Cemiplimab, a human monoclonal anti-PD-1, in patients (pts) with advanced or metastatic hepatocellular carcinoma (HCC): Data from an expansion cohort in a phase I study


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Background: For pts with unresectable HCC, systemic therapy options are limited. Sorafenib is approved in the US and Europe for HCC treatment. For pts who progress on sorafenib, regorafenib and nivolumab are approved as second-line therapy. Cemiplimab (REGN2810) has demonstrated encouraging efficacy and safety profile in a Phase 1 dose escalation study in pts with advanced malignancies (NCT02383212). We present results of the Phase 1 HCC expansion cohort.

Methods: HCC pts who were not candidates for surgery and had progressed on, could not tolerate, or refused first-line systemic therapy received cemiplimab 3 mg/kg Q2W for up to 48 weeks. The main objectives were to evaluate the safety, tolerability, and antitumour activity of cemiplimab.

Results: As of 1 Sept, 2017, 26 pts were enrolled (25 M/1 F), median (range) age was 65 (40–78) years; 24 pts (92.3%) had ≥1 prior systemic therapy; ECOG performance status was 1 in 19 pts (73.1%), 0 in 6 (23.1%) and missing in 1. Median duration of follow-up was 7.2 (range: 1.8–15.5) months. By investigator assessment, 5 pts (19.2%) had partial response, 14 (53.8%) had stable disease, 6 (23.1%) had progressive disease and 1 was not evaluable. Median progression-free survival was 3.7 months (95% CE: 2.3–9.1). Five pts (19.2%) completed the planned 48-week treatment, and 21 (80.8%) discontinued prematurely, mainly due to disease progression (65.4%). Three of the 5 pts who completed planned treatment remained without disease progression at the last response assessment. The most common treatment-emergent adverse events (TEAEs) of any grade were fatigue (26.9%), decreased appetite, increased aspartate aminotransferase (AST), abdominal pain, pruritus, and dyspnea (each 23.1%). Grade ≥3 TEAEs occurring in ≥2 pts were hyponatremia (3 pts), autoimmune hepatitis (2 pts) and increased AST (2 pts). Two pts (7.7%) had a TEAE resulting in death: 1 with pulmonary embolism that was considered unrelated to treatment and another with hepatic failure considered possibly related to treatment.

Conclusions: Cemiplimab demonstrated evidence of antitumour activity in pts with advanced or metastatic HCC. The safety profile is comparable with that of other anti-PD-1 inhibitors.

Clinical trial identification: NCT02383212.

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