A randomized phase Ib/II study of the selective small molecule AXL inhibitor bemcentinib (BGB324) in combination with either dabrafenib/trametinib or pembrolizumab in patients with metastatic melanoma.

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Background & objective

This phase Ib/II trial of bemcentinib (BGB324) in combination with either dabrafenib/trametinib or pembrolizumab is investigating the safety, antitumor activity and immunomodulatory effects of bemcentinib in patients with metastatic melanoma.

Study rationale

The study utilizes the low MITF-high AXL melanoma phenotype, which is characterized by an immune suppressive microenvironment.

Key inclusion and exclusion criteria

Eligibility criteria:
- Histologically confirmed metastatic melanoma
- Performance status 0-2
- Adequate hematopoietic, liver, and renal function
- Prior treatment with immunotherapies

Exclusion criteria:
- Prior treatment with AXL inhibitors
- Prior treatment with non-immune checkpoint inhibitors
- Active second malignancy

Safety

The study is monitoring for treatment-emergent adverse events and immune-related adverse events as per the NCI-CTCAE V.4.03.

Key finding:

Cohort A (dabrafenib/trametinib) and cohort B (pembrolizumab) are comparable in terms of the number of grade III/IV adverse events and treatment discontinuations due to adverse events.

Conclusions

Significant positive responses were observed in the majority of patients.

Blood based biomarkers that predict response have been identified.

All treatment combinations were well tolerated.

Safety, efficacy & biomarker performance will continue to be explored.