Doctor's Note — Clinical Trial Summary

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TRIAL

Different Doses of BI-1607 in Combination With Pembrolizumab and Ipilimumab, in Participants With Unresectable or Metastatic Melanoma

NCT ID: NCT06784648 Phase: PHASE1 / PHASE2 Sponsor: BioInvent International AB Status: Active Not Recruiting

SUMMARY

Why the research is needed: Researchers are looking for a better way to treat melanoma that has spread or cannot be removed surgically. Melanoma is a type of skin cancer that starts in melanocytes, the cells that make the pigment that gives skin its color. In people with cancer, the body cannot control the growth of cells, which can come together to form tumors. This trial's new treatment is called BI-1607. BI-1607 is designed to work by improving the effectiveness of other targeted therapies already used for melanoma treatment; ipilimumab and pembrolizumab. BI-1607 will improve the ability of these two treatments to help the body's defense system to destroy cancer cells.

KEY ELIGIBILITY CRITERIA

- 1. Is willing and able to provide written informed consent for the trial.
- 2. Is e 18 years of age on the day of signing informed consent.
- 3. Has histologically confirmed advanced melanoma (unresectable or metastatic melanoma) with established disease progression.
- 4. Participants must have progressed on treatment with an anti-PD-1/L1 mAb. Subjects with uveal melanoma are not required to have received any prior anti-PD-1/L1 treatment. PD-1 treatment progression is defined by meeting all of the following criteria:
- 1. Has received at least 2 doses of an approved anti-PD-1/L1 mAb.
- 2. Has demonstrated disease progression after anti PD-1/L1 as defined by RECIST v1.1.
- The initial evidence of disease progression is to be confirmed by a second assessment no less than four weeks from the date of the first documented disease progression, in the absence of rapid clinical progression.
- 3. Progressive disease has been documented within 12 weeks from the last dose of anti-PD-1/L1 mAb.
- 5. Participants may have received previous treatment with BRAF inhibitors alone or in combination with mitogen extracellular kinase (MEK) inhibitors.
- 6. Has at least 1 measurable disease lesion as defined by RECIST v1.1 criteria.

Total sites: 9 | 0 currently recruiting