Durvalumab in Combination With Chemotherapy in Treating Patients With Advanced Solid Tumors, DURVA+ Trial

NCT03907475

Status	RECRUITING
Phase	Phase 2
Sponsor	National Cancer Institute (NCI)
Enrollment	115 participants

Key Eligibility Criteria

Inclusion (33)

- Patients with histologically documented metastatic or locally advanced (not amenable to surgery) solid tumors whose disease has progressed following at least one line of standard therapy and/or no standard of treatment exists that has been shown to prolong survival.
- If anti-PD-1 or one of the 6 chemotherapy agents is standard-of-care, prior therapy with the agent would not be required.
- Patient must have tumor amenable to biopsy and be willing to undergo a tumor biopsy.
- Flash frozen tissue collected as part of another study or from a procedure performed due to medical necessity may be acceptable as the baseline sample if the samples were collected within 3 months prior to registration and the patient has not received any investigational or targeted treatment since that time.
- A patient who cannot be safely biopsied may be considered for the study upon discussion with Principal Investigator.

... and 28 more (see full listing online)

Exclusion (22)

- Patients who received prior therapy with a checkpoint inhibitor and were taken off drug for serious adverse events are excluded. Patients who had prior CTLA-4 inhibitor treatment and did not experience serious adverse events are eligible for all arms. Patients who had prior PD-L1/PD-1 inhibitor treatment and did not experience serious adverse events are excluded from the durvalumab monotherapy arm but are eligible for the chemotherapy combinations.
- Patients with pancreatic cancer, prostate cancer, or microsatellite stable (MSS) colorectal cancer, or other histologies where clinical evidence exists that single-agent inhibition of PD-L1/PD-1 has minimal activity will not receive single-agent durvalumab but may be eligible to receive this agent with chemotherapy (Arms 2-7).
- Women who are pregnant or breastfeeding.
- Patients who are receiving any other investigational agents. Patients on other trials will be eligible as long as they are no longer receiving study treatment.
- Active or prior documented autoimmune or inflammatory disorders (including inflammatory bowel disease \[e.g., colitis or Crohn's disease\], diverticulitis \[with the exception of diverticulosis\], systemic lupus erythematosus, sarcoidosis syndrome, or Wegener syndrome \[granulomatosis with polyangiitis, Graves' disease, rheumatoid arthritis, hypophysitis, uveitis, etc.\]). The following are exceptions:

... and 17 more (see full listing online)

Locations (1 total)

National Cancer Institute Developmental Therapeutics Clinic, Bethesda, Maryland, United States