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POSTER ABSTRACTS

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

Efficacy and Safety of Pembrolizumab and Chemotherapy in Newly-Diagnosed, Early Unfavorable or Advanced Classic Hodgkin Lymphoma: The Phase 2 Keynote-C11 Study

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Introduction: The phase 2 KEYNOTE-C11 study (NCT05008224) evaluates the safety and efficacy of pembrolizumab (pembro) followed by AVD chemotherapy (chemotherapy) and pembro consolidation in patients with untreated, early unfavorable or advanced-stage cHL without radiotherapy. The criteria for study continuation were met at the pre-specified interim futility analysis after pembrolizumab induction and 2 cycles of AVD, with approximately 3 months of follow-up. We present results of an analysis of efficacy and safety in all enrolled patients with an additional 8 months of follow-up.
Methods: Patients aged ≥18 years with newly-diagnosed, early unfavorable or advanced stage cHL, received induction with pembrolizumab 200 mg IV on d1 Q3W for 3 cycles, followed by a PET2 to determine response. All patients then received 2 cycles standard dose AVD on d1 and 15 for 2 cycles (chemotherapy phase 1) followed by PET3. Patients who were PET3-negative (Deauville score 1-3) received 2-4 additional cycles AVD based on bulk. Patients aged ≤60 years who were PET3-positive (Deauville score 4-5) received 2-4 cycles of escalated bleomycin plus etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, and prednisone (escBEACOPP, chemotherapy phase 2). All patients then received consolidation pembrolizumab 400 mg Q6W for 4 cycles followed by a PET4 assessment. The primary endpoint for this analysis was investigator assessed PET3-negativity response in all treated patients. A posthoc PET analysis was also performed in the actuarial population of all treated patients who reached PET2 or PET3.
Results: At data cut-off (Apr 5, 2023), the median (range) follow-up was 11.8 months (9.7-17.6). A total of 146 patients with untreated cHL were enrolled. Median (range) age was 34.5 years (18-78); 32 (22%) patients had bulky disease, 84 (57%) and 62 (43%), respectively, had advanced and early unfavorable disease. Of 146 patients, 137 (94%) had completed pembrolizumab monotherapy, 130 of 136 (96%) who proceeded to chemotherapy phase 1 completed chemotherapy phase 1, and 127 of 130 (98%) completed chemotherapy phase 2 (111 [AVD]; 16 [BEACOPP]). The PET2-negativity rate was 29% and 31% in all treated patients (N=146) and the actuarial population (n=137), respectively. The PET3-negativity rate was 70% and 78% in all treated patients (N=146) and the actuarial population (n=131), respectively. The ORR at end of PET2 and PET3 was 78% and 88%, respectively. Grade ≥3 drug related adverse events (AEs) were reported in 23 of 146 (16%) patients who received pembrolizumab alone or at consolidation, 94 of 136 (69%) patients who received AVD, and in 10 of 17 (59%) patients who received escBEACOPP. Immune mediated AEs were reported in 37 (25%) patients who received pembrolizumab alone and

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consolidation, most commonly hyperthyroidism (10%) and hypothyroidism (6%). There were no deaths due to study drug related or immune-mediated AEs.

Conclusion: Pembrolizumab induction followed by chemotherapy continued to be well tolerated in patients with newly-diagnosed, early unfavorable, or advanced-stage cHL, with 70% achieving a PET3-negative response as assessed by investigator after the initial chemotherapy phase. There were no new safety concerns and study is ongoing.

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