

OncoTherapy Science, Inc.

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The announcement of the initiation of Phase I clinical study of OTS167
for breast cancer patients in Japan

OncoTherapy Science, Inc. (President & CEO: Jae-Hyun Park; hereinafter, “OncoTherapy”) announces that Phase I clinical study of OTS167 in patients with advanced, metastatic breast cancer will be initiated in Japan following the acceptance of the protocol by Pharmaceuticals and Medical Devices Agency (PMDA).

This study is designed to assess the safety and the recommended dose for oral administration of OTS167 capsule in patients with breast cancer including Triple Negative Breast Cancer (TNBC)* as primary objective, and the clinical efficacy for TNBC as secondary objective. The study has been initiated at MD Anderson Cancer Center, Norwalk Hospital and Memorial Sloan-Kettering Cancer Center in USA. Japanese patients will be registered when the study is opened in the investigational sites in Japan.

OTS167 is a small molecule compound that has a potent inhibitory activity on MELK (maternal embryonic leucine zipper kinase), a novel protein kinase involved in formation and maintenance of cancer stem cells. Experiments using xenograft mice models have demonstrated that OTS167 has potent antitumor activities against tumors such as lung, prostate, breast and pancreatic cancers.

Phase I clinical study of OTS167 with oral administration to healthy adults conducted in Australia for the evaluation of bioavailability was completed and demonstrates its favorable oral absorption. In addition, the Phase I/II clinical study of an intravenous administration of OTS167 for acute myeloid leukemia has been undergoing at University of Chicago and Weill Cornell Medicine.

*TNBC (Triple-negative breast cancer): A type of breast cancer which does not express any of estrogen receptor, progesterone receptor, or HER2. TNBC accounts for nearly 15 - 20 percent of breast cancers.