

OncoTherapy Science, Inc.

October 28, 2019

Announcement of the presentation of results for exploratory study of peptide vaccine  
S-588410 at the 57<sup>th</sup> Annual Meeting of Japan Society of Clinical Oncology

OncoTherapy Science, Inc. (President & CEO: Kyoko Fujiya; hereinafter, “OncoTherapy”) announces that results for exploratory study of peptide vaccine S-588410 were reported by an oral presentation entitled “Exploratory study for evaluating the functional mechanism of cancer peptide vaccine” at the 57<sup>th</sup> Annual Meeting of Japan Society of Clinical Oncology, Fukuoka, on October 25, 2019.

This presentation included the results of collaborative research between OncoTherapy and Shionogi & Co., Ltd. (President & CEO: Isao Teshirogi; Osaka).

Summary of this presentation is similar to the previous presentation at European Society for Medical Oncology 2019 Congress. Please refer to the following press release on October 1.

“Announcement of the presentation of results for exploratory study of peptide vaccine S-588410 at European Society for Medical Oncology 2019 Congress”.

[https://www.oncotherapy.co.jp/en/wp-content/uploads/2019/10/20191001\\_01.pdf](https://www.oncotherapy.co.jp/en/wp-content/uploads/2019/10/20191001_01.pdf)

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. To evaluate the effect of S-588410 on CD8 positive (+) T-lymphocytes and PD-L1 expression, tumor tissue and blood in pre- and post-vaccination were collected from esophageal cancer patients. Following the previous poster presentation at the European Society for Medical Oncology 2019 Congress (press released on October 1), results of this study were also presented at the 57<sup>th</sup> Annual Meeting of Japan Society of Clinical Oncology on October 25.

[Summary of the presentation]

Several studies have reported that cancer peptide vaccines (CPVs) induce cytotoxic T-lymphocytes (CTL) in cancer patient. However, the effect of CPVs on tumor microenvironment has not been clarified.

To evaluate the effects of S-588410 on CD8 positive (+) T-lymphocytes in both blood and tumor tissue and PD-L1 expression in tumor tissue, the specimens from pre- and post-vaccination were analyzed. Total 15 HLA-A\*24:02-positive patients (pts) with

esophageal cancer were enrolled in this study. Peptide-specific CTL were induced in all pts after vaccination. Immunohistochemical analysis demonstrated that the densities of CD8+, CD8+GranzymeB+, CD8+PD1+ and PD-L1+ cell in tumor tissue after vaccination were higher than those before vaccination. Furthermore, TCRs identified from peptide-specific CTLs were detected from tumor tissue and PBMC after vaccination\*. These results suggest that S-588410 induced peptide-specific CTL that can infiltrate into tumor and increased CD8+PD1+ cells and PD-L1+ cells in tumor microenvironment. These findings show that the combination therapy of S-588410 with anti-PD-1 / PD-L1 antibody has the possibility of generating a synergistic effect.

\*TCR repertoire analysis was conducted in collaborative research between OncoTherapy and Shionogi & Co., Ltd.