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OS Therapies Announces Osteosarcoma Scientific and Medical Advisory Board

ROCKVILLE, MD / ACCESSWIRE / August 6, 2024 /[OS Therapies](#) (NYSE American:OSTX) ("OS Therapies" or "the Company"), an Antibody Drug Conjugate (ADC) and Immunotherapy research and clinical-stage biopharmaceutical company, highlights its Scientific and Medical Advisory Board (SMAB), comprised of experts in osteosarcoma from six institutions in the United States.

The following physicians have agreed to serve on the OS Therapies SMAB:

- Nabil M. Ahmed, MD - Texas Children's Hospital
- Peter M. Anderson, MD - Cleveland Clinic
- Doug S. Hawkins, MD - Seattle Children's Hospital
- Meenakshi Hedge, MD - Texas Children's Hospital
- Alejandro Sweet-Cordero, MD - University of California, San Francisco
- Brenda Weigel, MD - Masonic Cancer Center, University of Minnesota
- Felasfa M. Wodajo, MD - Inova Fairfax Hospital, Virginia

The SMAB will assist the Company in engaging with the US Food & Drug Administration (FDA) regarding the safety and efficacy of its lead immunotherapy product candidate, OST-HER2, for the treatment of osteosarcoma. This includes evaluating how OST-HER2 compares with the current standard of care in osteosarcoma, particularly in relation to a potential Biologics License Authorization (BLA) following the completion of the ongoing clinical trial for 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, and increase overall survival. The Company has fully enrolled a potentially pivotal Phase IIb clinical trial in recurrent, resected osteosarcoma, dosing 41 patients with OST-HER2 at 21 clinical trial sites across the United States. Positive interim data was reported in June 2024 with topline data expected in the fourth quarter of 2024.

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).

OS Therapies is seeking Breakthrough Therapy Designation for OST-HER2 for

osteosarcoma from the FDA based on data from its Phase IIb clinical trial. Upon any BLA from the FDA for OST-HER2 in osteosarcoma, the Company will be granted a Priority Review Voucher based upon the RPDD. In 2023, the US FDA approved 28 drugs and 12 biologics for the treatment of orphan diseases.

OST-HER2 has completed a Phase 1 clinical trial, primarily in breast cancer patients, in addition to strong preclinical data demonstrating efficacy on a standalone basis and in combination with HER2-targeting therapeutic antibodies such as Herceptin®. The Company intends to pursue therapeutic development of OST-HER2 in breast cancer following FDA approval for OST-HER2 in osteosarcoma.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy any securities.

About Osteosarcoma

Osteosarcoma is a solid tumor of the bone that predominantly occurs in children and young adults. It is an extremely challenging and often aggressive cancer that has particular treatment challenges due to its location, changing genotypes and high recurrence rates. Standard treatment includes surgery and chemotherapy. For patients with metastatic or recurrence after chemotherapy, there is a significantly poorer prognosis.

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 strong preclinical efficacy data in various models of breast cancer. 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. OS Therapies' drug development efforts, clinical trial results, patient enrollments, FDA regulatory approvals, designations, and intellectual property protections. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, including those described under the caption "Risk Factors" and elsewhere in

the prospectus filed with the SEC relating to the offering and that actual results may differ materially from those indicated by such forward-looking statements. 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.

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