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OS Therapies Receives Positive Feedback from UK MHRA Scientific Advice Meeting and Submits Innovative Licensing and Access Pathway (ILAP) Request for OST-HER2 in the Prevention or Delay of Recurrent, Fully Resected, Pulmonary Metastatic Osteosarcoma

- *MHRA seeks to harmonize UK & US regulatory review via Project Orbis*
- *EMA Rapporteur Scientific Advice Meeting scheduled for October 2025*

New York, New York--(Newsfile Corp. - August 7, 2025) - OS Therapies (NYSE American: OSTX) ("OS Therapies" or "the Company"), a clinical-stage immunotherapy and Antibody Drug Conjugate (ADC) biopharmaceutical company, today announced that it held a successful Scientific Advice Meeting with the United Kingdom's (UK) Medicines and Healthcare products Regulatory Agency (MHRA) in July and has submitted an invited Innovative Licensing and Access Pathway (ILAP) application to begin the regulatory process towards approval of OST-HER2 in the prevention or delay of recurrent, fully resected, pulmonary metastatic osteosarcoma. MHRA suggested applying for Project Orbis at the time of regulatory approval submission to synchronize its Marketing Authorization Application process with the United States Food & Drug Administration's (FDA) Biologics Licensing Application (BLA) Accelerated Approval Program. In addition, a European Medicines Agency rapporteur, the Netherlands Medicines Evaluation Board (MEB) granted the Company a SAM meeting to begin the requisite processes towards a European Union-wide Marketing Authorisation via the Centralised Procedure.

"We are pleased with the outcome of our meeting with MHRA in the UK and are working to ensure that we provide FDA and MHRA everything they need to be able to rapidly approve OST-HER2 for metastatic osteosarcoma patients," said Paul Romness, MPH, CEO of OS Therapies. "We have officially begun the regulatory process in Europe as the next part of our regulatory strategy to bring this novel immunotherapy to osteosarcoma patients worldwide."

Project Orbis is an innovative global initiative designed to facilitate international collaboration in the field of oncology. Launched by the U.S. Food and Drug Administration (FDA), this program seeks to streamline the process of drug approval for cancer treatments by partnering with regulatory agencies from other countries. The goal of Project Orbis is to provide patients with faster access to promising therapies through simultaneous submission and review of oncology products across multiple nations. By sharing critical insights and harmonizing standards, participating countries aim to enhance the development of effective cancer treatments and improve patient outcomes worldwide.

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 Designation (RPDD) from the U.S. Food & Drug Administration and Fast-Track and Orphan Drug designations from the U.S. FDA and European Medicines Agency. The Company reported positive data in its Phase 2b clinical trial of OST-HER2 in recurrent, fully resected, lung metastatic osteosarcoma, demonstrating statistically significant benefit in the 12-month event free survival (EFS) primary endpoint of the study. The Company anticipates submitting a Biologics Licensing Application (BLA) to the U.S. 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) and Drug Conjugates (DC), known as *tunable ADC* (tADC), which features tunable, tailored antibody-linker-payload candidates. This platform leverages the Company's proprietary silicone Si-Linker and Conditionally Active Payload (CAP) 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. This information concerns product candidates that are under clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA). These product candidates are currently limited by Federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated. 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 FDA and other risks and uncertainties described under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K and other subsequent documents the Company files with the Securities and Exchange Commission. 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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