OncoTherapy Science, Inc.
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# The commencement of patient enrollment in Phase I clinical study of OTS167, a novel small molecule compound targeting cancer stem cells

OncoTherapy Science, Inc. (President & CEO: Masaharu Mori; hereinafter, "OncoTherapy") announces that the protocol amendment of Phase I clinical study of OTS167, which aim to evaluate the bioavailability (BA) of OTS167 by oral administration, was approved by the US Food and Drug Administration (FDA) and the medical center's Institutional Review Board at the University of Chicago Medicine, and all procedures to conduct this study have been completed now.

The safety, efficacy and pharmacokinetic profiles of OTS167 given intravenously have been evaluated through the on-going clinical trial. The purpose of current protocol amendment is to facilitate the clinical development of OTS167, because high BA results will make it possible to conduct the clinical trial using not only intravenous but oral administration.
The clinical development using both formulations will hold the promise of the shortening development period and the expansion of indications.

OTS167 is a targeted compound that has a potent inhibitory activity on MELK (maternal embryonic leucine zeipper kinase), a novel protein kinase in formation and maintenance of cancer stem cells. Experiments using xenograft mice models have demonstrated that OTS167 shows potent anti-tumor activities against lung, prostate, breast and pancreatic cancers.

OncoTherapy will proceed with the enrollment of the patients with careful safety monitoring.