Comparing Retreatment of 177Lu-DOTATATE PRRT Versus the Usual Treatment in Patients With Metastatic Unresectable Gastroenteropancreatic Neuroendocrine Tumors, NET RETREAT Trial

NCT05773274

Status	RECRUITING
Phase	Phase 2
Sponsor	National Cancer Institute (NCI)
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (24)

- Patients must be at least \>= 18 years of age
- Metastatic, histologically confirmed grade 1 or 2 well-differentiated gastroenteropancreatic neuroendocrine tumours, including NETs of unknown primary thought to be of gastroenterogancreatic origin, with positive Gallium-68 DOTATATE scan, Copper-64 DOTATATE scan or octreotide scan within the last 12 months is recommended but within the last 36 months is allowed. Lesions on Gallium-68 or Copper-64 DOTATATE scan or octreotide scan will be considered positive if the maximum standardized uptake value (SUVmax) of target lesion is \> SUV mean of normal liver parenchyma
- th Edition of the TNM Classification of Malignant Tumours
- Have received 3 or 4 cycles of PRRT using 177Lu-DOTATATE or a cumulative exposure of 22,200 MBq (600mCi) or 29,600 MBq (800 mCi) within +/- 10% variation within a 52-week period. No previous targeted alpha therapy is permitted
- Have had radiological progression per RECIST 1.1 after prior PRRT treatment and no sooner than 12 months from last scan performed post completion of initial PRRT where either stable disease, partial response, or complete response has been maintained throughout. Patients may have received previous systemic anti-cancer therapy subsequently, as long as they had benefited from initial PRRT for at least 12 months and have had confirmed progression per RECIST 1.1 on the intervening systemic anti-cancer therapy. Somatostatin analogues (SSA) administered for functional control are not considered an intervening systemic anti-cancer therapy. If intervening systemic anti-cancer therapy included a vascular endothelial growth factor (VEGF)-inhibitor, sunitinib can not be selected as standard of care on Arm 2. If intervening systemic anti-cancer therapy included an mammalian target of rapamycin (mTOR)-inhibitor, then everolimus can not be selected as the standard of care on Arm 2. If the intervening therapy is an alkylating agent, exposure of alkylating agent cannot exceed 12 months. The 12-month limit will also be applied to pre PRRT alkylator use as well

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

Exclusion (6)

- Major surgical procedures within 6 weeks from randomization date
- Known brain metastases, unless these metastases have been treated, stabilized and off steroids for at least 4 weeks prior to enrollment in the study. Patients with a history of brain metastases must have a head CT and/or MRI with contrast to document stable disease prior to enrollment in the study
- Uncontrolled congestive heart failure no worse than New York Heart Association Class (NYHA) IIB
- Inability to swallow oral medications or gastrointestinal disease limiting absorption of oral agents
- Patients with any other significant medical or surgical condition, currently uncontrolled by treatment, which may interfere with completion of the study

... and 1 more (see full listing online)

Locations (33 total)

University of Alabama at Birmingham Cancer Center, Birmingham, Alabama, United States
Mayo Clinic Hospital in Arizona, Phoenix, Arizona, United States
Banner University Medical Center - Tucson, Tucson, Arizona, United States

... and 30 more locations

https://clinicaltrials.gov/study/NCT05773274