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OS Therapies Accepts New FDA Meeting Request to Review Biomarker Data as Part of BEST Program

CDER meeting expected to take place in the summer of 2026 in parallel with CBER's Type B Statistical Methods Meeting

New York, New York and Rockville, Maryland--(Newsfile Corp. - July 8, 2026) - **OS Therapies, Inc. (NYSE American: OSTX) ("OS Therapies" or "the Company")**, the world leader in gene-edited, Listeria-based cancer immunotherapies, today announced that it has accepted a new Meeting Request from the U.S. Food and Drug Administration (FDA)'s Center for Drug Evaluation and Research (CDER) to review the Company's pharmacodynamic response biomarker data (the "OST-HER2 Biomarker Data") – patent pending. CDER's Biomarkers, EndpointS, and other Tools (BEST) resources is part of its Biomarker Qualification Program (BQP). This meeting is in addition to the forthcoming Type B Statistical Methods Meeting being scheduled with FDA's Center for Biologics Evaluation and Research (CBER) to review the 2.5-year overall survival data alongside the OST-HER2 Biomarker data developed from the Company's clinical development program for OST-HER2 in the prevention of delay of recurrence in fully resected, pulmonary metastatic osteosarcoma. CBER is the regulatory agency that will make the regulatory approval decision on OST-HER2.

Alignment between CBER and CDER on the use of the OST-HER2 Biomarker Data is an important step in preparation for formal evaluation of the pending final 3-year overall survival data that will be included in the Company's Biologics License Application (BLA) submission under the Accelerated Approval Program expected in early Fall 2026. CBER has invited the Company to a Type B Pre-BLA meeting following the Company's January 2026 submission of the Non-Clinical and Chemistry, Manufacturing and Controls (CMC) BLA modules in the first quarter of 2026. The Company announced final 2-year overall survival data on October 10, 2025. The Company expects to announce interim 3-year overall survival data in the summer of 2026.

OST-HER2 has received Orphan Drug Designation (ODD), Fast Track Designation (FTD) and Rare Pediatric Disease Designation (RPDD) from the FDA, and ODD, FTD and ATMP from the EMA and MHRA. Under the RPDD FDA program, if the Company receives a BLA in the United States, it will become eligible to receive a Priority Review Voucher (PRV) that it intends to sell. The Company's Commissioner's National Priority Review Voucher (CNPV) letter of intent was accepted by FDA, with a final decision expected following full submission of the OST-HER2 BLA. The Company is seeking to obtain a BLA under the Accelerated Approval Program for OST-HER2 in osteosarcoma by year-end 2026 in the U.S., in addition to Conditional Marketing Authorisation Applications in Europe, the U.K. and Australia.

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. The Company is the world leader in gene-edited, Listeria-based cancer immunotherapies. 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 is designed to target two mutated extracellular epitopes and one mutated intracellular epitope of the HER2 oncogene, requiring only one of these three epitopes to be present in a tumor (or micro-metastasis) to trigger the desired immune response. OST-HER2 has received Orphan Drug Designation (ODD), Fast Track Designation (FTD) and Rare Pediatric Disease Designation (RPDD) from the U.S. Food & Drug Administration and has received ODD, FTD and Advanced Therapy Medicinal Products (ATMP) from the European Medicines Agency.

The Company reported positive data in its Phase 2b clinical trial of OST-HER2 in the prevention or delay of recurrence in fully resected, pulmonary metastatic osteosarcoma, demonstrating clinically significant benefit in the 12-month event free survival (EFS) primary endpoint of the study and the overall survival (OS) secondary endpoint. The Company is seeking a Biologics License Application (BLA) from the U.S. FDA for OST-HER2 in osteosarcoma in 2026 and, if approved, would become eligible to receive a Priority Review Voucher that it could then sell. The Company also anticipates receiving Conditional Marketing Authorisation Applications from the U.K.'s Medicines and Healthcare products Regulatory Agency and the EMA for OST-HER2 in 2026. 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 previously been conditionally approved by the U.S. Department of Agriculture for the treatment of canines with osteosarcoma. The Company has also completed dosing in a Phase 1 study of OST-504 for castration-resistant prostate cancer.

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. OS Therapies cautions readers that forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to certain risks and uncertainties that could cause actual results to differ materially, including, but not limited to the potential approval of OST-HER2 by the U.S. FDA and other risks and uncertainties described in "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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