

Abstract 2097

Preliminary results from subsets of patients (pts) with advanced gastric cancer (GC) and esophageal carcinoma (EC) in a dose-escalation/expansion study of BGB-A317, an anti-PD-1 monoclonal antibody (mAb)

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Background

BGB-A317 is a humanized IgG4 anti-PD-1 mAb that blocks PD-L1/L2 binding to PD-1 restoring T-cell-mediated tumor inhibition. The Fc-hinge region has been engineered to preclude FcγR1-mediated binding to macrophages/myeloid-derived suppressor cells (MDSCs). Upregulation of PD-1/L1 and predominance of macrophages and MDSCs have been reported in GC and EC supporting the rationale of evaluating BGB-A317 in pts with GC or EC.

Methods

This ongoing, open-label, dose-escalation/expansion study is being conducted to evaluate the safety, tolerability and anti-tumor activity of BGB-A317 in pts with advanced solid tumors. Pts with histologically confirmed advanced GC or EC were eligible and treated with BGB-A317 at 2 mg/kg or 5 mg/kg every two weeks (Q2W) or Q3W. Adverse events (AEs) were assessed per NCI-CTCAE v4.03 and tumor assessments were performed approximately every two months via RECIST v1.1.

Results

As of 6 MAR 2017, 55 pts [median age 62 yrs (22-81)] with recurrent/refractory GC (n=28) or EC (n=27) were treated. Most were Caucasian (n=36) and all pts had received ≥1 prior line of anti-cancer treatment. Median treatment duration was 51 days (5–363); 19 pts remain on study. The most common treatment-emergent AEs were fatigue (n=11), nausea (n=9) and dysphagia (n=8); 46% pts experienced AEs ≥Grade (Gr) 3 but none were treatment related. One serious AE (diarrhea [Gr 2]) was considered related to treatment by investigators. Of the 47 evaluable pts, the disease control rate, defined as the proportion of pts who achieved complete or partial response (CR or PR) or stable disease (SD), is 32%. PRs have been reported in 3 pts (GC=2; EC=1) with duration of responses being 96, 125 and 188 days respectively, 2 pts are still on treatment; 5 initial

documentations of PRs awaiting confirmation (GC, n=2; EC, n=3) have been reported in 12 pts with SD (GC=5; EC=7).

Conclusions

BGB-A317 appears to be generally well tolerated in pts with recurrent/refractory GC or EC. The preliminary safety profile and anti-tumor activity appear to be consistent with other checkpoint inhibitors and support continued exploration and development of BGB-A317 in pts with advanced GC or EC.

Clinical trial identification

NCT02407990, March 26, 2015