OncoTherapy Science, Inc.
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Announcement of the Presentation of Interim Results for Phase I Clinical Study of a Combination of OTSGC-A24 and Immune Checkpoint Inhibitor in Patients with Gastric Cancer

OncoTherapy Science, Inc. (President & CEO: Junichi Shimada; hereinafter, "OncoTherapy") today announces that interim results for Phase I clinical study of a combination of OTSGC-A24 and nivolumab were presented by a poster entitled "da VINci: Safety and efficacy of the OTSGC-A24 vaccine and nivolumab in metastatic gastric cancer" at European Society for Medical Oncology Congress 2022 (Paris, France) on September 12, 2022 (CET).
This is an investigator-initiated study conducted at National University Hospital (NUH) since 2019, and OncoTherapy has provided the study drug OTSGC-A24 as a collaborator.

OTSGC-A24 is the cocktail peptide vaccine product which contains multiple peptides targeting the tumor-specific antigens that are highly expressed in gastric cancer (GC). Each peptide contained in this cocktail is identified through cancer genome analysis and expected to induce strong cytotoxic T lymphocyte (CTL) response. Phase I/II clinical study of OTSGC-A24, which is a single agent for refractory GC, was conducted in Singapore, Korea and Japan and had been completed with favorable results on safety and immune reactivity.

[Summary of the presentation]
The aim of this study is to evaluate the safety and efficacy of the combination of OTSGC-A24 and immunotherapy in the patients (pts) with unresectable or metastatic GC.
Total 18 HLA-A*24:02 subtype pts with unresectable/advanced GC have been enrolled in this study. No significant safety concerns were observed. Most frequent adverse event was injection site reactions, fatigue and rush (27.8% in 5 out of 18 pts respectively). In terms of efficacy, 3 pts (16.7%) had partial response (PR) and 6 pts (33.3%) had stable disease (SD). The median progression-free survival (PFS) was 1.7 months[1] and median overall survival (OS) was 3.6 months[1]. Of note, for the patients with SD or PR, the median PFS was 13.1 months[1] and median OS was 18.6 months.

These results suggest that acceptable safety profile and clinical response of a combination of OTSGC-A24 and nivolumab may provide beneficial effect for a maintenance therapy for pts with unresectable or metastatic GC.

[1] The data in the abstract was updated at the time of poster presentation as follows.

- Median PFS and OS were updated from 1.7 to 1.64 months and from 3.6 to 5.98 months, respectively.
- Median PFS at the pts with SD or PR was also updated from 13.1 to 13.50 months.

The abstract has been published online in ESMO website.
https://cslide.ctimeetingtech.com/esmo2022/attendee/confcal_2/presentation/list?q=da+vinci
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