Phase I Trial to Determine the Dose and Evaluate the PK and Safety of Lutetium Lu 177 Edotreotide Therapy in Pediatric Participants With SSTR-positive Tumors

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 24 months to 18 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Key Inclusion Criteria:

- Participants aged ≥ 2 years and < 18 years
- Confirmed diagnosis somatostatin receptor-positive (SSTR-positive) disease.
- Tumor which is relapsed or is refractory to at least one line of previous therapy
- Positive SSTR protein expression confirmed by immunohistochemistry of a tumor histology sample
- Radioactivity uptake within the primary tumor or metastatic tumor sites measured by locally available SRIs (111In-based, 99mTc-based, or 68Ga-based SSTR single-photon emission computed tomography (SPECT)/ computed tomography (CT) or positron emission tomography (PET)/CT imaging, which is higher than the liver uptake)
- Participants must have recovered from the acute treatment related toxicities (defined as ≤ grade 1 if not defined in eligibility criteria, excluding alopecia, stable treated electrolyte abnormalities on replacement and stable treated hypothyroidism) of all prior treatment modality prior to entering this trial
- In case of sequential treatment followed by SoC or prior therapy, washout period applies before starting targeted RPT

Screening Consent Participant/legal guardian is willing to sign a screening consent. The screening consent is to be obtained according to institutional guidelines. Assent, when appropriate, will be obtained according to institutional guidelines.

Key Exclusion Criteria:

- Known hypersensitivity to Lutetium Lu 177 Edotreotide, DOTA/Edotreotide, or excipients
- Previous history of acute leukemia unless in remission for at least two years
- Extensive bone/bone marrow involvement as per Investigator's judgement unless peripheral blood stem cells (PBSC) are available at a minimum of 2.5x106 CD34+ cells/kg
- Patients who have received previous systemic targeted RPT
- Previous treatment with metaiodobenzyl guanidine (MIBG) if the predicted overall exposure is expected to exceed 2 Gy (gray) to the bone marrow or 23 Gy to the kidney.
- Previous treatment with external beam radiation therapy (EBRT) if the predicted overall exposure is expected to exceed more than 2 Gy to the bone marrow or 23 Gy to the kidney.
- Previous treatment with oncologic immune vaccine or CAR-T cell therapy
- Bulky disease in the CNS
- Presence of severe renal, hepatic, electrolyte, cardiovascular, or hematological dysfunction
- Participants who have received a live-attenuated vaccine up to four weeks prior to enrolment
- Pregnant or breastfeeding women.
- Other known malignancies.
- Serious non-malignant disease.

Conditions & Interventions

Interventions:
DRUG: Lutetium Lu 177-Edotreotide, OTHER: Amino Acid Solution
Conditions:
Somatostatin Receptor Positive, NETs, Lymphoma, Solid Tumor, CNS Tumors, Rhabdomyosarcoma, Peripheral Primitive Neuroectodermal Tumor, GIST
Keywords:
Pediatric, CNS tumors, Solid tumors, Lymphoma, Somatostatin Receptor (SSTR)-positive Tumors, Lutetium Lu 177 Edotreotide, Targeted RPT, ITM, GEP-NET, Neuroendocrine tumors, Radiopharmaceutical Therapy, Childhood

More Information

Description:

KinLET ITM-1191-01 The purpose of the study is to determine the appropriate pediatric dosage and evaluate the pharmacokinetics (PK) and safety of Lutetium Lu 177 Edotreotide Targeted Radiopharmaceutical Therapy (RPT) as a monotherapy or following standard of care (SoC) in participants ≥2 to \<18 years of age with somatostatin receptor (SSTR)-positive tumors. The description of this study may contain information specific to Cincinnati Children's Hospital Medical Center. It was last updated 10/6/2026.

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