Doctor's Note — Clinical Trial Summary

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TRIAL

Neoadjuvant Tebentafusp in Patients With Metastatic Uveal Melanoma

NCT ID: NCT07057596 Phase: PHASE2 Sponsor: Grupo Español Multidisciplinar de Melanoma Status: Recruiting

SUMMARY

Uveal melanoma (UM) is a rare type of melanoma, with an incidence of 4.4 cases per million in Europe each year. During recent years, different treatment approaches have been tested in patients with metastatic UM. Responses have been reported primarily with localized treatment in patients with a limited number of liver metastases. In cases of diffuse liver involvement or extrahepatic disease, systemic therapies are justified. However, to date, systemic therapies such as targeted therapy with selumetinib or conventional chemotherapy have failed in metastatic UM.

Neo-TB is a Phase II, single arm, multicentre clinical trial designed to evaluate efficacy and safety of tebentafusp used as a single agent in patients with metastatic uveal melanoma with resectable / potentially resectable liver metastasis and absence of extrahepatic disease.

The main questions it aims to answer are:

1. Which is the capacity of tebentafusp used as a single agent to generate pathological complete response (pCR) in patients with metastatic uveal melanoma with resectable liver metastasis and absence of extrahepatic disease.
2. Which is the efficacy of tebentafusp used as a single agent to maintain disease control and delay relapse / progression.
3. Which is the safety of tebentafusp used as a single agent in metastatic uveal melanoma.

The main hypothesis is that neoadjuvant treatment with Tebentafusp could achieve e20% pathological complete response (pCR) in patients with metastatic uveal melanoma with resectable/potentially resectable liver metastasis and absence of extrahepatic disease. It is assumed that untreated patients would not present a pCR (response rate of d1%).

KEY ELIGIBILITY CRITERIA

- 1. Patients must have histologically confirmed metastatic uveal melanoma with Human leukocyte antigen-A*0201 positive determined by local assay.
- 2. Patients with histologically proven metastatic uveal melanoma in the liver with reectable or potentially resectable liver metastases evaluated by imaging in a multidisciplinary committee. Metastasis can be considered resectable by any of the following:
- 1. Minor resection (i.e., less than a hemihepatectomy)
- 2. Major resection (i.e., hemihepatectomy or extended hepatectomy)
- 3. Bilobar resection (including atypical resection).
- 3. Must meet the following criteria related to prior treatment:
- 1. No prior systemic therapy in the metastatic or advanced setting including chemotherapy, immunotherapy, or targeted therapy.

• 2. No prior local, liver-directed therapy including chemotherapy, radiotherapy, radiofrequency ablation (RFA), or embolization.

• 3. Prior neoadjuvant or adjuvant therapy is allowed provided it was administered in the curative setting in patients with localized disease.

• 4. Institutional Review Board (IRB)/Independent Ethics Committee (IEC) approved written and signed informed consent.

ENROLLMENT CONTACT

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