A First-in-Human Phase I Trial With Antibody Drug Conjugate ADCT-701 in Neuroendocrine Tumors, Carcinomas and Malignant Peripheral Nerve Sheath Tumors

NCT06041516

Status	RECRUITING
Phase	Phase 1
Sponsor	National Cancer Institute (NCI)
Enrollment	70 participants

Plain Language Summary

This study is testing a new antibody-drug conjugate called ADCT-701 — a targeted cancer drug that delivers chemotherapy directly to cancer cells — in patients with neuroendocrine tumors (slow- or fast-growing tumors that arise from hormone-producing cells) or adrenocortical carcinoma (cancer of the adrenal gland).

You may be eligible if...
- You have been confirmed to have a neuroendocrine tumor or adrenocortical carcinoma that has spread or cannot be removed
- Your cancer has progressed after standard treatments or you cannot tolerate them
- You are 18 or older with measurable disease on scans
- Your blood counts and organ function are within acceptable ranges

You may NOT be eligible if...
- You have had recent blood transfusions or your blood counts are too low
- You have active brain metastases or serious infections
- You are pregnant or breastfeeding

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

Key Eligibility Criteria

Inclusion (24)

- Participants must have histologically or cytologically confirmed neuroendocrine neoplasms or malignant adrenocortical carcinoma (ACC) or malignant peripheral nerve sheath tumors (MPNST).
- Locally advanced, unresectable or metastatic disease (as confirmed by a radiological evaluation)
- Participants must have measurable disease per RECIST 1.1.
- Participants must have received prior standard of care treatment and be refractory to or intolerant to standard of care therapy(s). Note: Patients with MPNST who have refused cytotoxic chemotherapy or for whom treatment on this protocol prior to receiving cytotoxic
- chemotherapy is felt to be in the best interest for the patient by the local investigator and treating investigator will also be eligible.

... and 19 more (see full listing online)

Exclusion (13)

- Major surgery, prior treatment with chemotherapy, hormonal therapy, immunotherapy, treatment with an investigational agent, and/or radiation therapy within 4 weeks or 5 half-lives, whichever is shorter, prior to treatment initiation.
- Participants taking any herbal supplements within 14 days prior to treatment initiation.
- Participants who have wound dehiscence from prior surgeries.
- Clinically significant third space fluid accumulation (i.e., ascites requiring drainage or any serosal effusion that is either requires drainage or is associated with shortness of breath) at screening.

- Active infection requiring systemic antibiotic therapy at screening.

... and 8 more (see full listing online)

Locations (1 total)

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