OncoTherapy Science, Inc.
January 18, 2017

Poster presentation at 2017 Gastrointestinal Cancers Symposium (ASCO GI)
on Phase 1 Clinical Study of OTS103/104 (OCV-C02) for colorectal cancer

The Phase 1 Clinical Study of OTS103/104 (OCV-C02), a mixture of two peptide vaccines derived from two oncoproteins frequently transactivated in various types of cancer including colorectal cancer, which OncoTherapy Science, Inc. (President & CEO: Masaharu Mori) out-licensed to Otsuka Pharmaceutical Co., Ltd. (Head office: Chiyoda-ku, Tokyo, President and CEO: Tatsuo Higuchi; hereinafter, "Otsuka") has been conducted by Otsuka. The poster describing the results of this trial is going to be presented and the abstract has been published as below.
Otsuka has completed this trial by announcing the abstract of this poster presentation.

【Abstract】

Phase 1 trial of OCV-C02, a peptide vaccine for metastatic colorectal cancer patients refractory to all standard chemotherapies.

Background: OCV-C02 is a peptide vaccine consisting of 2 peptide epitopes derived from ring finger protein 43 and translocase of outer mitochondrial membrane 34. In colorectal cancer (CRC), they are upregulated in approximately 80% of tumor tissues. This study was conducted to assess safety, preliminary efficacy and immunological responses to OCV-C02.

Methods: Key eligibility criteria for this open label, sequential cohort, dose escalation study were patients (pts) with unresectable metastatic CRC (mCRC) refractory to all standard chemotherapies and HLA-A*24:02. Pts in cohorts 1 to 4 received OCV-C02 0.3, 1, 3 and 6 mg/body respectively, subcutaneously, on days 1, 8, 15 and 22 of the 28-day treatment cycle. Cycle was repeated in pts without progressive disease, until occurrence of unacceptable toxicity or disease progression. Primary endpoint was dose limiting toxicity (DLT) that was defined as treatment-related ≥grade 3 or 4 hematological or ≥grade 3 non-hematological adverse events (AEs) observed from days 1 to 29 of Cycle 1. Secondary endpoints were treatment emergent AEs (TEAEs), efficacy and immunological responses. Efficacy was evaluated by overall response rate, disease control rate (DCR), time to treatment failure (TTF) and overall survival (OS). Immunological responses were evaluated by cytotoxic T lymphocytes (CTL) and delayed-type hypersensitivity (DTH).

Results: A total of 24 pts were treated. No DLT occurred in cycle 1 and no major safety issues throughout the trial. All pts had ≥1 TEAE. Frequently reported TEAEs included injection site

reaction (25%), vomiting (25%), decreased appetite (20.8%) and pyrexia (16.7%). More than 50% of TEAEs were of grade 1 or 2 in severity. None achieved complete or partial response. Six pts had stable disease and DCR were 16.7%, 50% and 33.3% for cohorts 2, 3 and 4, respectively. TTF was 1.8, 0.9, 2.3 and 1.6 months and OS was 7.9, 11.6, 8.4 and 7.4 months for cohorts 1, 2, 3 and 4, respectively. CTL and DTH responses following vaccination were observed across the 4 cohorts.

Conclusions: OCV-C02 at 0.3 to 6 mg/body exhibited a safe and well tolerated profile, and showed immunological responses in mCRC pts refractory to all standard chemotherapies.

(URL: http://meetinglibrary.asco.org/content/174849-195)