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LONG-TERM FOLLOW-UP OF PATIENTS WITH ADVANCED (UNRESECTABLE/METASTATIC) MELANOMA TREATED WITH FIANLIMAB + CEMIPLIMAB: SUBGROUP ANALYSIS FROM BLINDED INDEPENDENT CENTRAL REVIEW (BICR) EFFICACY ASSESSMENT

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Background: Fianlimab (anti–LAG-3) + cemiplimab (anti–PD-1) has shown a 61% ORR (investigator assessment) and an acceptable risk–benefit profile in patients with advanced melanoma; here, we present efficacy (BICR) from a 23-month median follow-up and safety data.

Patients and Method: Patients with advanced melanoma who were anti–PD-(L)1 treatment-naïve for advanced melanoma were enrolled across three cohorts to receive fianlimab 1600 mg + cemiplimab 350 mg IV Q3W (≤24 months; NCT03005782).

Results: As of 31 October 2023 data cutoff, 98 patients (median age: 68 years; median treatment duration: 36 weeks) were enrolled. Grade ≥3 TEAEs occurred in 47% of patients, serious TEAEs in 39%

and immune-mediated AEs in 39%. Of the 76 (78%) patients who discontinued treatment, 17 (22%) discontinuations were due to TEAEs.

CR rate, ORR and median PFS were 25%, 57% (95% CI 47–67) and 24 months (95% CI 12–NE), respectively. Median time to response and CR were 1.5 and 4.1 months, respectively. DCR, median OS and median DOR were 78% (95% CI 68–85), NR (95% CI 42–NE) and NR (95% CI 23–NE), respectively; 31% of patients completed 1 year of treatment, and 4% completed 2 years.

In patients with prior (neo)adjuvant anti–PD-1 treatment (n=13), CR rate, ORR and median PFS were 31%, 46% (95% CI 19–75) and NR (95% CI 1–NE), respectively. There were no differences in median OS in neoadjuvant/adjuvant pretreated (NAP; NR [95% CI 26–NE]) vs NAP-naïve (NR [95% CI 31–NE]) patients. Median PFS in NAP and NAP-naïve patients was NR (95% CI 3–NE) and 24 months (95%CI 12–NE), respectively. In patients with: liver metastases (n=20), CR rate, ORR, median PFS and median OS were 0%, 35% (95% CI 15–59), 7 months (95% CI 1–NE) and 15 months (95% CI 9–NE), respectively; LDH>ULN (n=31), CR rate, ORR, median PFS and median OS were 13%, 55% (95% CI 36–73), 14 months (95% CI 4–NE) and 42 months (95% CI 23–NE), respectively; any-grade drug-related adrenal insufficiency (n=12), CR rate, ORR, median PFS and median OS were 58%, 92% (95% CI 62–100), NR (95% CI 8–NE) and NR (95% CI 21–NE), respectively.

Conclusions: With longer follow-up, fianlimab + cemiplimab showed persistent high clinical activity and a generally acceptable safety profile in patients with advanced melanoma, and across high-risk subgroups. CR prevalence increased over time.

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