Abstract 2098

Preliminary results from a subset of patients (pts) with advanced head and neck squamous carcinoma (HNSCC) in a dose-escalation and dose-expansion study of BGB-A317, an anti-PD-1 monoclonal antibody (mAb)

Authors: L. Horvath[1], J. Desai[2], S. Sandhu[3], A. O'Donnell[4], A.G. Hill[5], S. Deva[6], B. Markman[7], M.B. Jameson[8], Z. Chen[9], X. Tan[9], J. Hou[10], A. Lim[11]; [1]Medical Oncology, Chris O'Brien Lifehouse, Camperdown, NSW, AU, [2]Medical Oncology, Peter MacCallum Cancer Centre, Melbourne, VIC, AU, [3]Department of Oncology, Peter MacCallum Cancer Center, Melbourne, VIC, AU, [4]Endocrine, Diabetes & Research Centre, Wellington Hospital, Wellington, NZ, [5]Medical Oncology, Tasman Oncology Research, Southport, AU, [6]Internal Medicine, Auckland City Hospital, Auckland, NZ, [7]Department of Oncology, Monash Cancer Center, Monash Health, Melbourne, VIC, AU, [8]Regional Cancer Center, Waikato Hospital, Hamilton, NZ, [9]Oncology, BeiGene (Beijing) Co. Ltd, Beijing, CN, [10]Immunoncology, BeiGene USA, Inc, Emeryville, US, [11]Oncology, Linear Clinical Research, Nedlands, AU

Background

BGB-A317 is a humanized IgG4 anti-PD-1 mAb that blocks PD-L1/PD-L2 binding to PD-1 restoring T-cell mediated tumor response. The Fc-hinge region has been engineered to preclude FcγR1 mediated binding to macrophages/myeloid-derived suppressor cells, a potential mechanism of PD-1 bound T-cell clearance. Regulatory $Foxp3^+$ T-cells and $PD\text{-}1^+$T-cell infiltration in the tumor microenvironment have been reported in HNSCC supporting the rationale for evaluation of BGB-A317 in pts with HNSCC. Here we present the preliminary results from a subset of pts with HNSCC treated with BGB-A317.

Methods

This ph 1, open-label, multi-center, dose-escalation/expansion study was conducted to evaluate the safety, tolerability, and anti-tumor activity of BGB-A317 in pts with advanced solid tumors. Pts with histologically confirmed advanced HNSCC who progressed following standard of care treatment were eligible to receive BGB-A317 administered at a dose of 5 mg/kg Q3W. Adverse events (AEs) were assessed per NCI-CTCAE v4.03. Tumor assessments were performed Q9W per RECIST v1.1.

Results

As of 6 Mar 2017, 18 pts with recurrent HNSCC were enrolled (median age, 63 years [25-78]). Most pts were male (89%), Caucasian (67%) and had received ≥2 prior lines of anti-cancer treatment. The median treatment duration for BGB-A316 was 104 days (30-245); 7 pts remain on study. Most treatment-emergent AEs were Grade (Gr) 1/2 in severity and the more common AEs were fatigue (n=6), constipation (n=3) and ear discomfort (n=3). Eleven unique AEs ≥Gr 3 were reported in 7 pts: dysphagia, nausea salivary gland enlargement, dyspnea, pleuritic pain, aspiration pneumonia, infection-related COPD exacerbation, parotitis, ocular hyperemia, and

wound hemorrhage. A partial response (PR) has been confirmed in 1 pt, and 8 pts have stable disease (SD,) including 2 unconfirmed PRs. The disease control rate, defined as the proportion of pts who have achieved CR, PR and SD, is 50%.

Conclusions

BGB-A317 appears to be well tolerated in pts with recurrent HNSCC. The preliminary safety profile and anti-tumor activity support continued investigation of BGB-A317 in this setting.

Clinical trial identification

NCT02407990, March 26, 2015