Background

Objective: To assess the safety profile of fianlimab + cemiplimab in patients with advanced melanoma.

Methods

Patients with advanced melanoma, and a confirmatory expansion cohort to assess efficacy were randomized to fianlimab + cemiplimab or cemiplimab monotherapy. The primary endpoint was the rate of treatment-emergent adverse events (TEAEs) of any grade.

Results

Cohort 15 (N=40)

- 96.3% of patients experienced treatment-emergent AEs (TEAEs) of any grade.
- Rate of grade ≥3 treatment-related adverse events (AE) was 20.0%.

Conclusions

- Fianlimab + cemiplimab combination treatment for patients with advanced melanoma.
- Fianlimab blocks LAG-3 and major histocompatibility complex (MHC) class II–driven immune checkpoint signaling.
- Combination anti–lymphocyte activation gene-3 (LAG-3) and anti–programmed cell death-1 (PD-1) checkpoint blockade results in an impressive overall response rate (ORR) of 37.5% in advanced melanoma.

Safety A

- The safety profile of fianlimab + cemiplimab combination treatment was comparable to that of cemiplimab monotherapy.
- Most adverse events were grade 1 or 2 and were consistent with the class II–driven immune checkpoint signaling.
- Patients were monitored for up to 51 weeks.