Osmol Therapeutics Initiates IND Enabling Studies to Develop First Therapy for Prevention of Chemotherapy-Induced Peripheral Neuropathy

-- Founded by Barbara Ehrlich, Ph.D. at Yale University

-- Bob Linke appointed Chief Executive Officer

New Haven, CT. May 13, 2021 – Osmol Therapeutics today announced that it has initiated Investigational New Drug (IND) enabling studies to develop a therapy to prevent chemotherapy-induced peripheral neuropathy (CIPN). A phase 1 clinical study is projected to begin in 2022. There are currently no Food and Drug Administration (FDA) approved therapies for the prevention or treatment of CIPN, a debilitating condition resulting from the off-target toxicity of many chemotherapy treatments.

Osmol was founded by Dr. Barbara Ehrlich, Professor of Pharmacology and of Cellular and Molecular Physiology, Yale School of Medicine. Her research on neuronal calcium sensor-1 (NCS1), a critical calcium binding protein that regulates intracellular calcium levels, forms the basis of Osmol's CIPN treatment, OSM-0205 and future potential NCS1 therapeutics. OSM-0205's mechanism addresses the off-target toxicity of microtubule-based chemotherapy agents that results in a calcium surge leading to CIPN. OSM-0205 modulates NCS1 to prevent the calcium surge and maintain neuronal integrity.

The company's initial focus is CIPN in breast cancer patients resulting from taxane-based chemotherapy treatment. Taxanes are the most widely used chemotherapy treatment for breast cancer and can lead to CIPN in up to 80% of patients. Independent market research conducted with breast cancer oncologists at leading US cancer centers confirmed that CIPN is the most significant toxicity issue facing clinicians and patients when treating breast cancer.

"Chemotherapy-induced peripheral neuropathy is a devastating adverse event that can leave patients and their treating physicians with a very difficult choice – reduce taxane therapy with the possibility of negatively impacting patient outcomes or continue therapy at the recommended dose with the potential of causing increased and possibly permanent, disabling CIPN," said Dr. Ehrlich. "OSM-0205 is being developed with the goal of preventing CIPN before it occurs. By blocking the calcium surge that causes neuropathy, optimal treatment with taxanes can continue. This is particularly important in the treatment of breast cancer where taxanes remain the foundation of most therapeutic regimens."

"There are currently no FDA-approved therapies to avoid or reduce CIPN, creating an urgent need for patients being treated with chemotherapy," said Robert Berman, M.D., Executive Chairman of Osmol Therapeutics and co-founder and former Chief Medical Officer at Biohaven Pharmaceuticals. "Over 225,000 patients in the U.S. and the European Union with early stage or metastatic breast cancer are treated with taxanes each year. We have recruited an experienced and capable executive team, led by Bob Linke, Osmol's Chief Executive Officer, to advance OSM-0205 to address this need as well as explore

the potential use of neuronal calcium sensor-1 (NCS1) in other indications. We are excited by the potential of OSM-0205 and expect to begin clinical development as early as next year."

Bob Linke, MBA, is an experienced biopharma entrepreneur, who is also Executive Chairman of Embera NeuroTherapeutics and IonSense. He has an established track record developing strategies, building and leading emerging companies through all phases of growth – from research, product development and clinical studies to successful commercialization, partnership and acquisitions. Bob brings an open management style to create cohesive, high-functioning teams. He has raised over $70 million in private equity and non-dilutive financing to fund these companies' development and commercialization efforts. His early career was spent at Baxter, developing and commercializing pharmaceuticals and drug delivery systems.

About OSM-0205 and CIPN

Osmol's lead drug, OSM-0205, is based on Dr. Barbara Ehrlich's research in neuronal calcium sensor-1 (NCS1) at Yale University 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 neuronal damage from taxanes in mice by preventing the off-target intracellular calcium surge caused by these chemotherapy agents. It is hypothesized that OSM-0205 modulates NCS1 in patients to protect neurons from damage leading to a reduction of CIPN. CIPN affects hundreds of thousands of cancer patients every year and can compromise optimum chemotherapy dosing. There are no effective treatments for CIPN, a condition which can diminish quality of life and lead to lifelong disability.

About Osmol Therapeutics

Osmol Therapeutics is a privately held biopharma company focused on developing a treatment to prevent chemotherapy-induced peripheral neuropathy (CIPN) based on the ground-breaking work of Dr. Barbara Ehrlich on the role of NCS1 in calcium signaling and regulation in preventing nerve damage associated with chemotherapy. The company's lead indication will be for the prevention of CIPN in breast cancer patients treated with taxane-based therapy, a treatment regimen in which up to 80% of patients experience CIPN. For more information, please go to https://osmoltherapeutics.com/ .

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