OncoTherapy Science, Inc.
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Publication of a paper describing Phase II study of cancer peptide vaccine S-588410 in urothelial carcinoma

OncoTherapy Science, Inc. (President & CEO: Jae-Hyun Park; hereinafter, "OncoTherapy") announces that full results for Phase II study of peptide vaccine S-588410 were published in *Bladder Cancer* entitled "A Phase 2 Study of S-588410 Maintenance Monotherapy for Platinum-Treated Advanced or Metastatic Urothelial Carcinoma". S-588410 is cancer peptide vaccine licensed out from OncoTherapy to Shionogi & Co., Ltd.

S-588410 is 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 monotherapy on the induction of peptide-specific cytotoxic T-lymphocytes (CTL) and the safety profile in 81 patients with advanced or metastatic urothelial carcinoma after chemotherapy in Japan and Europe. The results have been previously reported at American Society of Clinical Oncology, 2021 Genitourinary Cancers Symposium (ASCO GU 2021), and the full results were published in *Bladder Cancer* online this time.
https://content.iospress.com/download/bladder-cancer/blc211592?id=bladder-cancer%2Fblc211592

[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. The antitumor response rate (immune-related complete response (irCR) + immune-related partial response (irPR)) was 8.9% (4/45 patients) in S-588410 group and 0% in observation group. Disease control rate (the proportion of irCR, irPR, and immune-related stable disease (irSD)) was 22.2% (10/45 patients) in S-588410 group and 13.9% in observation group. 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, which was also observed in previous clinical studies of cancer peptide vaccine.

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 urothelial carcinoma.