**Title**

Updated Results from a Multicenter, Single-Arm, Phase 2 Study of CS1001, an Anti-Programmed Death-Ligand 1 (PD-L1) Human Monoclonal Antibody (mAb), in Patients (pts) with Relapsed or Refractory Extranodal Natural Killer/T Cell Lymphoma (R/R ENKTL)

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**Background**

ENKTL is a rare type of non-Hodgkin lymphoma (NHL) with an aggressive clinical course and poor prognosis, accounting for 3-10% of NHL in Asia and South America. Epstein-Barr virus

infection is one of the etiology and characteristics of ENKTL, which induces immune tolerance by upgrading PD-L1 expression in tumor cells. Blocking the PD-1/PD-L1 pathway could, therefore, be an effective treatment for ENKTL. Here we report the updated results from CS1001, a first full-length, fully human IgG4 mAb directed against PD-L1, for the treatment of R/R ENKTL.

**Method**

This is a multicenter, single-arm, Phase 2 study to evaluate CS1001 monotherapy in R/R ENKTL. Pts aged 18-75 yrs with R/R ENKTL failing prior asparaginase-based chemotherapy or chemoradiotherapy were eligible. All the pts received CS1001 1200 mg IV Q3W. The primary endpoint was ORR assessed by an independent radiological review committee (IRRC) per Lugano 2014 criteria. Key secondary endpoints included ORR assessed by investigators, CR and PR rates, DoR, PFS rate, OS rate and safety.

**Result**

As of Feb 19, 2020, 38 pts (male: 60.5%; median age: 48 yrs, range: 30-74) were enrolled with a median follow-up of 10.4 (range: 0.9+-19.7+) months. 14 pts (36.8%) remained on treatment. Among the 35 pts in the efficacy analysis set, the investigator-assessed ORR was 42.9% (15/35, 95% CI: 26.3-60.6). 11 pts (31.4%, 95% CI: 16.9-49.3) achieved CR and 4 pts (11.4%, 95% CI: 3.2-26.7) achieved PR. The mDoR was 16.8 (range: 1.0-16.8) months. The mOS was 14.0 (range: 0.9-19.7) months and 1-year OS rate was 58.1% (95% CI: 36.7-74.4). The IRRC assessments will be reported in the conference presentation.

The median duration of treatment was 12.1 (range: 3.0-77.3) wks. 27 pts (71.1%) had treatment-related AEs (TRAEs), 6 (15.8%) of whom had grade (G) ≥3 TRAEs. The most common TRAEs were pyrexia (9, 23.7%) and WBC decreased (6, 15.8%). Nine pts (23.7%) reported SAEs, 2 of whom had treatment-related SAEs (G4 sinus node dysfunction and G1 myositis, both recovered). Seven pts (18.4%) reported immune-related AEs (irAEs), 2 of whom had G3 irAEs (hypothyroidism and rash). Two pts had TRAEs that led to treatment withdrawal (one with G1 myositis and G1 troponin T increased, one with G2 facial nerve disorder). No CS1001-related death was reported.

**Conclusion**

In this study, CS1001 was well-tolerated and demonstrated robust efficacy with high CR rate and durable responses in R/R ENKTL pts. The promising safety and efficacy profiles of CS1001 support further clinical development in this indication.

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