OS Therapies Announces Dosing of First Patient in a Phase IIb Trial of OST-HER2 (Listeria monocytogenes) in Recurred, Resected Osteosarcoma

Nationwide Enrollment to Occur in Next 6-9 Weeks with study outcome potentially leading to a New Drug Application (NDA) filing with the FDA

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OS Therapies →
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CAMBRIDGE, Md., Oct. 22, 2021 /PRNewswire/ -- **OS Therapies**, a research and clinical-stage biopharmaceutical company announced today the dosing of the "First Patient In" for its lead OST-HER2 (OST31-164) program in a potentially pivotal Phase IIb clinical trial. OST-HER2 has already received Fast-Track and Orphan Designation from the EMA and FDA. The nationwide open-label trial will enroll 39 to 45 Osteosarcoma patients whose cancer has metastasized to the lungs and has been surgically resected.

OST-HER2 is targeting Osteosarcoma in children and young adults, and potentially other solid tumors. It is a *L*m vector-based off-the-shelf Immunotherapy intended to prevent metastasis, delay recurrence, and increase overall survival. "The OST-HER2 treatment has been highly successful in multiple trials in canine osteosarcoma, demonstrating 3x improvement in Overall Survival and Disease Progression, with significant similarities between human and canine Osteosarcoma. We hope to demonstrate that it works as well - or even better - in kids," said Dr. Robert Petit, CMO/CSO of OS Therapies.

The clinical trial is being conducted across 20 Children's Oncology Group (COG) affiliated institutions, starting at Seattle Children's Hospital. "The Osteosarcoma Community and Clinicians have a great deal of Institutional Enthusiasm regarding the OST-HER2 trial," said COG

Group Chair Dr. Douglas S. Hawkins, Professor of Pediatrics, Seattle Children's Hospital and University of Washington. "It is our intent to enroll this trial as quickly and safely as possible to see if the results are as good as we have anticipated. This is potentially a very important new treatment option in Osteosarcoma."

"We are all very excited to get this trial started – the technology has shown great promise in Osteosarcoma," said Principle Investigator Dr. Damon Reed, Moffitt Cancer Center. "It is our goal to get the other sites up and enrolling the remaining patients over the next few weeks."

About Osteosarcoma

Osteosarcoma is a solid tumor of the bone that predominantly occurs in adolescent and young adults (AYA). Standard treatment includes surgery and chemotherapy. For patients with initially metastatic or recurrence after chemotherapy, there is a significantly poorer prognosis.

About OS Therapies

OS Therapies Inc. (OST) is a research and clinical-stage therapeutic company focused on the identification, development and commercialization of treatments for Osteosarcoma (OS) and other deadly cancers in kids and adults. OS Therapies has two platform technologies being developed for therapies to treat and cure Osteosarcoma (OS) and other solid tumors including ovarian, esophageal, endometrial and lung cancers.

About The Children's Oncology Group (COG)

COG (childrensoncologygroup.org), a member of the NCI National Clinical Trials Network (NCTN), is the world's largest organization devoted exclusively to childhood and adolescent cancer research. COG unites over 10,000 experts in childhood cancer at more than 200 leading children's hospitals, universities, and cancer centers across North America, Australia, and New Zealand in the fight against childhood cancer. Today, 90% of the 16,000 children and adolescents diagnosed with cancer each year in the United States are cared for at COG member institutions. Research performed by COG institutions over the past 50 years has transformed childhood cancer from a virtually incurable disease to one with a combined 5-year survival rate of 80%. COG's mission is to improve the cure rate and outcomes for all children with cancer.

About OST-HER2

The OST-HER2 *Lm* vector platform technology has been administered to over 450 cancer patients in ongoing and completed clinical trials. AOST-2121 is a Phase IIB clinical trial intended to prevent metastasis and improve Overall Survival (OS) in Osteosarcoma. OST-HER2 has already received Fast-Track and Orphan Designations by the FDA and EMA - the company has filed for Rare Disease Designation (RDD). OST hopes to seek a Break-Through Designation (BTD) based on data from this Phase IIb clinical trial. OST31-164 has previously received USDA provisional approval for treatment of Osteosarcoma in canines. In a completed phase III study in canines (n=180), early data demonstrated a clear separation of treated and untreated canine patients (p=.0007) in Overall Survival (OS) and Disease Progression.

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

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