Nivolumab plus relatlimab vs nivolumab in previously untreated metastatic or unresectable melanoma: 2-year subgroup analyses from RELATIVITY-047

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Results

- Baseline characteristics have been previously reported and are consistent with historical melanoma populations described in pivotal studies.

- MS5 - RELA was generally favored over NIVO for efficacy outcomes (PFS, OS, ORR, and CR) across subgroups in all analyses (Figure 4).

- In patients with baseline liver and lung metastases, PFS and OS were longer and ORR was higher in the NIVO + RELA arm (Figure 5).

- MS5 - RELA was more often associated with the development of new CNS lesions in patients without CNS lesions at baseline (Figure 6).

- Analysis did not include scans beyond BICR-assessed progression per RECIST v1.1.

- In patients without CNS lesions at baseline (n = 148 in each arm), 17 patients (5%) in the NIVO + RELA arm (CR: 15% [95% CI, 8–25]) and 9 patients (3%) in the NIVO arm (CR: 16% [95% CI, 7–30]) had a radiographic finding of brain metastasis.

- The incidence of new CNS lesions was similar across different subgroups.

- The incidence of new CNS lesions was low in both arms, with no new or unexpected safety signals identified.

- The incidence of new CNS lesions was low, however, the incidence of new CNS lesions was low in both arms.

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Conclusions

- Efficacy outcomes (PFS, OS, ORR, and CR) and melanoma-specific survival (MSS) of NIVO + RELA in all patients were consistent with previous reports (with no new or unexpected safety signals identified).

- The incidence of new CNS lesions was low in both arms, however, the incidence of new CNS lesions was low in both arms.

- This may suggest CNS activity with NIVO + RELA; however, this should be confirmed in future studies.

- These post-hoc exploratory analyses suggested an efficacy benefit for NIVO + RELA over NIVO alone in patients with selected demographic characteristics (such as the presence of baseline liver or lung lesions) and provide an encouraging signal of CNS activity with NIVO + RELA.

- Safety of NIVO + RELA was consistent with previous reports and remained manageable with a favorable risk/benefit profile.

References


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