# 1711 - Preliminary safety, pharmacokinetics (PK) and efficacy results from a phase I study of CS1001, an anti-programmed death ligand-1 (PD-L1) monoclonal antibody (mAb) in patients (pts) with advanced tumors


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**Background**
Anti-PD-L1 mAbs have demonstrated anti-tumor activities in multiple indications. CS1001 is the first full-length, fully human anti-PD-L1 mAb developed by OMT transgenic animal platform, which mirrors natural IgG4 human antibody with expected PK profiles, and may potentially reduce the risk of immunogenicity and toxicity in pts.

**Methods**
A phase I, multi-center study was conducted to evaluate the safety, tolerability, PK and anti-tumor activity of CS1001 in pts with advanced tumors. A 3 + 3 dose-escalation design was undertaken. Pts received CS1001 intravenously once every three week (Q3W). Safety and tolerability were assessed by monitoring adverse events (AEs). Tumor assessments were performed per RECIST v1.1 (solid tumors) or Lugano 2014 (lymphomas).

**Results**
As of 8 Apr 2018, a total of 19 Asian pts [median age 50 (31–74) yrs] with advanced tumors were treated by CS1001 Q3W across 5 dose-escalating cohorts (3 mg/kg, N = 3; 10 mg/kg, N = 4; 20 mg/kg, N = 3; 40 mg/kg, N = 3; and 1200 mg, N = 6). All pts had received at least 1 prior line of anti-cancer treatment (median 2 [1–7]). Median duration of study treatment was 63 (6–172) days. 14 pts remain on study. No dose-limiting toxicity was observed, and maximum tolerated dose was not reached. The most frequent treatment-emergent AEs were grade (G) 1/2 anemia (n = 7), nausea (n = 6), decreased appetite (n = 5), blood bilirubin increased (n = 4), protein urine present (n = 4), white blood cell count decreased (n = 4) and proteinuria (n = 4). Immune-related AEs (G1-3) occurred in 5 pts. No treatment-related serious AE was reported. PK analysis was conducted using observed CS1001 serum concentrations from 16 pts across all 5 cohorts. The PK of CS1001 was linear and the terminal elimination half-life was about 12 days. Among 12 efficacy evaluable pts, four

achieved unconfirmed partial response and all remain on treatment. Three additional pts achieved a best overall response of stable disease.

**Conclusions**

CS1001 appears to be generally well tolerated in pts with advanced tumors, with a linear PK profile. The preliminary safety profile and anti-tumor activity support continued exploration and development of CS1001.

**Clinical trial identification**

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