Title:

Platinum-based chemotherapy (chemo) with CS1001, an anti-PD-L1 antibody, for first-line advanced NSCLC: preliminary results from Phase Ib cohorts of CS1001-101 study

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Background:

Immuno-oncology (IO) monotherapy or combination with platinum-based chemo is the current standard of care for pts with PD-L1 expression ≥ 50% and EGFR, ALK, ROS1, BRAF negative advanced NSCLC in China. CS1001-101 phase Ib study is to evaluate the efficacy and safety of CS1001, anti-PD-L1 mAb, in pts with solid tumors or lymphomas. Here we present the results of 2 cohorts: CS1001 plus platinum-based chemo for 1L advanced NSCLC.

Method:

Pts with non-squamous (nsq)-NSCLC received 4-6 cycles of CS1001 (1200 mg, IV, Q3W), carboplatin (AUC=5), and pemetrexed (500 mg/m^2), followed by maintenance therapy with CS1001 and pemetrexed. Pts with squamous (sq)-NSCLC received

CS1001 (1200 mg, IV, Q3W), carboplatin (AUC=5), and paclitaxel (175 mg/m^2), followed by maintenance therapy with CS1001.

Results:

By July 1st, 2019, 21 nsq-NSCLC and 20 sq-NSCLC pts were treated, with a median treatment duration of 135 and 109 days, respectively. 15 nsq-NSCLC pts remained on the study and 6 discontinued CS1001, 5 due to progressive disease (PD). 17 sq-NSCLC pts remained on the study and 3 discontinued CS1001, 2 due to adverse events (AEs). 10 had partial response (PR) in each cohort, leading to a response rate of 47.6% (nsq) and 58.8% (sq). The median duration of response (mDoR) and median progression-free survival (mPFS) were not reached (Table). In nsq-NSCLC cohort, 18 (85.7%) had CS1001-related AEs and 6 (28.6%) had G≥3 TRAEs. irAEs occurred in 5 pts with the most frequent ones being aspartate aminotransferase (AST) increased (4, ≤G2) and alanine aminotransferase (ALT) increased (3, ≤G2). 18 (90.0%) sq-NSCLC pts had CS1001-related AEs and 5 (25%) had G≥3 TRAEs. irAEs occurred in 3 pts with the most frequent ones being rash (2, ≤G2). AEs that led to CS1001 withdrawn only occurred in 2 sq-NSCLC pts, which were not related to CS1001.

Conclusion:

The combination of CS1001 and platinum-based chemo regimen demonstrated promising anti-tumor activity with a tolerable safety profile. The results of this study support further evaluation of CS1001 and platinum-based chemo in 1L NSCLC. Currently, a randomized phase III study (NCT03789604) of this treatment regimen in pts with chemo-naive advanced NSCLC is recruiting pts in China.

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Outcome, n(%)	**nsq-NSCLC (N=21)**	**sq-NSCLC (N=17)**
ORR	10 (47.6)	10 (58.8)

PR	10 (47.6)	10 (58.8)
SD	9 (42.9)	7 (41.2)
PD	2 (9.5)	0
DCR	19 (90.5)	17 (100)
mPFS (month, range)	NR (1.87^{+}, 8.48^{+})	NR (1.64^{+}, 8.25^{+})
mDoR (month, range)	NR (0.03^{+}, 4.37^{+})	NR (0.03^{+}, 6.28^{+})

+ is for the mini/max value from censored pts.