Intravenous and Intrathecal Nivolumab in Treating Patients With Leptomeningeal Disease

NCT03025256

Status	RECRUITING
Phase	Phase 1
Sponsor	M.D. Anderson Cancer Center
Enrollment	75 participants

Key Eligibility Criteria

Inclusion (38)

- 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:

... and 33 more (see full listing online)

Exclusion (16)

- Patients must not have active autoimmune disease that has required systemic treatment in past 2 years (i.e., with use of disease modifying agents, corticosteroids or immunosuppressive drugs). Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency, etc.) is not considered a form of systemic treatment
- Subjects with a condition requiring systemic treatment with either corticosteroids (\> 4 mg daily dexamethasone equivalents) or other immunosuppressive medications within 14 days of study drug administration. Tocilizumab and vedolizumab are permitted, as are inhaled or topical steroids and adrenal replacement doses in the absence of active autoimmune disease
- Subjects that require premedication with corticosteroids for a contrast allergy are excluded from this restriction and can proceed with enrollment
- Patients who have previously received alpha-PD-1 and/or anti-CTLA-4 will be eligible, unless they have ongoing \> grade 2 adverse event (AE) side effects of such therapy. Ongoing physiologic replacement doses for adrenal and thyroid insufficiency are allowed on protocol
- Currently receiving cancer therapy (chemotherapy, radiation therapy, immunotherapy, or biologic therapy) or investigational anti-cancer drug (concurrent treatment with approved targeted therapies is allowed.)

... and 11 more (see full listing online)

Locations (1 total)

M D Anderson Cancer Center, Houston, Texas, United States