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OS Therapies Announces Positive Safety Data from Phase 1 Clinical Trial of OST-HER2 in HER2-Expressing Breast Cancer and in Preclinical Efficacy in Models of Breast Cancer

- *10 of 12 patients treated in HER2 expressing solid tumor Phase 1b trial were breast cancer patients*
- *Dose selected for ongoing Phase 2b clinical trial in Osteosarcoma was shown to be well tolerated in breast cancer patients*
- *Preclinical breast cancer efficacy models showed positive data to prevent breast cancer metastases to the brain, reduce tumor growth by over 90% in combination with HER2-targeted antibodies, and prevent the formation of breast cancer compared with controls*

ROCKVILLE, Md.--(BUSINESS WIRE)-- **OS Therapies, Inc.** (NYSE-A: OSTX), a clinical-stage oncology-focused immunotherapy company developing cancer vaccines and antibody drug conjugate (ADC) therapeutic candidates, today announced positive data from a Phase 1 clinical trial of OST-HER2 in patients with HER2-expressing solid tumors in breast cancer and other cancers. Additionally, the Company announced positive preclinical efficacy data for OST-HER2 in multiple models of breast cancer.

The FDA has granted Rare Pediatric Disease Designation (RPDD), Orphan Drug Designation (ODD), and Fast Track Designation (FTD) for OST-HER2 in Osteosarcoma. OST-HER2, a biologic therapeutic candidate, is a *Lm* (*Listeria monocytogenes*) vector-based off-the-shelf immunotherapeutic vaccine designed to prevent metastasis, delay recurrence, and increase overall survival in patients with osteosarcoma and other solid tumors. The proposed OST-HER2 mechanism of action is based on innate and adaptive immune stimulating responses activated by the *Lm* vector. This treatment generates T cells that can eliminate or slow potential micrometastases that can grow into recurrent osteosarcoma and other solid tumors, including breast cancer. T cell responses home in on HER2 expressed by the tumor and then kill the cell, releasing additional tumor targets. There are currently no approved adjuvant treatments for recurrent osteosarcoma in the United States.

A total of twelve (12) patients with a history of HER2 positive cancer were enrolled in the Phase 1b clinical study, comprised of ten (10) patients with breast cancer, one (1) patient with esophageal cancer and one (1) patient with GE junction cancer. OST-HER2 was determined to be safe and well tolerated in patients with HER2-expressing solid tumors, including at the dose currently being used in the Company's ongoing Phase 2b clinical trial in recurrent, resected osteosarcoma (AOST-2121, NCT04974008). The Company previously announced positive AOST-2121 interim data and is now in active discussions with the US FDA regarding a Breakthrough Therapy (BTD) designation application submitted for OST-

HER2 based on the interim results. The Company is focused on approval for OST-HER2 in osteosarcoma, and thereafter plans to expand development into breast cancer and other HER2 expressing cancers such as esophageal cancer and colorectal cancer.

In addition, the Company announced positive data from multiple preclinical models of breast cancer. The key data for OST-HER2 include:

- 78% reduction in tumor size (3mm for OST-HER2 treated vs. 14mm for control arm) in FVB/N HER2 transgenic mouse model of breast cancer treatment at day 75
- 33% prevention of breast cancer in OST-HER2 treated mice vs. 0% prevention of breast cancer in FVB/N HER2 transgenic model of breast cancer prevention at week 50
- 20% reduction of tumor size for OST-HER2 plus HER2-targeted antibody vs. HER2-targeted antibody alone Tg tumor regression model of breast cancer at day 42
- 65% reduction cellular concentration of metastatic cells for OST-HER2-treated mice compared with controls in brain metastasis model of primary breast cancer

About OS Therapies

OS Therapies, Inc. (NYSE-A: OSTX) is a clinical stage oncology company focused on the identification, development and commercialization of treatments for Osteosarcoma (OS) and other solid tumors. OST-HER2 is an immunotherapy leveraging the immune stimulatory effects of Listeria bacteria to initiate a strong immune response targeting the HER2 protein. The Company has fully-enrolled 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 also completed a Phase 1b clinical trial in other solid tumors and has demonstrated efficacy in multiple preclinical models of breast cancer. OS Therapies is also developing the next generations Antibody Drug Conjugate (ADC) platform *tunable ADC* (tADC) centered around tunable, tailored antibody-linker-payload candidates built around the Company's unique silicone linker technology that allows for multiple payloads to be delivered per linker.

About OST-HER2

The OST-HER2 Lm vector platform technology has been administered to over 450 cancer patients in ongoing and completed clinical trials. AOST-2121 is a Phase IIB clinical trial intended to prevent or delay metastasis and improve Overall Survival (OS) in Osteosarcoma. OST-HER2 has already received Fast-Track, Orphan, and Rare Disease Designation (RDD). OST hopes to seek a Break-Through Designation (BTD) based on data from this Phase IIb clinical trial. OST31-164 has previously received USDA provisional approval for treatment of Osteosarcoma in canines. In a completed Phase III study in canines (n=180), early data demonstrated a clear separation of treated and untreated canine patients (p=.0007) in Overall Survival (OS) and Disease Progression.

For more information, please see the Company's website at www.ostherapies.com

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