The combination of COM701 + nivolumab demonstrates preliminary antitumor activity in patients with metastatic breast cancer.

Background: COM701, a novel, first in-class immune checkpoint inhibitor, anti-PVRIG, that leads to activation of T-cells. PVRL2, the ligand of PVRIG, is highly expressed in breast cancer. We have reported preliminary antitumor activity with objective responses [partial responses and a complete response] in patients with solid tumors (MSS-CRC, platinum resistant OVCA, anal squamous CA, MSSendometrial cancer] who received COM701 +/- nivolumab + BMS986207 (anti-TIGIT antibody) (1,2). We present results from the dose expansion cohort with COM701 + nivolumab in patients with metastatic breast cancer (MBC) (NCT03667716).

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Methods: We enrolled 17 patients with MBC, all received COM701 20 mg/kg + nivolumab 480 mg, both IV Q4 weeks. Primary objectives were to determine safety and tolerability and secondary objective was to evaluate preliminary antitumor activity. Key inclusion criteria: Age ≥ 18 years, histologically confirmed locally advanced or MBC (regardless of ER/PR and HER2 status) with measurable disease, who exhausted all available 1 2 3 4 5 6 7 8 9 10 11 12 10 13 14 standard treatments. Prior treatment with anti-PD-(L)-1, anti-CTLA-4 ICI was permissible. Key exclusion criteria: history of immune-related events that to immunotherapy treatment discontinuation, history of pneumonitis. Safety was evaluated per CTCAE v4.03 and investigator responses per RECIST v1.1.

Results: Treatment related adverse events reported in 12/17 (71%) patients, the majority [11/12 pts] were ≤G2, the most frequent was diarrhoea in 3 pts (all G1). One patient with G3 TRAE of pneumonitis (recovered), no ≥G4 TRAEs. Tumor assessments (by site): PD-L1 negative 9/17 (53%), positive/present 2/17 (12%), missing/not assessed 6/17 (35%); TMB low (

Conclusion: The combination is well tolerated with no dose-limiting toxicity. Encouraging preliminary antitumor activity with PR and CR reported in heavily pretreated patients with TMB-low MBC. Additional clinical and translational data will be presented at the conference. Data extract 06/09/2023.

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