Somatostatin-Receptors (SSTR)-Agonist [212Pb]VMT-alpha-NET in Metastatic or Inoperable SSTR+ Gastrointestinal Neuroendocrine Tumor and Pheochromocytoma/Paraganglioma Previously Treated With Systemic Targeted Radioligand Therapy

NCT06427798

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	National Cancer Institute (NCI)
Enrollment	66 participants

Key Eligibility Criteria

Inclusion (31)

- Participants must have histopathologically confirmed gastrointestinal neuroendocrine tumors (GI NET) or pheochromocytoma/paraganglioma (PPGL) cancers that are metastatic or inoperable per Standard of Care.
- Have received at least 1 prior systemic radioligand therapy for definitive therapeutic purposes. Note: Participants with prior external beam radiation treatment (EBRT) will also be eligible as long as they have had at least 1 prior administration of a systemic radioligand therapy.
- Must have at least 1 measurable lesion by RECIST 1.1 (phase II only).
- History of progression by imaging (e.g., RECIST 1.1) or clinically (defined as increase in severity or frequency of symptoms related to disease) within the past 36 months prior to the first dose of \[203Pb\]VMT-alpha-NET.
- Evidence of somatostatin receptors (SSTR) expression on at least 50 percent of the radiographically identifiable (i.e., visible on an anatomic scan such as CT or magnetic resonance imaging \[MRI\]) tumor, as indicated by a positive (uptake qualitatively identifiable as above the local background) on SSTR PET scan.

... and 26 more (see full listing online)

Exclusion (5)

- History of allergic reactions attributed to compounds of similar chemical or biologic composition to VMT-alpha-NET.
- Positive Beta human chorionic gonadotropin (Beta-HCG) serum or urine pregnancy test performed in i IOCBP at screening.
- QTc \> 450 ms on electrocardiogram (EKG) at screening. Note: Framingham correction for QTc will be used
- History of or detection at screening of active/untreated secondary malignancy except nonmelanoma skin cancer and carcinoma in situ of the uterine cervix.
- Uncontrolled intercurrent illness, factors, evaluated by medical history and physical exam which would potentially increase in the risk of the participant.

Locations (1 total)

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