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Abstract CT130: Neoadjuvant botensilimab plus balstilimab in MMR proficient and deficient early stage cancers: First results of the pan-cancer NEOASIS study FREE

Peter G. de Gooyer; Lauren D. van den Dungen; Marnix H. Geukes Foppen; Cecile Grootscholten; Simone Dokter; Thomas R. de Wijkerslooth; Brechtje A. Grotenhuis; Caroline A. Drukker; Winan J. van Houdt; Sara Balduzzi; John B. Haanen; José G. van den Berg; Marleen Kok; Myriam Chalabi

+ Author & Article Information

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Abstract

Background:

Dual immune checkpoint inhibition with botensilimab (bot, Fc-enhanced anti-CTLA4) plus balstilimab (bal, anti-PD1) has shown promising efficacy across a variety of classically non-immunogenic tumors, such as mismatch-repair proficient (pMMR) colorectal cancers (CRC) and sarcomas. In the adaptive, pan-cancer, phase II NEOASIS study, we hypothesize a high rate of pathological responses to neoadjuvant bot/bal in both pMMR and MMR deficient (dMMR) tumors. Here we present the safety and efficacy data from the safety run-in cohorts of the NEOASIS study.

Methods:

Patients (pts) with non-metastatic solid tumors were assigned to the dMMR or pMMR safety run-in cohorts based on IHC assessment of MMR proteins and were planned for surgery within 8 weeks of start of study treatment. Each cohort consisted of 10 pts. Patients were treated with bal 450mg on D1 and D22 plus bot on D1, at a dose of 25mg for the first 5 pts and 50mg for the next 5 pts. The primary objective of the safety run-ins was safety. Secondary objectives included pathological response (≤50% residual viable tumor, RVT), major pathological response (MPR, ≤10% RVT) and pathological complete response (pCR).

Results:

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A total of 20 pts were treated: 10 with a dMMR and 10 with a pMMR tumor. The dMMR cohort included 9 pts with CRC and 1 with duodenal cancer (25mg bot cohort). The pMMR cohort

consisted of pts with triple negative breast cancer (TNBC, *n*=6), ER+ BC (*n*=2), Merkel cell carcinoma (MCC, *n*=1) and sarcoma (*n*=1). No dose-limiting toxicities occurred at either 25mg or 50mg bot doses and all pts underwent timely surgery. One grade 3 immune-related adverse event (irAE, hepatitis) was observed in the 50mg cohort. Grade 1-2 irAEs occurred in 75% of pts, with fatigue (25%), dermatitis (20%) and hypothyroidism (15%) being the most frequent. IrAEs led to omission of the second dose of bal in 2 (10%) pts. All 5 pts in the pMMR 25mg bot cohort had a pathological response including 2 pts with a pCR (MCC, TNBC) and 3 pts with an MPR (sarcoma, ER+ BC, TNBC). In the pMMR bot 50 mg cohort, 2 pts had a pathological response, both an MPR (2 TNBC). In the dMMR 25mg bot cohort, 4 pts with CRC had a pathological response, including 2 pCR, 1 MPR and 1 PR. The only pt with limited response (duodenal cancer) had suspicion of peritoneal metastases per-operatively and while biopsies revealed no RVT in these lesions, the primary tumor showed limited response. All 5 CRC pts treated with bot 50mg had a pCR.

Conclusion:

Data of the safety run-in of 20 pts show that neoadjuvant bot/bal was safe and did not lead to surgical delays. In addition, the observed pathological responses are encouraging and suggest a potential for neoadjuvant immunotherapy using bot/bal across tumor types, including pMMR BC and sarcoma. Accrual in efficacy baskets for both dMMR and pMMR tumors is currently ongoing at the bot 50mg dose level.

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