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OS Therapies Announces Nationwide Open Enrollment of Remaining 36 to 42 Patients in Phase IIb Trial of OST-HER2 (Listeria monocytogenes) in Recurred, Resected Osteosarcoma

Provisional Safety Launch of First Three Patients Exhibited No Serious Adverse Events (SAEs), With Sites Open Across the Country

CAMBRIDGE, Md., Jan. 27, 2022 /PRNewswire/ --**OS Therapies**, a research and clinical-stage biopharmaceutical company announced today that the Data Safety & Monitoring Committee (DSMC) approved open enrollment for AOST-2121: an open label Phase IIb Trial of OST-HER2 (*Listeria* monocytogenes) in Recurred, Resected Osteosarcoma (OS). OS is a deadly and debilitating cancer of the bone that usually occurs in adolescence and young adults (AYA).

OS Therapies' OST-HER2 is a *L*m vector-based off-the-shelf Immunotherapy intended to prevent metastasis, delay recurrence, and increase overall survival. The FDA had requested a safety roll-out staggering the first three patients by three weeks - safety data from these patients has given the safety committee the ability to open the trial nationally to the remaining patients.

"The Osteosarcoma Community has been anxiously awaiting the clinical trial of this very promising technology ever since it was provisionally approved for dogs by the USDA – we just want to try it on our kids," said Miriam Cohen, Chair of the Osteosarcoma Collaborative (www.oscollaborative.org), an OS patient advocacy organization that has supported the trial.

Eleven of the twenty clinical trial sites currently open include:
Seattle Children's Hospital
Connecticut Children's Hospital
UPMC Children's Hospital of Pittsburgh
Kaiser Permanente Downey Medical Center
St. Jude's Children's Research Hospital
Johns Hopkins Baltimore
UT Southwestern Children's Medical Center
Hackensack University Medical Center
Children's Hospital of Orange County
Rady Children's Hospital
Children's Hospital of Philadelphia (CHoP)

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 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 received Rare Disease Designation (RDD), Fast-Track and Orphan Designations by the FDA and EMA. 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), 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 atwww.ostherapies.com

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