FDA Notifies Osmol Therapeutics that the First-in-Human Phase 1 Clinical Trial of OSM-0205 for the Prevention of Chemotherapy-induced Peripheral Neuropathy (CIPN) May Proceed

Up to 80% of taxane treated breast cancer patients are diagnosed with some degree of CIPN

Currently there are no FDA-approved treatments for CIPN

New Haven, CT – September 18, 2023– Osmol Therapeutics, a privately held biopharmaceutical company focused on developing a treatment to prevent chemotherapy-induced peripheral neuropathy (CIPN), today announced that the U.S. Food and Drug Administration (FDA) notified the company that the first-in-human clinical trial of OSM-0205 in healthy subjects for the prevention of CIPN may proceed. Osmol filed the Investigational New Drug application (IND) with the FDA for OSM-0205 in August 2023.

Microtubule-based chemotherapy treatments, which destroy cancer cells based on microtubule disruption, produces an intracellular calcium surge that damages neurons, leading to CIPN. Each year, approximately 360,000 cancer patients in the U.S. and E.U. are treated with taxanes most commonly for the treatment of breast cancer but also for prostate cancer as well as other malignant solid tumors. Approximately 80% of breast cancer patients experience some degree of CIPN. Currently there are no FDA-approved treatments for CIPN, and the only way to mitigate the effect of this painful and often debilitating condition is by interrupting treatment or reducing the dosage of chemotherapy, which can adversely impact patient outcomes.

“Preventing CIPN would address a major women’s health issue for which there are currently no FDA-approved disease modifying treatment options,” said Arthur DeCillis, MD, Chief Medical Officer, Osmol Therapeutics. “OSM-0205 is administered intravenously immediately prior to chemotherapy treatment and has the potential to protect neurons in patients by preventing the surge in intracellular calcium associated with CIPN. This first-in-human Phase 1 clinical trial in healthy subjects will determine the safety, tolerability, and pharmacokinetics of single ascending doses of OSM-0205 intravenous infusion to select a dose to evaluate in Phase 2 clinical studies in breast cancer patients.”

About OSM-0205

Osmol’s lead drug, OSM-0205, is based on Dr. Barbara Ehrlich’s research in neuronal calcium sensor-1 (NCS1) at Yale School of Medicine and is designed to prevent the off-target calcium surge caused by taxanes and potentially other chemotherapy treatments associated with peripheral nerve damage. Data from preclinical studies conducted by Osmol show that pre-treatment with OSM-0205 prevents the pathologic damage caused by these chemotherapy agents.

About Osmol Therapeutics

Osmol Therapeutics is a privately held, clinical stage biopharma company focused on developing a treatment to prevent chemotherapy-induced peripheral neuropathy (CIPN) based on the ground-breaking work of Dr. Barbara Ehrlich. The company’s lead indication will be for the prevention of CIPN related to taxane treatment. As an example of the extent of this condition, up to 80% of taxane-treated patients with breast cancer have been reported to experience CIPN. For more information, please go to https://osmoltherapeutics.com/.

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