OncoTherapy Science, Inc.
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The announcement of initiation of Phase I clinical study for OTS167 (oral administration) in patients with Breast Cancer including Triple-Negative Breast Cancer at Weill Cornell Medicine

OncoTherapy Science, Inc. (President & CEO: Kazuo Yamamoto; hereinafter" OncoTherapy") today announces that OncoTherapy and Weill Cornell Medicine have entered into the clinical trial for a Phase I clinical study of OTS167 (oral administration) to assess the safety, maximum tolerate dose (MTD) and preliminary efficacy in patients with breast cancer including Triple-Negative Breast Cancer (TNBC).

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 Phase I/II clinical trial in patients with advanced leukemia at the University of Chicago.

A 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 will be evaluated in TNBC patients. OTS167 (oral administration) is a capsule formulation and patients will be administered orally once daily. This study is an open-labeled, non-randomized, multicenter trial.