

OncoTherapy Science, Inc.

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The commencement of Phase I clinical study of OTS167, MELK specific inhibitor,
for breast cancer patients in USA

OncoTherapy Science, Inc. (President & CEO: Masaharu Mori; hereinafter, “OncoTherapy”) announces that we will conduct Phase I clinical study of OTS167, a MELK specific inhibitor, for breast cancer patients following the acceptance of the protocol by the US Food and Drug Administration (FDA).

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 Phase I/II clinical study of an intravenous administration protocol of OTS167 for acute myeloid leukemia has been undergoing at University of Chicago.

In addition, 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

OTS167 is a molecular-targeted 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.

OncoTherapy will proceed with the clinical studies to confirm clinical efficacy with careful safety monitoring in human patients.

*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.