Phase II Trial of Combination Anti-PD-1 and Aldesleukin for Metastatic Melanoma and Renal Cell Carcinoma

NCT05155033

Status	RECRUITING
Phase	Phase 2
Sponsor	National Cancer Institute (NCI)
Enrollment	78 participants

Plain Language Summary

This Phase II study is testing whether combining the immunotherapy drug pembrolizumab (anti-PD-1) with aldesleukin (IL-2, an immune-boosting protein) can help treat metastatic melanoma or metastatic clear cell renal cell carcinoma (kidney cancer) that has stopped responding to immunotherapy alone.

You may be eligible if...
- You are 18 or older with confirmed metastatic melanoma or metastatic kidney cancer (clear cell type)
- Your cancer has progressed on prior immunotherapy, OR you have melanoma and have never received immunotherapy
- You have measurable disease on scans
- You are in good health (ECOG performance status 0 or 1)
- Your blood counts and organ function meet required minimums
- You are HIV-negative and hepatitis B/C-negative (or cured of hepatitis C)
- You are enrolled or will co-enroll in a companion NIH protocol

You may NOT be eligible if...
- You are pregnant or breastfeeding
- You are on systemic steroid therapy
- You have a history of severe immune-related side effects from prior immunotherapy (Grade 3–4)
- You have an active serious infection, primary immune deficiency, or major autoimmune disease
- You have had coronary artery procedures or a history of heart problems requiring cardiac evaluation
- You are receiving another investigational treatment

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (21)

- Participants must have histologically or cytologically confirmed cancer that falls into one of three cohorts: (1) metastatic melanoma or advanced locoregional melanoma not amenable to curative surgical resection and refractory to anti-PD-1 therapy; (2) metastatic renal cell carcinoma (clear cell histology) refractory to at least one line of PD1/PDL1 based therapy; (3) metastatic or advanced locoregional melanoma not amenable to curative surgical resection and naive to anti-PD-1 therapy.
- Participants must have measurable disease (per RECIST v1.1 criteria), metastatic melanoma or renal cell cancer.
- Age \>=18 years of age.
- Clinical performance status of ECOG 0 or 1.
- Willing to practice birth control from the time of enrollment on this study and for four months after treatment.

... and 16 more (see full listing online)

Exclusion (12)

- Participant is nursing because of the potentially dangerous effects of the treatment on the fetus or infant.

• Concurrent systemic steroid therapy.

• Active systemic infections requiring anti-infective treatment, coagulation disorders, or any other active or uncompensated major medical illnesses.

• Any form of primary immunodeficiency (such as Severe Combined Immunodeficiency Disease and AIDS).

• History of major organ autoimmune disease.

... and 7 more (see full listing online)

Locations (1 total)

National Institutes of Health Clinical Center, Bethesda, Maryland, United States