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ORAL ABSTRACTS

624.HODGKIN LYMPHOMAS AND T/NK CELL LYMPHOMAS: CLINICAL AND EPIDEMIOLOGICAL

IMM01 Plus Tislelizumab in Prior Anti-PD-1 Failed Classic Hodgkin Lymphoma: An Open Label, Multicenter, Phase 2 Study (IMM01-04) Evaluating Safety As Well As Preliminary Anti-Tumor Activity

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Background: IMM01, a recombinant SIRPa-Fc fusion protein, can activate macrophages to enhance anti-tumor activity by blocking CD47-SIRPa interaction. IMM01 showed unique property of weak human erythrocyte conjugation in preclinical studies, and low incidence of anemia in early clinical trials with no need for a priming dose. IMM01 plus tislelizumab has the potential to augment both innate and adaptive anti-tumor immune responses.
Methods: IMM01 at a dose of 2.0mg/kg was administered once a week and tislelizumab (200mg) was administered once every 3 weeks. 2.0mg/kg of IMM01 was determined as RP2D when combo with tislelizumab in patients with advanced solid tumors (e.g. SCLC, NSCLC, HNSCC). The primary objective of this phase 2 study was to evaluate the preliminary anti-tumor activity as well as safety of IMM01 plus tislelizumab in patients with classic Hodgkin lymphoma (cHL) who have failed prior check point inhibitor treatment. A total of 32 patients are planned to be enrolled in this phase 2 study according to pre-plan statistical assumption. Adverse events (AEs) were reported according to CTCAE v5.0. The anti-tumor activity was assessed according to the Lugano 2014 criteria.
Results: As of 19 Jul 2023, 20 cHL patients (median age: 34 years, range: 23-73 years) who have failed prior anti-PD-1 treatment were enrolled, 18 patients were relapsed on anti-PD1, and 2 patients were anti-PD1 refractory. 18 (90%) patients received 3 or more prior lines of therapy. All patients had Ann Arbor stage III-IV disease. Among total 14 evaluable patients, 2 patients achieved complete response (CR), 7 patients achieved partial response (PR). The objective response rate (ORR) and disease control rate (DCR) were 64.3% and 100%, respectively. Among the responders, 5 patients failed prior tislelizumab. As of 7 Jul 2023, for all 20 treated patients, treatment-related adverse events (TRAEs) of any grade occurred in 18 (90.0%) patients. The most frequent TRAEs (≥ 20%) were platelet count decreased (50.0%), lymphocyte count decreased (35.0%), anemia (30.0%), white blood count decreased (30.0%), neutrophil count decreased (25.0%) and Gamma-glutamyl transferase increased (20.0%). Most TRAEs were grade 1-2. TRAEs of grade ≥3 occurred in 7 (35%) patients, including lymphocyte count decreased (30.0%), platelet count decreased (10.0%), neutrophil count decreased (5.0%) and white blood count decreased (5.0%). 1 patient had treatment related SAE (platelet count decreased, grade 3) and recovered without bleeding. There was no reported hemolytic anemia or hemolysis in any of the patients. No TRAEs leading to drug discontinuation or death.
Conclusions: IMM01-04 showed a robust anti-tumor effectivity with a well-tolerated safety profile in prior anti-PD-1 failed classical Hodgkin Lymphoma patients. The phase 2 study is ongoing.

Disclosures Zhao: *ImmuneOnco Biopharmaceuticals (Shanghai) Inc:* Current Employment. **Meng:** *ImmuneOnco Biopharmaceuticals (Shanghai) Inc:* Current Employment. **Xu:** *ImmuneOnco Biopharmaceuticals (Shanghai) Inc:* Current Employment.

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