

OncoTherapy Science, Inc.

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The Phase I clinical study of the anti-cancer therapeutic antibody 'OTSA101' against synovial sarcoma

OncoTherapy Science, Inc. (President & CEO: Masaharu Mori; hereinafter, "OncoTherapy") announces that the positive results of the primary objectives which were safety and bio-distribution were confirmed from Phase I clinical study of the anti-cancer therapeutic antibody 'OTSA101' against synovial sarcoma conducted in France.

This clinical study has been conducted as an investigator-initiated trial under the direction of Prof. Jean-Yves Blay (ex-chairman of European Organization for Research and Treatment of Cancer; EORTC) at Centre Léon-Bérard in Lyon, France, and the analysis of the study results has completed

Study results

Twenty patients were enrolled in this study during January 2012 to June 2015. Some anticipated adverse events were observed, but no unexpected serious adverse drug reaction was observed. Good bio-distribution profile of OTSA101 leading to the clinical efficacy was also confirmed.

Based on the results from this study, we will plan the sponsor initiated clinical trial for the new drug application in Japan, USA and EU.

OTSA101 targets a tumor antigen that is expressed specifically in synovial sarcoma and not in any normal organs except the placenta. This antigen was initially found by comprehensive genetic analysis by Professor Yusuke Nakamura's laboratory at Institute of Medical Science, the University of Tokyo. Studies using animal model studies showed that <sup>90</sup>Y-conjugated antibodies effectively accumulated at a tumor site and revealed strong anti-tumor effect. OTSA101 is recognized as an orphan drug against synovial sarcoma by European Medicines Agency (EMA) and Food and Drug Administration (FDA).

OncoTherapy also announces that Laboratoires OncoTherapy Science France S.A.R.L. (Lyon, France) which is our consolidated subsidiary established for this study will be dissolved after the completion of procedures on account of the completion of this study.