Doctor's Note — Clinical Trial Summary

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TRIAL

Intravenous and Intrathecal Nivolumab in Treating Patients With Leptomeningeal Disease

NCT ID: NCT03025256 Phase: PHASE1 Sponsor: M.D. Anderson Cancer Center Status: Active Not Recruiting

SUMMARY

This phase I/Ib trial studies the side effects and best dose of intrathecal nivolumab, and how well it works in combination with intravenous nivolumab in treating patients with leptomeningeal disease. Immunotherapy with monoclonal antibodies, such as nivolumab, may help the body's immune system attack the cancer, and may interfere with the ability of tumor cells to grow and spread.

KEY ELIGIBILITY CRITERIA

- * Patients must have radiographic and/or CSF cytological evidence of LMD. For patient with melanoma: Must have a confirmed diagnosis of primary central nervous system (CNS) melanoma, melanocytomas or metastatic melanoma (cutaneous, acral-lentiginous, uveal and mucosal in origin), based on histological analysis of metastatic tissue and/or cancer cells, archival tissue permitted. For patients with lung cancer: non-small cell, based on histological analysis of metastatic tissue and/or cancer cells, archival tissue permitted
- * Patients must have an Eastern Cooperative Oncology Group (ECOG) performance status (PS) of =\< 2
- * Patients may receive steroids to control symptoms related to CNS involvement, but the dose must be =\< 4 mg per 24 hours of dexamethasone (or the equivalent). Physiologic replacement doses for adrenal insufficiency is allowed on this protocol
- * Patients who have received radiation to brain and/or spine, including whole brain radiation, stereotactic radiosurgery, or stereotactic body radiation therapy (SBRT), are eligible, but must have completed radiation treatment at least 7 days prior to the start of treatment
- * Patients who have been treated with an approved targeted therapy (BRAF inhibitor and/or MEK inhibitor) will be allowed to remain on concurrent approved targeted therapy. No other concomitant intrathecal therapy with another agent will be allowed. For patients that have received other systemic therapies, the minimum wash out period is as follows:
- * Patients that received previous IT therapy must have received their last treatment \>= 7 days prior to the start of treatment
- * Patients who have received systemic chemotherapy must have received their last treatment \>= 14 days prior to the start of treatment
- * Patients who have received an approved systemic biologic therapy (e.g. anti-PD-1, anti-CTLA4, IL2, interferon) must have received their last treatment \>= 2 weeks prior to the start of treatment
- * Patients who have received any other investigational agents must have received their last treatment \>= 14 days prior to the start of treatment
- * For patients with lung cancer:

Total sites: 1 | 0 currently recruiting