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FDA Transfers Investigational New Drug (IND) Application OST-HER2 (Listeria monocytogenes) to OS Therapies in Record Time - Phase IIb Trial in Osteosarcoma in Early 2021

CAMBRIDGE, Md., Oct. 15, 2020 /PRNewswire/ --**OS Therapies,** a clinical-stage biopharmaceutical company focused on discovering and developing innovative therapies to treat and cure Osteosarcoma (OS) and other deadly cancers in children and adults, today announced that they have initiated their sponsorship of the FDA Investigational New Drug (IND) application for OST-HER2 a live, attenuated *Listeria monocytogenes* vector, expressing a tLLO-chimeric HER2 fusion protein. This sets the pathway for initiation of the first clinical trial in Osteosarcoma patients in partnership with the Children's Oncology Group (COG) – AOST-2121: An Open-Label Phase 2 Study of Maintenance Therapy with OST-HER2 (OST31-164) After Resection of Recurrent Osteosarcoma - in early 2021.

A veterinary formulation of OST-HER2 had previously received accelerated approval from the USDA for Osteosarcoma in canines, and Phase I and III trials conducted in canines have had positive clinical benefit with manageable safety. The AOST-2121 clinical trial sponsored by OS Therapies and in coordination with COG will be the first trial in Adolescents and Young Adults (AYA) with Osteosarcoma, a deadly and debilitating bone cancer.

"OST-HER2 holds the promise of stimulating the patient's immune system to seek out and combat hidden micro-metastases that can cause the osteosarcoma to recur," said Dr. Robert Petit, Chief Medical & Scientific Officer for OS Therapies. "In the Canine version of osteosarcoma, this form of treatment significantly delayed or prevented further osteosarcoma metastases and improved overall survival by three-fold. This clinical trial of OST-HER2 is an essential step towards bringing this potential clinical benefit to the children and young adults who are battling osteosarcoma."

About OS Therapies
OS Therapies Inc. (OST) is a clinical stage therapeutic company focused on the identification, development and commercialization of treatments for Osteosarcoma (OS) and other deadly cancers in children and adults.

For more information, please see the Company's website atwww.ostherapies.com
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