Doctor's Note — Clinical Trial Summary

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TRIAL

A Randomised Phase II Study of Roginolisib in Patients With Advanced/Metastatic Uveal Melanoma

NCT ID: NCT06717126 Phase: PHASE2 Sponsor: iOnctura Status: Active Not Recruiting

SUMMARY

The goal of this clinical trial is to learn how roginolisib works in comparison to standard treatment in adult patients with uveal/ocular melanoma. The main questions it aims to answer are:

Does roginolisib extend overall survival compared to standard treatment? How does dosing of roginolisib impact quality of life compared to standard treatment?

KEY ELIGIBILITY CRITERIA

- 1. Male or female aged 18 years or older;
- 2. Histologically or cytologically proven diagnosis of advanced or metastatic UM or ocular melanoma (arising from ocular melanocytes regardless of intraocular location)
- 3. Patients who have progressed following at least 1 prior immunotherapy treatment for advanced or metastatic UM. For patients who are HLA-A*02:01 positive prior treatment should have included tebentafusp, if available or patients clinically suitable. Patients who have also received prior melphalan hepatic infusion may be included;
- 4. Presence of at least one lesion suitable for biopsy. Biopsies will be mandatory at Screening and C5D1 (see Sections 8.1.3 and 8.6 for more information);
- 5. Presence of at least one measurable lesion as per RECIST v1.1. Any lesion that is biopsied cannot be used as a measurable lesion for the purposes of RECIST v1.1 assessments;
- 6. ECOG performance status of 0 to 1;
- 7. Male or female patients of child-bearing potential must be willing to use highly effective forms of contraception (refer to APPENDIX 7 for details on highly effective methods of contraception and definitions of women of childbearing potential and of fertile men)
- 8. All other relevant medical conditions must be well managed and stable, in the Investigator's opinion, for at least 28 days prior to first dose of roginolisib;
- 9. Provision of signed and dated, written informed consent prior to any study specific procedures, sampling and analyses.
- 1. Inability to swallow oral medication;

Total sites: 16 | 0 currently recruiting

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