

OncoTherapy Science, Inc.

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The first-patient enrollment in Phase I/II clinical study of OTS167, MELK specific inhibitor,
for Acute Myeloid Leukemia patients in USA

OncoTherapy Science, Inc. (President & CEO: Masaharu Mori; hereinafter, “OncoTherapy”) announces that the first patient has been enrolled in Phase I/II clinical study of OTS167, an MELK-specific inhibitor, for Acute Myeloid Leukemia (AML), which was announced on January 25th, 2016.

This study at the University of Chicago is designed to assess the safety and the recommended dose of intravenous OTS167 administration in patients with AML. Once the assessment is completed, a serial study for the confirmation of POC (Proof of Concept: the clinical verification of the mechanism of action of OTS167) will be performed for various types of high risk leukemia in addition to AML.

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.

OncoTherapy will proceed with the clinical study for the confirmation of efficacy with careful safety monitoring in human patients.