

OncoTherapy Science, Inc.

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Announcement of the First Patient In for Phase I study of OTSA101
in Japanese patients with synovial sarcoma

OncoTherapy Science, Inc. (President & CEO: Jae-Hyun Park; hereinafter “OncoTherapy”) today announces that the first patient has been enrolled for Phase I study of OTSA101 and the treatment initiated. This is a Phase I study to assess the safety of OTSA101 in Japanese patients with refractory, relapsed and/or advanced synovial sarcoma.

In this study, the safety and pharmacokinetic profiles of radioisotope-conjugated OTSA101 will be evaluated in the synovial sarcoma patients.

OTSA101 is an anti-FZD10 chimeric monoclonal antibody. Frizzled homolog 10 (FZD10) was identified through genome-wide gene expression analysis by Yusuke Nakamura, a former professor in the University of Tokyo. FZD10 is a transmembrane protein which is highly expressed in synovial sarcoma but not in human normal vital organs. Radioisotope-conjugated OTSA101 was specifically accumulated in tumor tissue and showed strong anti-tumor effect in preclinical study, and it is being developed as a radioimmunotherapy (RIT) for synovial sarcoma. The investigator-initiated Phase I study in France was completed with the favorable results about the primary objectives of this study, safety and bio-distribution profile. OTSA101 has been designated as an orphan drug against synovial sarcoma by European Medicines Agency (EMA) and Food and Drug Administration (FDA).