OncoTherapy Science, Inc.
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Completion of patient enrollment in Phase I clinical study of OTS167 for patients with advanced solid tumors in the US

OncoTherapy Science, Inc. (President & CEO: Masaharu Mori; hereinafter, “OncoTherapy”) announces that the patient enrollment of the Phase I clinical study of OTS167, MELK specific inhibitor, for patients with advanced solid tumors (hereinafter, “the Study”) has been completed.

The Study is a first-in-human Phase I clinical study, designed to assess the safety and pharmacokinetic profiles in patients with an advanced solid tumor that did not respond to standard therapies. The total number of enrollment has counted 32 since its commencement in August 2013, and patient registration for medium dose administration has finished.

This intravenous-administration study, has significantly contributed to the subsequent OTS167 clinical studies and its formulation development. As already announced, Phase I clinical study of OTS167 with oral administration to health adults conducted in Australia for the evaluation of bioavailability has been completed with favorable results. Further, a phase I/II clinical study of OTS167, for Acute Myeloid Leukemia (AML) commenced. Due to the results from those clinical studies, OncoTherapy has judged that the original purpose of the Study (determination of safety and pharmacokinetic profiles) has already achieved and decided to finalize patient registration.

OTS167 is a 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, which was identified as a cancer-specific molecule through genome-wide expression profile analysis. Experiments using xenograft mice models have demonstrated that OTS167 has potent anti-tumor activities against lung, prostate, breast and pancreatic cancers.