Abstract 2099

# Preliminary results from a subset of patients (pts) with advanced ovarian cancer (OC) 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 OC supporting the rationale of evaluating BGB-A317 in pts with OC.

**Methods**

An open-label, multi-center, 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 OC were eligible and treated at different dose levels (0.5, 2, 5, 10 mg/kg intravenously [IV] every 2 weeks [Q2W] in dose escalation, or at 2 or 5 mg/kg IV Q2W or Q3W, or 200 mg IV Q3W in dose expansion, or 5 mg/kg IV Q3W in indication expansion). Tumor assessments, including CA125, occurred approximately every 2 months and response was collected according to both RECIST 1.1 and GCIG criteria. Adverse events (AEs) were assessed per NCI-CTCAE v4.03.

**Results**

As of 6 Mar 2017, 51 pts [median age 62 (19–80) yrs] with recurrent/refractory OC were enrolled. Most pts were Caucasian (88%), all had received ≥1 prior line of anti-cancer treatment (median 3 [1–12]). Median duration of treatment was 68 (22–446) days; 7 pts remain on study. The most common treatment-emergent AEs were nausea (37%), fatigue (28%), and abdominal pain (28%). 49% of pts experienced an AE ≥Grade (Gr) 3; stomatitis (n=1) and diarrhoea (n=1) were Gr 3 AEs considered treatment-related by investigators. Mucosal inflammation, pyrexia and colitis were

serious AEs considered treatment-related by investigators (n=1, each). Among 51 evaluable pts, the disease control rate is 43%; 2 PRs have been reported including 1 pt who remains on study and to date has achieved an 89% reduction in target lesions.

**Conclusions**

BGB-A317 appears to be generally well tolerated in pts with recurrent/refractory OC. The preliminary safety profile and anti-tumor activity are consistent with that observed with other checkpoint inhibitors and support continued investigation of BGB-A317.

**Clinical trial identification**

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