Doctor's Note — Clinical Trial Summary

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TRIAL

Immune Response to Percutaneous Hepatic Perfusion With Melphalan for Ocular Melanoma Metastatic to the Liver

NCT ID: NCT07364474 Phase: NA Sponsor: Massachusetts General Hospital Status: Recruiting

SUMMARY

This study seeks to better understand the liver's immune response to receiving chemotherapy agent melphalan through Percutaneous Hepatic Perfusion (PHP) alone or in combination with Ipilimumab and Nivolumab for patients with Uveal Melanoma that has metastasized to the liver.

KEY ELIGIBILITY CRITERIA

- * Patient has histologically or cytologically confirmed diagnosis of uveal melanoma metastatic to the liver and is determined to be a candidate for percutaneous hepatic perfusion with melphalan
- * In Cohort B only: patient is determined to be a candidate for percutaneous hepatic perfusion with melphalan combined with Ipilimumab and Nivolumab
- * The subject has read, signed and dated the Informed Consent Form (ICF), having been advised of the risks and benefits of the trial in a language understood by the subject.
- * Age \> 18 years at date of informed consent signature having the ability to comply with the protocol.
- * Contrast-enhanced cross-sectional imaging of the abdomen (either CT or MRI) obtained within two months prior to study enrollment
- * Measurable metastatic disease. Subject must have at least one site of metastatic disease e 1 cm in size and amenable to percutaneous image-guided biopsy
- * Life expectancy \> 12 weeks.
- * Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- * Laboratory requirements:
- * Absolute neutrophil count (ANC) \> 1 x 109/L

Total sites: 1 | 1 currently recruiting

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