

OncoTherapy Science, Inc.

August 15, 2019

Announcement of the initiation of Phase I study for OTSA101
in Japanese patients with synovial sarcoma

OncoTherapy Science, Inc. (President & CEO: Kyoko Fujiya; hereinafter “OncoTherapy”) today announces the initiation of Phase I clinical study for OTSA101 in Japanese patients with refractory, relapsed and/or advanced synovial sarcoma. The clinical study protocol has been accepted by Pharmaceuticals and Medical Devices Agency (PMDA) in Japan.

In this study, the safety and pharmacokinetic profiles of radioisotope-conjugated OTSA101 will be evaluated in synovial sarcoma patients. Patient recruitment will be started in the clinical study sites when all process is completed.

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 organs except placenta. Radioisotope-conjugated OTSA101 was specifically accumulated in tumor tissue and showed strong anti-tumor effect in preclinical study and it is developing as radioimmunotherapy (RIT) for synovial sarcoma. The investigator-initiated Phase I study has been conducted in France. OTSA101 has been designated an orphan drug against synovial sarcoma by European Medicines Agency (EMA) and Food and Drug Administration (FDA).