

OncoTherapy Science, Inc.

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Announcement of the presentation of results for
Phase II study of S-588410 in bladder cancer at ASCO GU 2021

OncoTherapy Science, Inc. (President & CEO: Jae-Hyun Park; hereinafter, “OncoTherapy”) today announces that results for Phase II study of peptide vaccine S-588410 were presented as a poster presentation entitled “Phase II open-label study of S-588410 as maintenance monotherapy after first-line platinum-containing chemotherapy in patients with advanced or metastatic urothelial carcinoma” at American Society of Clinical Oncology, 2021 Genitourinary Cancers Symposium (ASCO GU 2021). S-588410 is cancer peptide vaccine licensed out from OncoTherapy to Shionogi & Co., Ltd.

S-588410 is cancer peptide vaccine composed of five HLA-A*24:02 restricted peptides derived from five cancer-testis antigens: DEPDC1, MPHOSPH1, URLC10, CDCA1 and KOC1; all of which are highly expressed in bladder cancer. This Phase II open-label study evaluated the effect of S-588410 maintenance therapy on the induction of peptide-specific cytotoxic T-lymphocytes (CTL) and the safety profile in 81 patients (S-588410 group, n=45; observation group, n=36) with advanced or metastatic urothelial carcinoma after first-line chemotherapy in Japan, the United Kingdom and Europe.

[Summary of the results]

The CTL induction to any of the five peptides was detected in 42 (93.3%) patients received S-588410 during the initial 12 weeks (primary endpoint), and the CTL induction rate steadily increased to 95.6% during 48 weeks.

The response rate was 8.9% (4/45 patients) in S-588410 group and 0% in observation group on the immune-related response criteria. Median progression free survival (PFS) was 18.1 weeks in S-588410 group and 12.5 weeks in observation group. Median overall survival (OS) was 71 weeks in S-588410 group and 99 weeks in observation group. The most frequent treatment-related adverse event was injection site reaction (42/45 patients, 93.3%) in S-588410 group.

These results suggest that potent immune response and acceptable safety profile of S-588410 may provide beneficial effect for a maintenance therapy in patients with advanced or metastatic bladder cancer.