

OncoTherapy Science, Inc.

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

The phase I clinical study of the anti-cancer therapeutic antibody against synovial sarcoma 'OTSA101' has been completed.

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. The study results will be assessed as soon as possible. After the primary objectives of the study which are safety and bio-distribution will be determined as planned, the next clinical studies will be performed. We will continue to pursue an approval in USA and EU countries as well as Japan.

OTSA101 targets a tumor antigen that is specifically expressed in synovial sarcoma cells, 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 Human Genome Center, the Institute of Medical Science, the University of Tokyo. Studies using animal model studies showed that ⁹⁰Y-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).