

OncoTherapy Science, Inc.

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The announcement of the initiation of a Phase I/II clinical study for OTS167 in patients with refractory or relapsed leukemia at Weill Cornell Medicine

OncoTherapy Science, Inc. (President & CEO: Kazuo Yamamoto; hereinafter, “OncoTherapy”) announces that OncoTherapy and Weill Cornell Medicine have entered a Phase I/II clinical study of OTS167, an MELK-specific inhibitor, for refractory or relapsed Acute Myeloid Leukemia (AML), Acute Lymphoblastic Leukemia (ALL), advanced Myelodysplastic Syndromes (MDS), advanced Myeloproliferative Neoplastic disorders (MPN), or advanced Chronic Myelogenous Leukemia (CML).

This study has been started at the University of Chicago in 2016 and is designed to assess the safety and the recommended dose for intravenous administration of OTS167 in patients with refractory or relapsed-AML, -ALL, advanced-MDS, -MPN or -CML. Once the assessment is completed, a serial Phase II 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.