OncoTherapy Science, Inc.
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MELK inhibitor, OTS167, Phase I clinical study commencement in Australia

OncoTherapy Science, Inc (President and CEO: Masaharu Mori; hereinafter, "OncoTherapy") announces that the Human Research Ethics Committee (HRECs) at the trial site in Australia has approved the commencement of Phase I clinical study of MELK inhibitor, OTS167. MELK (maternal embryonic leucine zipper kinase), which is a novel protein kinase essential for formation and maintenance of cancer stem cell. This clinical study aims to primarily evaluate the bioavailability (BA) of OTS167 by oral administration in healthy adults.

The safety, efficacy and pharmacokinetic profiles of OTS167 administered intravenously in solid cancer patients have been evaluated in the ongoing clinical study being held at University of Chicago, Chicago, USA. All the procedures to initiate this clinical study involving oral administration of OTS167 have been completed. Once this clinical study in Australia verifies high BA in human, such clinical result would expedite the clinical development of OTS167 in oral formulation.

OTS167, which was developed by OncoTherapy, is a molecular targeted drug of which mode of action is new and is expected to be efficacious to various types of human cancer with high expression of MELK.

Experiments using mice models have demonstrated that OTS167 shows potent anti-tumor activities against lung, prostate, breast and pancreatic cancers. OncoTherapy will proceed with the clinical study with careful safety monitoring.