Lu-177-DOTATATE (Lutathera) in Combination With Olaparib in Inoperable Gastroenteropancreatico Neuroendocrine Tumors (GEP-NET)

NCT04086485

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	National Cancer Institute (NCI)
Enrollment	56 participants

Key Eligibility Criteria

Inclusion (40)

- Clinical diagnosis of GEP-NET disease, histologically consistent with neuroendocrine tumor.
- Inoperable disease (metastatic, non-candidate for surgery with curative intent, locally advanced into vessels or other critical structures, etc.)
- NOTE: Presence of at least one non-irradiated index lesion (Phase II only).
- Patients on somatostatin analogue therapy (e.g., but not only limited to sandostatin or lanreotide therapy) must have initiated and been on a consistent dose of therapy for at least 3 months prior to study enrollment.
- Patients on short-term octreotide must have dose held for 24 hours without octreotide because this is necessary for study Lu-177-DOTATATE therapy.

... and 35 more (see full listing online)

Exclusion (23)

- Patients who have any GEP-NET lesions that are negative by Ga-68-DOTATATE-PET imaging but positive by FDG-PET imaging, unless they have progressed on at least one other line of prior systemic treatment (such as chemotherapy or tyrosine kinase inhibitor) and the majority of their tumor lesions are Ga-68-DOTATATE-avid.
- Because there is an unknown but potential risk for adverse events in nursing infants secondary to treatment of the mother with study drugs, breastfeeding should be discontinued if the mother is treated with study drugs.
- Other known co-existing malignancies except non-melanoma skin cancer and carcinoma in situ of the uterine cervix, unless definitively treated and proven no evidence of recurrence for 5 years.
- Patients who are receiving any other investigational agents.
- Patients receiving any systemic chemotherapy or radiotherapy (except for palliative reasons) within 4 weeks prior to study enrollment.

... and 18 more (see full listing online)

Locations (1 total)

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