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GEMSTONE-201: pre-planned primary analysis of a multicenter, single-arm, phase 2 study of sugemalimab (suge) in patients (pts) with relapsed or refractory extranodal natural killer/T cell lymphoma (R/R ENKTL).

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Background: R/R ENKTL is a rare and aggressive type of non-Hodgkin’s lymphoma. Responses to chemotherapy after failure of prior asparaginase-based regimen were not durable with a median OS of < 7 months (mos) and 1-year OS rate of < 20% (Lim et al, Ann Oncol 2017; Bellei et al, Haematologica 2018). The only targeted therapy approved in China for R/R peripheral T cell lymphoma (ENKTL included) showed an ORR of 18.8% and a CR rate of 6.3% (Shi et al, Ann Oncol 2015). Here, we present the primary analysis from GEMSTONE-201, the largest registrational study reported to date to evaluate an anti-PD-L1 mAb in R/R ENKTL. Suge received breakthrough therapy designation from US FDA in 2021 for adult R/R ENKTL pts based on preliminary data of this study.

Methods: Pts with ECOG PS of 0/1 and histologically confirmed ENKTL who failed prior asparaginase-based regimen were enrolled. Pts accepted suge at 1200 mg Q3W, iv, for up to 24 mos, until progression, death, or withdrawal from study. The primary endpoint was ORR (CR+PR) assessed by independent radiological review committee (IRRC) per Lugano 2014 criteria. Key secondary endpoints included investigator-assessed ORR, CR and PR rate, DoR assessed by IRRC and investigators, and safety.

Results: As of the data cutoff date, Nov 10, 2021, 80 pts were enrolled and treated (median follow-up of 13.4 mos). Median age was 48 years (range 29-74); 64% were males; 74% had ECOG PS of 1 at baseline; 68% had stage IV disease; about half (49%) received ≥ 2 lines of prior systemic therapy. The median duration of treatment was 5.2 mos (range 0.7-37.4); 23 pts remained on treatment. Among the 78 evaluable pts as per IRRC, ORR was 46.2% (95% CI: 34.8%, 57.8%); 29 (37.2%) pts achieved CR; median DoR was not reached (NR); 12-mo DoR rate was 86%. Investigator’s assessments in 79 evaluable pts were consistent with IRRC results, i.e. ORR of 45.6% (95% CI: 34.3%, 57.2%), 24 (30.4%) pts with CR, and median DoR of NR. The 1- and 2-year OS rates were 68.6% and 54.6%, respectively; median OS was NR (range 0.9-37.2^{+} mos).

Of all pts, 96% (n = 77) had at least one AE. The most common AEs were pyrexia and WBC decreased (n = 24 each, 30%). Grade ≥ 3 AEs occurred in 31 (39%) pts. Suge-related AEs occurred in 61 (76%) pts and were mostly (60%) Grade 1/2. The most common irAE assessed by sponsor was hypothyroidism (n = 13, 16%). SAEs occurred in 18 (23%) pts; 5 (6%) pts had suge-related SAEs which had all been resolved (1 with sequelae). Fatal AEs occurred in 5 (6%) pts and none were suge-related as assessed by investigators.

Conclusions: Suge has demonstrated deep and durable anti-tumor activity in R/R ENKTL pts, with a high CR rate and a promising OS benefit trend comparing to historical data. Suge had a well-tolerated safety profile and no new safety signals were detected. Primary analysis indicates that suge could provide a new treatment option to R/R ENKTL pts.

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