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OS Therapies Appoints Kerry Clem as Chief Commercial Officer and Frank Knuettel II as Chief Financial Officer

Experienced biotech leaders to focus on preparations for U.S., U.K., and European commercial launch of the Company's lead product candidate Herlystic™(OST-HER2; daznelimgene lisbac)

Grasonville, Maryland--(Newsfile Corp. - October 1, 2026) -**OS Therapies, Inc. (NYSE American: OSTX) ("OS Therapies" or the "Company")**, the world leader in gene-edited, Listeria-based cancer immunotherapies, today announced the appointment of Kerry Clem as Chief Commercial Officer (CCO) and Frank Knuettel II as Chief Financial Officer (CFO).

Mr. Clem now leads the Company's U.S., U.K., and European commercialization strategy and launch planning for Herlystic™ (OST-HER2; daznelimgene lisbac), the Company's investigational immunotherapy for the prevention or delay of recurrence in patients with fully resected, pulmonary metastatic osteosarcoma. His responsibilities will include developing the commercial organization and launch infrastructure, assessing patient and treatment-center needs, and preparing for potential U.S. market entry, subject to regulatory approval.

Upon regulatory approval in each of the U.S., U.K., and Europe, the Company will launch Herlystic initially in the United States. The Company anticipates that the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) may be the first regulator to reach a regulatory decision, ahead of the U.S. Food & Drug Administration (FDA) and the European Medicines Agency (EMA). OS Therapies is pursuing MHRA Conditional Marketing Authorization Application (CMAA) under Project Orbis via its Innovative Licensing and Access Pathway (ILAP), with a submission targeted for early in fourth quarter of 2026. The Company has described plans to pursue a U.S. Biologics License Application (BLA) under the Accelerated Approval pathway and a CMAA in Europe in parallel. The timing and outcome of each review remain subject to regulatory review and other conditions.

Mr. Clem has extensive experience in commercial leadership and product launches within biotechnology and specialty therapeutics. His previous roles include serving as CEO of Solaxa, CCO at Acorda Therapeutics, and holding commercial leadership positions at Allos Therapeutics, Solstice Neurosciences, and Guilford Pharmaceuticals

"I'm excited to join OS Therapies at an important point in the development of Herlystic. My near-term focus will be building a disciplined, patient-centered launch plan and the commercial capabilities in the U.S. when the FDA approves the therapy, while the Company advances its regulatory work internationally," said Mr. Clem.

Mr. Knuettel brings more than two decades of executive leadership experience across dynamic, early-stage public companies in the technology and life sciences sectors. He recently served as the CFO of Pelthos Therapeutics following its merger with Channel

Therapeutics Corporation, where he was the CEO. Known for his operational discipline and M&A acumen, Mr. Knuettel has helped companies scale aggressively deep capital markets knowledge, a proven ability to lead and scale businesses, and transactional experience across more than 15 M&A deals. Throughout his career, Mr. Knuettel has raised over $500 million in public and private capital and has held leadership roles at multiple high-growth companies. Mr. Knuettel holds a B.A. with honors in Economics from Tufts University and earned his MBA in Finance and Entrepreneurial Management from The Wharton School at the University of Pennsylvania.

"I am excited to help OS Therapies transition from a development-stage biotechnology company into a commercial organization with significant growth potential through the full exploitation of its gene-edited, Listeria-based cancer immunotherapies," said Mr. Knuettel.

"Kerry's appointment reflects our commitment to preparing for the U.S. opportunity for Herlystic. While our current regulatory sequence may bring the U.K. review first, our commercial planning is focused on building the capabilities needed to serve patients and providers in the United States, should the product be approved," said Paul Romness, MPH, Chairman and CEO of OS Therapies. "Frank's expertise in helping to manage finance and accounting operations and corporate governances gives the Board of Directors confidence that we have the right financial stewardship to help guide the Company's growth and revenue generations towards profitability."

The appointments of Clem and Knuettel are made concurrent with the Company's completed implementation of its U.K. subsidiary's (OS Therapies UK Limited, "OSTUK") research and development refundable tax credit strategy. As part of that, the Company has received over $3 million in non-dilutive capital to date from Value Added Tax (VAT) refunds, with additional VAT refunds pending, and has accrued over $7 million in R&D Tax Credits that will begin to flow back into OSTUK. The funds flowing back into the Company are earmarked to be spent on additional research and development activities, primarily centered on commercial manufacturing and confirmatory Phase 3 clinical development expenses for Herlystic. Under the R&D Tax Credits program, a portion of the R&D expenses become eligible to be reimbursed to OSTUK (the "Evergreen Reimbursement") that will allow for additional reimbursement from those additional research and development expenses. In parallel, the Company disclosed that it has come to agreement with its largest vendors delaying the due date of the majority of its outstanding AP until the second quarter of 2027. Mr. Knuettel anticipates that this delay in AP due dates provides the Company with sufficient time to align the Company's cash flow needs with its anticipated cash inflows.

OST-HER2 has received Orphan Drug Designation (ODD), Fast Track Designation (FTD), and Rare Pediatric Disease Designation (RPDD) from the FDA. OST-HER2 has received ODD, FTD, and ATMP from the EMA. OST-HER2 has received ODD and ATMP from MHRA, who also recruited the Company into Project Orbis. Under the RPDD program, if the Company is granted a BLA in the United States, it will become eligible to receive a Priority Review Voucher (PRV) that it intends to sell. A recent PRV sale occurred in August 2026 for $220 million. However, there can be no assurance that the Company would realize a comparable value, if any, in connection with any future PRV sale. OS Therapies has completed resubmission of a Regenerative Medicine Advanced Therapy (RMAT) request and the Company's Commissioner's National Priority Review Voucher (CNPV) letter of intent has been accepted by FDA. OS Therapies is seeking a Conditional Marketing Authorization

Application from MHRA in the U.K. under Project Orbis for OST-HER2 in metastatic osteosarcoma in the fourth quarter of 2026, and immediately thereafter is seeking to obtain a BLA under the Accelerated Approval Program in the U.S., followed by CMAAs in Europe 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 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 expectations regarding its cash runway; the timing, amount, and receipt of VAT refunds and R&D tax credits; the Company's ability to obtain additional financing on acceptable terms or at all; 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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