OncoTherapy Science, Inc.
October 23, 2018

Announcement of the presentation of interim results for exploratory study of peptide vaccine S-588410 at European Society for Medical Oncology 2018 Congress.

OncoTherapy Science, Inc. (President & CEO: Kazuo Yamamoto; hereinafter, "OncoTherapy") announces that interim results for exploratory study of peptide vaccine S-588410 were presented a poster entitled "Interim results from exploratory study to determine S-588410-induced tumor infiltrating lymphocytes and changes in the tumor microenvironment in esophageal cancer patients" at European Society for Medical Oncology 2018 Congress (ESMO2018), Munich, Germany, on 20th October 2018 (local time).

S-588410 is cancer peptide vaccine licensed out from OncoTherapy to Shionogi & Co.,Ltd.. It composed of five HLA-A*24:02 restricted peptides derived from five cancer-testis antigens: DEPDC1, MPHOSPH1, URLC10, CDCA1 and KOC1.
In this study, tumor tissues of pre- and post-treatment were collected to analyzing tumor-infiltrating lymphocytes, PD-L1 and target antigens. The short-term treatment with S-588410 generated peptide-specific CTL and markedly increased CD8 TIL density and PD-L1 expression on tumor tissue of esophageal cancer patients. These interim results suggest that the combination of S-588410 with anti-PD-1/PD-L1 antibody is expected to be more effective than monotherapy, particularly in patients with low TIL/PD-L1 status.

[Summary of the presentation]
The aim of this study is evaluating the effects of S-588410 on the number of tumor-infiltrating CD8-positive lymphocytes (TIL) and PD-L1 expression in the tumor tissue before and after vaccination. Total 15 HLA-A*24:02-positive patients with esophageal cancer were enrolled in this study. The first half of the patients (eight patients) who received three to six vaccinations with S-588410 were analyzed. Peptide-specific cytotoxic T lymphocytes were induced in eight patients after vaccination. IHC analysis demonstrated that TIL density and PD-L1 expression on post-vaccine tissues clearly increased compared to the baseline; CD8 TIL density at baseline was ≤ 1% in 5 patients and 1%-10% in 3 patients and that for post-vaccine was 1%-10% in 2 patients, 10%-50% in 6 patients, and PD-L1 expression at base line was ≤ 1% in 7 patients and 1%-5% in 1 patient and that for post-vaccine was ≤ 1% in 1 patient, 1%-5% in 4 patients and 5%-50% in 3 patients. The number of tumor-infiltrating T lymphocytes and PD-L1 expression in tumor tissue are important factor on action mechanism of anti-PD-1 / PD-L1 antibody. These interim results suggest that the combination

therapy of S-588410 with anti-PD-1 / PD-L1 antibody has the possibility of generating a synergistic effect.