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OS Animal Health Receives USDA Feedback on Regulatory Pathway for OST-HER2 in Canine Osteosarcoma

- *Received notice for upcoming USDA meeting*
- *Company is reviewing strategic alternatives to monetize OS Animal Health ("OSAH")*

Grasonville, Maryland--(Newsfile Corp. - October 7, 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 its wholly-owned animal health subsidiary, OSAH received feedback from the U.S. Department of Agriculture (USDA) related to its submission to gain alignment on the commercial development pathway for OST-HER2 in the treatment of canine osteosarcoma. USDA provided guidance related to the OSAH's upcoming conditional licensure request in the areas of clinical efficacy, clinical safety, non-clinical and Chemistry, Manufacturing and Controls (CMC) as a prelude to commercialization.

OSAH intends to seek conditional licensure based upon clinical efficacy data it has already generated in various osteosarcoma disease settings, including prevention of metastasis, metastatic disease control and prevention of amputation in frontline osteosarcoma. OSAH expects to have to run additional clinical studies to ultimately gain full licensure from USDA.

"We are pleased that we have been able to open a dialogue with USDA in getting OST-HER2 commercially launched for canine osteosarcoma. Now that OS Therapies has made significant progress in the Herlystic^{TM} commercial manufacturing process for human osteosarcoma, OSAH will leverage those results for the animal commercial manufacturing process," said Edward Robb, DVM, Strategic Advisor for OS Animal Health. "We are hopeful to get this product commercially launched in 2027 for dogs in the United States."

Frank Knuettel II, Chief Financial Officer of OS Therapies, noted, "With the progress we have made at both OS Therapies and OSAH, we are now in a position to evaluate strategic and/or direct capital alternatives for OSAH, directly benefiting OS Therapies shareholders. Canine osteosarcoma is one of the leading causes of death in large breed canines and we believe there is substantial value in our gene-edited, cancer immunotherapy platform for companion animal health. OST-HER2 has the potential to be the first HER2-targeted therapy in companion animal cancer treatment."

The veterinary oncology market is expected to grow from $1.58 billion in 2024 to $4.77 billion in 2034 according to Towards Healthcare, driven primarily by the North American market due to its advanced veterinary infrastructure and high expenditure on pet healthcare. OS Animal Health plans to initiate a crowdfunding in the fourth quarter of 2026 to expand its shareholder base in order to meet the initial listing standards for a U.S. national stock exchange. Indications of interest from potential investors in the proposed crowdfunding are being received at: https://www.mrcrowd.com/ttw/osah.

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About OS Animal Health

OS Animal Health, Inc. ("OSAH") is a wholly-owned subsidiary of OS Therapies, Inc. (NYSE American: OSTX). OSAH develops cancer immunotherapies for companion animals based on OS Therapies' gene-edited, Listeria-based immunotherapy platform. Its lead candidate, OST-HER2, is being developed to treat osteosarcoma in dogs, and it was previously granted a conditional license by the U.S. Department of Agriculture's Center for Veterinary Biologics for that use. OSAH is seeking a new conditional license for OST-HER2 based on existing data, to be followed by additional studies intended to support a full license. OSAH's manufacturing draws on the commercial-scale work OS Therapies has done for the human version of OST-HER2.

About OS Therapies

OS Therapies is a clinical stage oncology company focused on the identification, development, and commercialization of treatments for Osteosarcoma 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 intends to submit a Biologics License Application (BLA) request to 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 requesting Conditional

Marketing Authorisation Applications from the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) the European Medicines Agency (EMA) and the Australian Therapeutic Goods Administration (TGA) for OST-HER2 in the fourth of 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 was previously 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 silicon 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 regarding future expectations, plans, prospects or performance, as well as any other statements that are not historical facts, may constitute forward-looking statements within the meaning of the federal securities laws. Forward-looking statements are generally identified by words such as "anticipate," "believe," "could," "expect," "intend," "may," "plan," "potential," "should," "will" and similar expressions, although not all forward-looking statements contain these words. These statements are based on the current expectations and assumptions of OS Therapies and its management and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, the Company's; the timing and outcome of regulatory submissions and potential approval of OST-HER2 by the U.S. Food and Drug Administration and applicable foreign regulatory authorities; and other risks and uncertainties described under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K and in its other filings with the Securities and Exchange Commission. The forward-looking statements contained in this press release speak only as of the date of this press release, and OS Therapies undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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