

OncoTherapy Science, Inc.

August 15, 2017

The first-patient enrollment in Phase I clinical study of OTS167,
MELK specific inhibitor, for breast cancer patients

OncoTherapy Science, Inc. (President & CEO: Kazuo Yamamoto; hereinafter, “OncoTherapy”) announces that the first patient has been enrolled in Phase I clinical study of OTS167, an MELK-specific inhibitor, for Breast Cancer, which was announced on May 29th and June 29th, 2017.

This study is conducting at Weill Cornell Medicine and MD Anderson Cancer Center and 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.

OTS167 is a small-molecule targeted compound that has a potent inhibitory activity against MELK (maternal embryonic leucine zipper kinase), a protein kinase identified as a cancer-specific molecule by genome-wide expression profile analysis. OTS167 is expected to have higher efficacy on cancer stem cells. Mice xenograft models have demonstrated potent anti-tumor activities of OTS167 against lung, prostate, breast and pancreatic cancers.

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

OncoTherapy will proceed with the clinical study for the confirmation of 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.