CS1001, an anti-PD-L1 antibody, combined with Standard of Care (SOC) Chemotherapy for First Line (1L) Advanced GC/GEJ and ESCC: Preliminary Results from 2 Phase 1b Cohorts of CS1001-101 Study

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Background:
CS1001-101 is an open label, multi-center study to evaluate the efficacy and safety of CS1001, an anti-PD-L1 mAb, as mono or combo therapy in patients (pts) with solid tumors or lymphomas. CS1001+XELOX regimen for 1L GC/GEJ and CS1001+CF regimen for 1L ESCC pts were evaluated in this study and preliminary results are reported herein.

Methods:
Pts with systemic therapy naïve GC/GEJ and ESCC were eligible. GC/GEJ pts received CS1001+XELOX (CS1001 1200 mg Q3W, Oxaliplatin: 130 mg/m^2, IV, D1/cycle, up to 6 cycles, Capecitabine: 1000 mg/m^2/time, bid, oral, D1-14/cycle, up to 6 cycles). ESCC pts received

CS1001+CF (CS1001 1200 mg Q3W, Cisplatin: 80 mg/m^2, IV, D1/cycle, up to 6 cycles, 5-fluorouracil: 800 mg/m^2/day, IV, D1-5/cycle, up to 6 cycles).

Results:

As of 19 Feb 2020, 29 GC/GEJ and 39 ESCC pts were treated, with a median treatment duration of 232 and 172 days, respectively. 22 (GC/GEJ) and 23 (ESCC) pts discontinued treatment. The ORR was 62% and 68%, and mDOR was 11.3 months and unreached, mPFS was 8.3 and 9.0 months for the 2 cohorts, respectively (Table). In GC/GEJ cohort, 28 (97%) pts reported CS1001-related AEs (TRAEs) and 14 (48%) pts had G≥3 TRAEs. 2 pts had TRAEs leading to CS1001 withdrawal: hypothyroidism and pneumonia. In ESCC cohort, 34 (87%) pts had TRAEs and 16 (41%) pts had G≥3 TRAEs. 2 pts had TRAEs leading to CS1001 withdrawal: hyponatraemia and pneumonitis. A CS1001-related death was reported in ESCC cohort.

Outcome, n (%)	**GC/GEJ (N=29)**	**ESCC (N=37*)**
ORR	18 (62)	25 (68)
PR	18 (62)	25 (68)
SD	6 (21)	8 (22)
PD	3 (10)	2 (5)
DCR	24 (83)	33 (89)
mDoR (month, range)	11.3 (1.0+, 14.1+)	NA (0.03+, 13.3+)
mPFS (month, range)	8.3 (1.4, 16.1#)	9.0 (2.0, 15.2#)
mOS (month, range)	17.0 (1.4,18.7#)	NA (2.5,18.2#)

* 2 ongoing pts have not reached the first post-baseline tumor assessment time and were excluded from the efficacy analysis.

for the max value from censored pts.

Conclusions:

CS1001 in combination with SOC chemotherapy demonstrated high and durable anti-tumor activities with a tolerable safety profile. These results supported further evaluation of CS1001+XELOX in GC/GEJ and CS1001+CF in ESCC pts in 2 ongoing randomized Phase 3 studies in China (NCT03802591 and NCT04187352).

Registration Number: NCT03312842