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POSTER ABSTRACTS

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

Keynote-B68: Updated Efficacy and Safety of Pembrolizumab Every Six Weeks in Relapsed/Refractory Classical Hodgkin Lymphoma or Primary Mediastinal B-Cell Lymphoma

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Background: Pembrolizumab 200 mg Q3W demonstrated robust antitumor activity and manageable safety in relapsed/refractory (R/R) classical Hodgkin lymphoma (cHL) and R/R primary mediastinal B-cell lymphoma (PMBCL), resulting in FDA approval. Recently, the FDA granted accelerated approval of pembrolizumab 400 mg Q6W in all approved indications based on data in solid tumors. The global Phase 2 KEYNOTE-B68 trial (NCT04875195) evaluates the efficacy and safety of pembrolizumab 400 mg Q6W in patients (pts) with R/R cHL or R/R PMBCL. We previously reported ORR of 65% for pts with R/R cHL, and 50% for pts with R/R PMBCL with approximately 9 months (mo) of follow up. Here we present data from 66 patients (pts) with an additional 6 mo of follow up.
Methods: In this nonrandomized, open-label trial, pts aged ≥18 years with PD-1 inhibitor naïve R/R cHL or PMBCL received 400 mg pembrolizumab Q6W for ≤ 18 cycles, until progression, unacceptable toxicity, or withdrawal. Eligible pts with cHL must have relapsed or failed to respond after ≥1 prior lines of therapy or relapsed or failed to respond after ≥1 prior multiagent lines of therapy, or autologous stem cell transplant (ASCT). Eligible pts with PMBCL must have relapsed or failed to respond after ≥2 prior lines of therapy including rituximab and relapsed or failed to respond to or were ineligible for ASCT. The primary endpoint was ORR per Lugano criteria by investigator. Secondary endpoints were DOR per Lugano criteria by investigator and safety. Exploratory endpoints were PFS per Lugano criteria by investigator and OS. Data cut-off date was May 15, 2023.
Results: At data cut-off, 66 pts (60 R/R cHL, 6 R/R PMBCL) were enrolled. Pts had a median age of 32.5 years (range, 19 to 85), and 35 (53%) were female. Overall, 47 (71%) pts discontinued treatment, 34 (52%) due to progressive disease, 8 (12%) due to ASCT, 2 (3%) due to adverse events (AE), 2 (3%) withdrawals and 1 (2%) due to physician decision. A total of 57 pts with

cHL and 5 with PMBCL had ≥2 prior lines of therapy. The median follow-up was 15.7 mo (range, 7.8 -22.7) for pts with R/R cHL and 17.5 mo (range, 12.0 - 22.2) with R/R PMBCL. The ORR was 66.7% (95% CI, 53.3 -78.3 [35.0% CR; 31.7% PR]) for pts with R/R cHL, and 50% (95% CI, 11.8 -88.2 [33.3% CR; 16.7% PR]) for R/R PMBCL. The median DOR was 16.6 mo (range, 1.6 -17.0) for pts with R/R cHL and 9.7 mo (range, 2.6 -9.7) for R/R PMBCL. Treatment-related AEs occurred in 26 pts with R/R cHL and 2 with R/R PMBCL. The most common treatment-related AEs were hypothyroidism in 8 pts with R/R cHL and 1 with R/R PMBCL, and neutropenia in 3 pts with R/R cHL and 1 with R/R PMBCL. Grade ≥3 treatment-related AEs occurred in 3 (5%) pts with R/R cHL and 1 (17%) with R/R PMBCL. No grade 5 treatment-related AE occurred. Immune-mediated AEs occurred in 14 (23%) pts with R/R cHL and 1 (17%) with R/R PMBCL. Grade 3 infusion-related reactions and immune-mediated AE of toxic epidermal necrolysis occurred in 2 (3%) pts and 1 (2%) pt, respectively, with R/R cHL.
No grade 4-5 immune-mediated AEs occurred in pts with R/R cHL and no grade ≥3 immune-mediated AEs occurred in pts with R/R PMBCL. Antitumor activity is summarized in the Table.
Conclusions: Following 15 months of follow-up the ORR and PFS rates in the cHL patient population have increased, further highlighting the consistency to pembrolizumab 200 mg Q3W as observed in KN-087 and KN-204 patient populations. Additionally, no new safety concerns occurred in either cHL or PMBCL patient populations. This KEYNOTE-B68 trial further demonstrates the continued antitumor activity in patients and confirms the acceptability of Q6W dosing in heme indications.

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Table. Antitumor activity

	R/R cHL N = 60	R/R PMBCL N = 6
ORR, n (%) [95% CI]	40 (66.7) [53.3-78.3]	3 (50.0) [11.8-88.2]
CR	21 (35.0)	2 (33.3)
PR	19 (31.7)	1 (16.7)
Median* DOR mo (range)	16.6 (1.6-17.0+)	9.7 (2.6-9.7)
9-mo DOR rate, %	53.1	66.7
Median OS mo (95% CI)*	NR (NR to NR)	NR (0.1 to NR)
12-mo OS rate, %	89.0	66.7
Median PFS mo (95% CI)*	8.3 (5.6-19.3)	4.1 (0.1 to NR)
12-mo PFS rate, %	38.3	33.3

NR = Not reached; *Kaplan-Meier estimates; "+" no progressive disease at time of last assessment

Figure 1

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