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OS Therapies Completes Acquisition of Advaxis Immunotherapies Clinical, Pre-clinical and IP Assets from Ayala Pharmaceuticals

- *Company now listeria-based cancer immunotherapy world leader*
- *Expands clinical pipeline with 3 new cancer immunotherapy candidates*
- *8 pre-clinical immunotherapy candidates targeting 30+ cancers added*

NEW YORK--(BUSINESS WIRE)-- OS Therapies (NYSE-A: OSTX) ("OS Therapies" or "the Company"), a clinical-stage immunotherapy and Antibody Drug Conjugate (ADC) biopharmaceutical company, today announced that it has completed the acquisition of the listeria-based cancer immunotherapy assets of Advaxis Immunotherapies from Ayala Pharmaceuticals. The Company is now positioned as the world leader in listeria-based cancer immunotherapies, poised to become a new commercial category of immunotherapy in oncology upon approval of the Company's lead asset OST-HER2 in the prevention of recurrence in fully-resected, lung metastatic osteosarcoma targeted for year-end 2025. New manufacturing-based intellectual property protects the listeria-based immunotherapy platform and cancer immunotherapy candidates into 2040.

"We are thrilled to have now consolidated all of the intellectual property for the listeria cancer immunotherapy platform into OS Therapies, positioning us to fully expand it in the years ahead and improve the standard of care across cancer treatment in the years ahead," said Paul Romness, CEO of OS Therapies. "We now have late-stage, mid-stage and early-stage cancer immunotherapy candidates, a rich pipeline of preclinical cancer immunotherapy candidates and a long IP runway to in order to fully leverage this powerful cancer immunotherapy platform."

A video explaining how the listeria platform works is available here.

Clinical-stage Cancer Immunotherapy Programs Acquired

1. OST-AXAL (previously AXAL/ADXS/HPV) for Human Papilloma Virus (HPV) associated cancers completed 1st (AIM2CERV) of 2 Phase 3 trials;
2. OST-503 (previously ADXS-503) for Non-Small Cell Lung Cancer (NSCLC) & Glioblastoma reported positive Phase 2 data in NSCLC;
3. OST-PSA (previously ADXS-504/ADXS31142) for Prostate Cancer.

Pre-clinical Cancer Immunotherapy Programs Acquired

8 un-named OST-HOT Listeria constructs designed for off-the shelf treatment of common cancers with shared hotspot mutations and cancer-testes antigen targets.

“The listeria cancer immunotherapy platform holds tremendous potential to improve the outcomes for cancer patients worldwide” said Dr. Robert Petit, Chief Medical & Scientific Officer of OS Therapies. “Immune-checkpoint inhibitors have revolutionized cancer treatment in settings where tumor antigens have generated a sufficient T cell response. However, in many cancers these treatments don’t help because T cell responses against key tumor antigens have not developed. The OST Listeria platform specifically delivers relevant cancer targets directly to the immune system and generates new T cell responses that can be used to fight these cancers and help eliminate metastases. With OST-HER2 and the rest of the listeria platform, we have the potential to generate novel, more potent immune and targeted immune responses against solid tumors, metastatic disease and micro metastases from early-stage to late-stage cancers. I am thrilled to be able to guide the OST-HER2 asset through approval in osteosarcoma, and then fully explore that listeria platform’s potential to improve treatment outcomes for cancer patients.”

The global cancer immunotherapy market size was valued at $126 billion in 2023 and is projected to surpass around $296 billion by 2033, according to Nova One Advisor.

About OS Therapies

OS Therapies is a clinical stage oncology company focused on the identification, development, and commercialization of new class immunotherapy candidates for solid tumors, beginning with osteosarcoma. OST-HER2, the Company's lead asset, is the first in a new class of immunotherapy leveraging the immune-stimulatory effects of *Listeria* monocytogenes to initiate a strong immune response targeting to specific cancer antigens. The Company’s lead asset OST-HER2 has received Rare Pediatric Disease Designation (RPDD) from the US Food & Drug Administration. OST-HER2 demonstrated positive data in a Phase 2b clinical trial of OST-HER2 in recurrent, fully resected, lung metastatic osteosarcoma and intends to submit a BLA Accelerated Approval request to the US FDA in the third quarter of 2025. Upon approval, the Company will become eligible to receive a Priority Review Voucher, currently valued at $150 million. OST-HER2 has completed a preclinical and clinical Phase 1 clinical study primarily in breast cancer patients. An animal OST-HER2 product candidate is indicated for the treatment of canine osteosarcoma and previously received conditional approval by the U.S. Department of Agriculture for the treatment of canine 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 through its wholly-owned subsidiary OS Drug 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 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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