Company expects the value of PRVs to increase going forward. The maximum sale price of a PRV was in 2015 when AbbVie bought a priority review voucher from United Therapeutics for $350 million.

The most recent continuing resolution (CR) negotiations in the US House of Representatives failed to reauthorize the PRV program for pediatric cancers such as osteosarcoma. Despite this, as a result of OS Therapies' having been granted OST-HER2's rare pediatric disease designation prior to December 20, 2024 in addition to the Company's aim to receive an approval for OST-HER2 in the rare pediatric disease osteosarcoma in 2025, prior to the September 30, 2026 deadline, OS Therapies remains eligible to receive the PRV upon approval of OST-HER2 in recurrent, resected metastatic osteosarcoma.

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.

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. The Company has completed enrollment for a 41-patient Phase 2b clinical trial of OST-HER2 in resected, recurrent osteosarcoma, with results expected in the fourth quarter of 2024. 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) platform, known as *tunable ADC* (tADC), which features tunable, tailored antibody-linker-payload candidates. This platform leverages the Company's proprietary silicone linker 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 grant of a priority review voucher 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 registration statement on Form S-1 filed with the Securities and Exchange Commission (the "SEC") on November 12, 2024, as amended on November 27, 2024, and other subsequent documents we file with the SEC, including but not limited to our Quarterly Reports on Form 10-Q. 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.

[1] Lagmay JP, Krailo MD, Dang H, et al: Outcome of patients with recurrent osteosarcoma enrolled in seven Phase II trials through Children's Cancer Group, Pediatric Oncology Group, and Children's Oncology Group: learning from the past to move forward. J Clin Oncol. 2016;34:3031-8

[2] A.H. Aljubran, A. Griffin, M. Pintilie, M. Blackstein; Osteosarcoma in adolescents and adults: survival analysis with and without lung metastases; Annals of Oncology; Volume 20, Issue 6; 2009;1136-41

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