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

Last Update: Jul 25, 2024
A Phase I/II, Multi-center, Open Label Study of DYP688 in Patients With Metastatic Uveal Melanoma (MUM) and Other GNAQ/11 Mutant Melanomas
ClinicalTrials.gov Identifier:
NCT05415072
Novartis Reference Number:CDYP688A12101
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

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. This is a First in Human (FIH), phase I/II, open label, multi-center study of DYP688 as a single agent. There will be two parts to this study: a phase I, dose escalation part followed by a phase II part. Dose escalation will be conducted in patients with MUM and other melanomas harboring GNAQ/11 mutations. Once the MTD and/or RD(s) is determined in the dose escalation part, the study may continue with a phase II part. The phase II part will be conducted in two groups of patients with MUM, a prior tebentafusp-treated group and a tebentafusp-naïve group. In addition to MUM, a third group of patients with non-uveal GNAQ/11 mutant melanomas may also be explored. This cohort may be opened based on emerging data from the dose escalation part of the study.

Condition
Metastatic Uveal Melanoma
Phase
Phase1, Phase2
Overall Status
Recruiting
Number of Participants
124
Start Date
Jul 04, 2022
Completion Date
Sep 30, 2025
Gender
All
Age(s)

18 Years - (Adult, Older Adult)

Interventions

Drug

DYP688

Single agent DYP688

Eligibility Criteria

Inclusion Criteria:

* Patients in the dose escalation part must be ≥ 18 years of age at the time of informed consent (ICF) signature. In the phase II part, patients ≥ 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 ≥ 18 years of age). Patients must have a minimum weight of 40 kg.
* ECOG performance status ≤ 1 for patients ≥ 18 years of age; Karnofsky performance status ≥ 70 for patients ≥ 16 and \< 18 years of age; Lansky performance status ≥ 70 for patients ≥ 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

Exclusion Criteria:

* Malignant disease, other than that being treated in this study.
* Active brain metastases, i.e. symptomatic brain metastases or known leptomeningeal disease.
* Evidence of active bleeding or bleeding diathesis or significant coagulopathy (including familial) or a medical condition requiring long term systemic anticoagulation that would interfere with biopsies.
* History of anaphylactic or other severe hypersensitivity / infusion reactions to ADCs or monoclonal

antibodies, which in the opinion of the investigator may pose an increased risk of serious infusion reaction.
* Treatment with any of the following anti-cancer therapies prior to the first dose of study treatment within the stated timeframes:

* 2 weeks for fluoropyrimidine therapy
* 4 weeks for radiation therapy or limited field radiation for palliation within ≤ 2 weeks prior to the first dose of study treatment.
* 4 weeks or ≤ 5 half-lives (whichever is shorter) for chemotherapy or biological therapy (including monoclonal antibodies) or continuous or intermittent small molecule therapeutics or any other investigational agent.
* 6 weeks for cytotoxic agents with major delayed toxicities, such as nitrosoureas and mitomycin C.
* 4 weeks for immuno-oncologic therapy, such as CTLA-4, PD-1, or PD-L1 antagonists.
* Clinically significant and / or uncontrolled heart disease such as congestive heart failure requiring treatment (NYHA grade ≥ 2) or clinically significant arrhythmia despite medical treatment.

Other protocol-defined inclusion/exclusion criteria may apply.

Australia

Novartis Investigative Site

Recruiting

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Novartis Investigative Site

Recruiting

Melbourne,Victoria,3000,Australia

France

Novartis Investigative Site

Recruiting

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Germany

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Recruiting

Essen,45147,Germany

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Recruiting

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Worldwide Contacts

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