June 3, 2024

OS Therapies Announces Positive Clinical Update from Ongoing Phase 2b Clinical Trial in Resected, Recurrent Osteosarcoma

- *1-year Event Free Survival (EFS) of 32.5% vs. 20% 1-year EFS for comparator*
- *Interim 1-year and 18-month Overall Survival (OS) of 90.4%*
- *0 Grade 3, 4 or 5 Treatment-related Adverse Events (AEs)*
- *41 patient trial fully enrolled*
- *Primary endpoint 12-month EFS data and interim co-primary endpoint 12-month OS data to be released in the fourth quarter of 2024*
- *No novel therapeutic interventions for resected, recurrent osteosarcoma in 40+years*

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 a positive clinical update for AOST-2121 (NCT04974008), its ongoing Phase 2b clinical trial of its immunotherapy OST-HER2 (OST31-154) in patients with resected, recurrent 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. The AOST-2121 study is designed to demonstrate efficacy in patients who have already had recurrent disease and are highly likely to recur again. A total of 18 OST-HER2 doses are administered once every three weeks, for a total 51 weeks. Radiographic evaluation of recurrence is evaluated throughout treatment.

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. 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.

AOST-2121 has achieved full enrollment of 41 patients treated with OST-HER2 at 21 clinical trial sites across the United States. A few patients remain in the active treatment stage with the remainder in follow-up for overall survival. The primary endpoints for the AOST-2121 study are Event Free Survival ('EFS', defined as absence of recurrence of primary tumor or metastasis) at 12 months and Overall Survival at 36 months, with interim Overall Survival endpoints at 12 months and 24 months. Topline EFS data, interim 1-year OS data, as well as additional secondary data analyses are expected to be reported in the fourth quarter of 2024. No novel therapeutic interventions have improved the clinical outcomes for patients with resected, recurrent osteosarcoma in over 40 years.

The clinical updates reported today include:

- 1-year EFS rate of 32.5% vs. 20% EFS rate for unsuccessful investigational therapeutic comparator[1]
- 1-year overall survival rate of 90.4%
- 18-month overall survival rate of 90.4%
- Treatment has been well tolerated and there have been no grade 3, 4 or 5 treatment-related adverse events reported for the 41 patients.

“OST-HER2’s strong safety profile supports its potential to become a practical adjuvant therapy to delay or prevent subsequent recurrences and improve overall survival in the very difficult challenge of recurrent osteosarcoma. Promoting innate and adaptive immune surveillance against lurking micrometastases could become a potentially powerful tool for oncologists as they seek to improve the quality of life and prolong survival of patients who have suffered from Osteosarcoma,” said Dr. Robert Petit, Chief Medical & Scientific Officer of OS Therapies. “OST-HER2 has the potential to significantly improve the standard of care in this difficult to treat patient population. In light of today’s encouraging clinical trial update, we are hopeful that final data coming in the fourth quarter of this year, combined with supplemental data that will follow in 2025, positions OST-HER2 to become available to help clinicians better protect people with difficult cancers like osteosarcoma.”

“With historical 1-year EFS estimated in the low-to-mid teens with the current standard of care, and the most recent investigational therapeutic comparator yielding 1-year EFS of 20%, we believe that the 32.5% EFS data observed to date in this trial compares favorably and positions OS Therapies to deliver final Phase 2b co-primary endpoint data by the end of 2024,” said Paul Romness, President & CEO of OS Therapies. “With OST-HER2’s strong safety profile and consistent overall survival at the 1-year and 18 month timepoints, and given the dearth of therapeutic options for the resected, recurrent osteosarcoma patient population, we are hopeful that OS Therapies will be gain approval for the first new osteosarcoma treatment, a novel immunotherapy, in over 40 years.”

The FDA has granted Rare Pediatric Disease Designation (RPDD), Orphan Drug Designation (ODD), and Fast Track Designation (FTD) for OST-HER2 in Osteosarcoma.

References

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.

About Osteosarcoma

Osteosarcoma is a solid tumor of the bone that predominantly occurs in adolescents and young adults (AYA). Standard treatment includes surgery and chemotherapy. For patients with metastatic osteosarcoma or have recurrence after chemotherapy, the prognosis is poor.

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. 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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