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OS Therapies Forms Osteosarcoma Patient Advocacy Advisory Board

ROCKVILLE, Md. & NEW YORK--(BUSINESS WIRE)-- [OS Therapies Incorporated](#) ("OS Therapies" or the "Company") (NYSE-A: OSTX), a Cancer Immunotherapy and Antibody Drug Conjugate (ADC) biopharmaceutical company, today announced the formation of a Patient Advocacy Advisory Board (PAAB) for its osteosarcoma program. The purpose of the PAAB is to represent voices from the osteosarcoma community regarding the need for new therapies as the Company prepares to engage in discussions with the US Food & Drug Administration (FDA). In particular, regarding a potential Biologics License Authorization (BLA) for OST-HER2 for the treatment of osteosarcoma following the completion of the ongoing clinical trial for OST-HER2 - the Company's immunotherapeutic product candidate.

Members of the PAAB include:

- Miriam Cohen – Chair of Osteosarcoma Collaborative
- Mac Tichenor – Chair of Osteosarcoma Institute
- Tony Trent – Chair of Tyler Trent Foundation
- Olivia Egge – Osteosarcoma Patient, OSTX Board
- Serena Subada – Osteosarcoma Patient, AOST-2121 OST-HER2 Trial Participant

Members of the PAAB will not receive financial compensation from OS Therapies. Members expect to meet on a quarterly basis to review information with regards to progress in the OS Therapies' osteosarcoma clinical program, and the meetings will be chaired by the Company's CEO.

OS Therapies' lead product candidate, 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 in the offering, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

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. Those statements include statements regarding the offer and sale of shares, the timing of the listing of OS Therapies' common stock on the NYSE American, the timing of the closing of the offering, the use of the proceeds from the sale of shares of common stock in the offering, and 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. 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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