OS Therapies Receives Rare Pediatric Disease Designation (RDD) in Osteosarcoma for OST-HER2 (Listeria monocytogenes)

Pathway to Priority Review Voucher (PRV) and Expedited Review by the FDA

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OS Therapies →
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CAMBRIDGE, Md., Nov. 3, 2021 /PRNewswire/ -- **OS Therapies**, a research and clinical-stage biopharmaceutical company whose lead program uses OST-HER2 (*Listeria* monocytogenes) is being developed for therapies to treat and cure Osteosarcoma (OS), today announced the U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease Designation (RDD) for OST-HER2 (OST31-164) for the treatment of Osteosarcoma.

"The timing and determination by the FDA that OST-HER2 is a potentially much-needed new treatment in this underserved disease underscores the importance of our recently initiated PhIIb clinical trial in recurred, resected Osteosarcoma" said Paul Romness, CEO of OS Therapies. "The RDD ensures a well-deserved expedited review by the FDA, as well as a Priority Review Voucher (PRV) if our current trial is successful."

The FDA grants RDD (Rare Disease Designation) status for serious and life-threatening diseases that primarily affect children ages 18 years or younger and involves fewer than 200,000 people in the U.S. In addition to expedited review, if a PRV (Priority Review Voucher) is issued it can – at the election of OS Therapies - be transferred to larger Pharmaceutical and Biotechnology companies for a cash or other benefit-in-kind.

"The entire team at OS Therapies has been working diligently through a global pandemic to address the necessary regulatory hurdles in order to get this technology to pediatric patients as soon as possible," said Dr. Colin Goddard, Executive Chair of OS Therapies. "Not only are we addressing an unmet medical need, but the PRV and expedited review will have significant financing advantages that will enable us to support our ever-expanding pipeline for patients with other solid tumors."

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 deadly cancers in kids and adults including ovarian, esophageal, endometrial, colorectal and lung cancers.

About OST-HER2

The OST-HER2 platform technology has already been administered into approximately 450 volunteers in successful and completed clinical trials. Two weeks ago, OS Therapies initiated a potentially pivotal, Phase IIB clinical trial intended to prevent metastasis and improve Overall Survival (OS) in Osteosarcoma. OST-HER2 has already received Orphan Drug Designations by the FDA and EMA, and the company plans to file for Break Through Designation (BTD) next year. OST-HER2 has received a USDA provisional approval for treatment of Osteosarcoma in canines. In a completed phase III study in canines (n=180), there was a clear separation of treated and untreated 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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