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# OS Therapies Receives Patent Notice of Allowance from U.S. Patent & Trademark Office Covering Commercial Manufacturing of OST-HER2

- *Patent Term Adjustment will provide market exclusivity in the United States into 2040 for all therapeutic indications*

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 that it received a Notice of Allowance from the United States Patent & Trademark Office (USPTO) that a patent will be issued covering the manufacturing methods required for the OST-HER2 commercial product. The USPTO granted a Patent Term Adjustment of 572 days, providing market exclusivity for the OST-HER2 commercial drug product into 2040. OS Therapies is preparing to initiate discussions with the United States Food & Drug Administration (FDA) following the successful treatment phase of its Phase 2b clinical trial in the prevention of recurrent, resected, lung metastatic osteosarcoma with a view towards submitting a Biologics Licensing Application (BLA) and gaining conditional or accelerated FDA approval in 2025. The Company recently completed a $7.1 million financing in January 2025 and has sufficient capital into mid-2026.

OST-HER2 has already received rare pediatric disease (RPDD), fast-track (FTD) and orphan drug (ODD) designations from the US FDA for osteosarcoma. The Company intends to (1) focus on gaining FDA BLA approval for OST-HER2 in osteosarcoma in late 2025, (2) sell the Priority Review Voucher (PRV) it would receive from the FDA BLA approval prior to the September 30, 2026 PRV deadline to a larger pharmaceutical company at prevailing market prices (most recent PRV sale transaction was $150 million), (3) commercialize OST-HER2 in osteosarcoma and (4) then expand the clinical development of OST-HER2 into breast cancer and other larger solid tumor indications for additional revenue potential.

OST-HER2 has successfully completed a Phase 1 trial in adult patients with HER2 overexpressing cancers, primarily breast cancer patients. Preclinical breast cancer results with OST-HER2 showed:

- 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

The osteosarcoma treatment market was estimated at $1.2 billion in 2022 according to Data Bridge Market Research. The Company believes the market opportunity for OST-HER2 in the prevention of lung metastases in osteosarcoma is over $500 million. The breast cancer treatment market was estimated at $29.2 billion in 2023 and expected to grow to $53.7 billion by 2030 according to Grandview Research. The Company believes the market opportunity for OST-HER2 in the treatment of breast cancer exceeds $1 billion.

**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. OST-HER2 has received rare pediatric disease, fast-track and orphan drug designations from the US FDA. The Company has completed enrollment for a 41-patient Phase 2b clinical trial of OST-HER2 in recurrent, fully resected, lung metastatic osteosarcoma, with positive results released in the first quarter of 2025. The Company anticipates submitting a Biologics Licensing Application (BLA) to the US FDA for OST-HER2 in osteosarcoma in 2025 and, if approved, would become eligible to receive a Priority Review Voucher that it could then sell. 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.

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