

Pembrolizumab Plus CA-4948 for the Treatment of Patients With Progressive Metastatic Urothelial Cancer Despite Prior Immunotherapy

NCT06439836

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| Status | RECRUITING |
| Phase | Phase 1 |
| Sponsor | National Cancer Institute (NCI) |
| Enrollment | 27 participants |

Key Eligibility Criteria

Inclusion (45)

- Patients must have histologically confirmed urothelial cancer that is metastatic or unresectable and must have had the prior treatments outlined
- Age \geq 18 years
- Because no dosing or adverse event data are currently available on the use of CA-4948 in combination with pembrolizumab in patients $<$ 18 years of age, children are excluded from this study, but will be eligible for future pediatric trials
- Eastern Cooperative Oncology Group (ECOG) performance status \leq 2 (Karnofsky \geq 60%) within 28 days prior to registration
- Leukocytes \geq 3,000/mcL

... and 40 more (see full listing online)

Exclusion (15)

- Patients who have not recovered from adverse events due to prior anti-cancer therapy (i.e., have residual toxicities $>$ grade 1) Note: Patients with grade \leq 2 neuropathy or grade \leq 2 alopecia are an exception to this criterion and may qualify for the study. Note: If patients received major surgery, they must have recovered adequately from the toxicity and/or complications from the intervention prior to starting therapy
- Diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy (in dosing exceeding 10 mg daily of prednisone equivalent) or any other form of immunosuppressive therapy within 7 days prior the first dose of study drug
- Grade \geq 3 immune related adverse event with prior PD-1/PD-L1 blockade
- History of allergic reactions attributed to compounds of similar chemical or biologic composition to CA-4948 and/or pembrolizumab
- Patients with uncontrolled intercurrent illness, including but not limited to interstitial lung disease or active, non-infectious pneumonitis, symptomatic congestive heart failure, unstable angina pectoris, or cardiac arrhythmia that would limit compliance with study requirements

... and 10 more (see full listing online)

Locations (11 total)

City of Hope Comprehensive Cancer Center, Duarte, California, United States
UCI Health - Chao Family Comprehensive Cancer Center and Ambulatory Care, Irvine, California, United States
UC San Diego Moores Cancer Center, La Jolla, California, United States

... and 8 more locations