Doctor's Note — Clinical Trial Summary

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TRIAL

A Phase I/II Study of DYP688 in Patients With Metastatic Uveal Melanoma and Other GNAQ/11 Mutant Melanomas

NCT ID: NCT05415072 Phase: PHASE1 / PHASE2 Sponsor: Novartis Pharmaceuticals Status: Active Not Recruiting

SUMMARY

This is a FIH, phase I/II, open label, multi-center study of DYP688 as a single agent. The purpose of this study is to characterize the safety, tolerability, and anti-tumor activity of DYP688 as a single agent in patients with metastatic uveal melanoma (MUM) and other melanomas harboring GNAQ/11 mutations.

KEY ELIGIBILITY CRITERIA

- * Patients in the dose escalation part must be e 18 years of age at the time of informed consent (ICF) signature. In the phase II part, patients e 12 years of age at the time of informed consent may be eligible for enrollment (not applicable in countries where enrollment is restricted by the local health authority to patients e 18 years of age). Patients must have a minimum weight of 40 kg.
- * ECOG performance status d 1 for patients e 18 years of age; Karnofsky performance status e 70 for patients e 16 and \< 18 years of age; Lansky performance status e 70 for patients e 12 and \< 16 years of age
- * Patients must be suitable and willing to undergo study required biopsies according to the treating institution's own guidelines and requirements. If a biopsy is not medically feasible, exceptions may be considered after documented discussion with Novartis.
- For all patients in Dose Escalation
- * MUM: uveal melanoma with histologically or cytologically confirmed metastatic disease. Patient must be either treatment naive or have received any number of prior lines and progressed on most recent therapy
- * Non-MUM: advanced cutaneous or mucosal melanoma with histologically or cytologically confirmed metastatic disease that has progressed following all standard therapies or that has no satisfactory alternative therapies and has evidence of GNAQ/11 mutation based on local data
- For patients in Phase II
- * Tebentafusp naïve group: Diagnosis of uveal melanoma with histologically or cytologically confirmed metastatic disease that has progressed following standard therapies or that has no satisfactory alternative therapies
- * Tebentafusp pre-treated group: Diagnosis of uveal melanoma with histologically or cytologically confirmed metastatic disease. Patients must be previously treated with tebentafusp and have progressed
- * Non-MUM: patients with diagnosis of cutaneous or mucosal melanomas harboring GNAQ/11 mutations based on local data, with histologically or cytologically confirmed metastatic disease that has progressed following all standard therapies or that has no satisfactory alternative therapies

Total sites: 11 | 0 currently recruiting