Protocol Title: DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors

Target Population: Rare Tumors

Summary: To evaluate the Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 overall response rate (ORR) in subsets of patients with advanced rare cancers treated with ipilimumab plus nivolumab combination immunotherapy.

Key Inclusion Criteria:
- Patients must have histologically confirmed rare cancer and / or cancer of unknown primary, that did not have a match to a molecularly-guided therapy on EAY131 "National Cancer Institute (NCI)-Molecular Analysis for Therapy Choice (MATCH)" protocol or who progressed on molecularly-matched therapy and have no further molecularly-matched treatment recommendations per EAY131, "NCI-MATCH".
- Patients that do not qualify for one of the histologic cohorts may be considered for registration in the "Not Otherwise Categorized" Rare Tumors cohort with confirmation of the study chairs via email.
- Patients that are determined to have a rare cancer with unknown primary site are eligible provided that there is histologic documentation of metastatic malignancy with no discernible primary site identified from histopathologic review, physical examination, and associated cross-sectional imaging of the chest, abdomen, and pelvis.
- Patients must have a diagnostic quality CT or MRI performed within 28 Days prior to registration, which demonstrated measurable disease.
- Patients who have received prior anti-CTLA4 or other anti-PD-1/anti-PD-L1 therapy, not both.
- Patients with Brain Metastases or Primary Brain Tumors must have completed treatment, surgery, or radiation therapy ≥ 28 Days prior to registration and have stable disease at the time of registration.
  - Metastatic Brain Parenchymal Disease must have been treated and patient must be off steroids for 7 Days prior to registration.
- Patients who are known to be Human Immunodeficiency Virus (HIV)-positive at registration are eligible at the time of registration with certain requirements.

Key Exclusion Criteria:
- Patients are not eligible if they have had or are planned for solid organ transplant.
- No other prior malignancy is allowed except for the following:
  - Adequately managed Stage I or II Cancer from which the patient is currently in complete remission
  - Any other cancer from which the patient has been disease free for 5 Years
  - Adequately managed Stage I or II Follicular Thyroid or Prostate Cancer is also eligible, wherein patient is not required to be in complete remission

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For additional information: https://clinicaltrials.gov/ct2/show/NCT02834013

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