

OncoTherapy Science, Inc.

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Announcement of an additional investigational site opening for the Phase I clinical study for OTS167 (oral administration) in patients with Breast Cancer including Triple-Negative Breast Cancer

OncoTherapy Science, Inc. (President & CEO: Kyoko Fujiya; hereinafter “OncoTherapy”) today announces the initiation of patient recruitment for the Phase I clinical study of OTS167 in patients with breast cancer including Triple-Negative Breast Cancer (TNBC) at Memorial Sloan-Kettering Cancer Center (New York, USA).

This Phase I Study of OTS167 consists of 2 phases, a dose-escalation phase and a dose-expansion phase. In the dose-escalation phase, the safety, pharmacokinetic profile and MTD will be evaluated in advanced breast cancer patients. In the dose-expansion phase, the safety and preliminary efficacy of OTS167 will be evaluated in TNBC patients. OTS167 is a capsule formulation and patients will be dosed orally once daily. This study is an open-labeled, non-randomized, multicenter trial.

OTS167 is a molecular-targeted compound that has a potent inhibitory activity against MELK (maternal embryonic leucine-zipper kinase), a kinase identified as a cancer-specific molecule through genome-wide expression profile analysis. MELK is considered to play important roles in formation and maintenance of cancer stem cells and was shown to be highly expressed in breast cancer, especially in TNBC. OTS167 intravenous administration is currently being studied in a Phase I/II clinical trial in patients with advanced leukemia at the University of Chicago and Weill Cornell Medicine.