

Ulixertinib/Palbociclib in Patients With Advanced Pancreatic and Other Solid Tumors

NCT03454035

Status	RECRUITING
Phase	Phase 1
Sponsor	UNC Lineberger Comprehensive Cancer Center
Enrollment	45 participants

Plain Language Summary

This trial is testing a combination of two targeted drugs — ulixertinib and palbociclib — to see if they can slow or stop the growth of advanced cancers, including pancreatic cancer and melanoma that have stopped responding to other treatments.

****You may be eligible if...****

- You are 18 or older
- You have an advanced solid tumor that no longer responds to standard treatment
- For the expanded group: you have metastatic pancreatic cancer or advanced melanoma that has already received at least one prior treatment
- For melanoma specifically: your tumor has certain genetic mutations (in NRAS, KRAS, HRAS, or NF1 genes) and your cancer progressed after immune checkpoint therapy
- You are well enough to perform basic daily activities (not bedridden)
- Your life expectancy is at least 3 months
- Your liver, kidneys, and blood counts are within acceptable ranges

****You may NOT be eligible if...****

- Your cancer has spread to your brain or spinal cord (unless stable)
- You have serious heart problems, including a history of heart attacks or a dangerously irregular heartbeat
- You are pregnant or breastfeeding
- Your organ function (liver, kidney, bone marrow) is significantly impaired
- You have had certain recent infections or uncontrolled illnesses

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

Key Eligibility Criteria

Inclusion (21)

- Written informed consent and HIPAA authorization for release of personal health information. NOTE: HIPAA authorization may be included in the informed consent or obtained separately.
- Age e 18 years at the time of consent (no upper age limit)
- Eastern Cooperative Oncology Group (ECOG) Performance Status of d 2
- Tumor Eligibility:
- Dose escalation cohorts: Histologically confirmed advanced solid tumor refractory to standard of care therapy, or for which there is no accepted standard of care
- ... and 16 more (see full listing online)

Exclusion (16)

- Pregnant or breastfeeding (NOTE: breast milk cannot be stored for future use while the mother is being treated on the study) <https://clinicaltrials.gov/study/NCT03454035>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).

- Treatment with any cancer-directed therapy (chemotherapy, hormonal therapy, biologic, radiation or immunotherapy, etc.) or investigational drug within 28 days or 5 half-lives (whichever is shorter) prior to day -6 of ulixertinib
- A history or current evidence/risk of retinal vein occlusion (RVO) or central serous retinopathy (CSR).
- Major surgery within 28 days prior to day -6 of ulixertinib
- Not willing to avoid grapefruit, grapefruit juices, grapefruit hybrids, oranges, pummelos, and exotic citrus fruits from 7 days prior to day -6 of ulixertinib and during the entire study due to potential CYP3A4 interaction with the study medications.

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

Locations (1 total)

Lineberger Comprehensive Cancer Center, Chapel Hill, North Carolina, United States