64Cu-LNTH-1363S in Patients With Sarcoma or Gastrointestinal Tract Cancer

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 15 years and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria: Part 1

Patients are eligible to be included in the study only if all of the following criteria apply:

1. Patient must be ≥ 15 years of age and must have provided written informed consent and assent, where applicable (by patient or legal guardian). Those aged ≥15 to <18 years must weigh at least 55 kg.
2. Patients with suspected FAP-expressing metastatic sarcoma.
3. Patients must have histological, pathological, and/or cytological confirmation of a metastatic sarcoma (e.g., undifferentiated pleomorphic sarcoma, liposarcoma, Leiomyosarcoma, myxofibrosarcoma, solitary fibrous tumor, Ewing's sarcoma, synovial sarcoma, sarcoma not otherwise specified, osteosarcoma).
4. Patients must be willing to consent to provide sufficient and adequate archived tumor tissue samples (formalin fixed, paraffin embedded sample), preferably from a biopsy of a tumor lesion obtained either at the time of or after the diagnosis of disease; if archival tissue sample is unavailable, a new biopsy should be performed on the most accessible lesion(s) to obtain the tumor tissue sample.
5. Adequate renal function as determined by a calculated creatinine clearance ≥ 60 mL/min (Cockcroft Gault equation).
6. Women of childbearing potential (WOCBP) must have a negative beta-human chorionic gonadotropin (β-hCG) test and must not be breastfeeding. WOCBP must agree to use a highly effective method of contraception during the study and for 28 days after the last injection of the study drug.
7. Male subjects who are able to father a child must agree to avoid impregnating a partner, to adhere to a highly effective method of contraception and to not donate sperm during the study and for 28 days after the last injection of the study drug.

Inclusion Criteria: Part 2

1. Patient must be ≥ 15 years of age and must have provided written informed consent and assent, where applicable (by patient or legal guardian). Those aged ≥15 to <18 years must weigh at least 55 kg.
2. Patients must have histological, pathological, and/or cytological confirmation of a sarcoma or GIT cancers e.g., esophageal, gastric, pancreatic, colorectal cancer.
3. Patients must have suspected FAP expressing sarcoma or GIT cancers and planned for surgery within 60 days (from study imaging).
4. Patients must be willing to consent to provide sufficient and adequate tumor tissue samples (formalin fixed, paraffin embedded sample), from their planned surgery after participating in study imaging.
5. Adequate renal function as determined by a calculated creatinine clearance ≥ 60 mL/min (Cockcroft Gault equation).
6. Women of childbearing potential (WOCBP) must have a negative beta-human chorionic gonadotropin (β-hCG) test and must not be breastfeeding. WOCBP must agree to use a highly effective method of contraception during the study and for 28 days after the last injection of the study drug.
7. Male subjects who are able to father a child must agree to avoid impregnating a partner, to adhere to a highly effective method of contraception and to not donate sperm during the study and for 28 days after the last injection of the study drug.

Exclusion Criteria: Part 1

Patients are excluded from the study if any of the following criteria apply:

1. Unlikely to comply with protocol procedures, restrictions and requirements as judged by the Investigator.
2. Known pregnancy or breastfeeding.
3. Any PET scan done within 10 physical half-lives of the PET agent prior to receiving study intervention.
4. Patients participating in another clinical trial at the time of screening for this study.
5. Patients who have had systemic anti-cancer therapy administered in the 14 days prior to IP administration.
6. Has undergone or plans to undergo PET or single-photon emission computerized tomography (SPECT) imaging with any other FAPi imaging agent within 6 months prior to or after participating in this trial.
7. History of QT/QTc interval prolongation, a marked baseline QT/QTc interval prolongation (e.g., repeated demonstration of a QTc interval, calculated with Fridericia's correction, > 450 milliseconds) or taking medication known to cause QT/QTc prolongation.
8. A history of additional risk factors for Torsades de Pointes (e.g., heart failure, hypokalemia, family history of long QT syndrome).

Exclusion Criteria: Part 2

1. Patients who have had neoadjuvant anti-cancer therapy administered in the 14 days prior to IP administration.
2. Evidence of metastatic or advanced, inoperable disease.
3. Unlikely to comply with protocol procedures, restrictions and requirements and judged by the investigator to be unsuitable for participation.
4. Known pregnancy or breastfeeding.
5. Any PET scan done within 10 physical half-lives of the PET agent prior to receiving study intervention.
6. Patients participating in another clinical trial at the time of screening for this study.
7. Has undergone or plans to undergo PET or SPECT imaging with any other FAPi imaging agent within 6 months prior to or after participating in

this trial.

8. History of QT/QTc interval prolongation, a marked baseline QT/QTc interval prolongation (e.g., repeated demonstration of a QTc interval, calculated with Fridericia's correction, > 450 milliseconds) or taking drugs known to cause QT/QTc prolongation.
9. A history of additional risk factors for Torsades de Pointes (e.g., heart failure, hypokalemia, family history of long QT syndrome

Conditions & Interventions

Interventions:
COMBINATION_PRODUCT: 64Cu-LNTH-1363S
Conditions:
Metastatic Sarcoma, Esophageal Cancer, Gastric Cancer, Pancreatic Cancer, Colorectal Cancer, Sarcoma
Keywords:
FAPi, Imaging, 64Cu-LNTH-1363S

More Information

Description:
This is a multicenter, open-label, prospective Phase 1/2a study to assess safety and tolerability, establish dosimetry and to identify an optimal imaging dose (radioactivity) and imaging time window of 64Cu-LNTH-1363S, and to compare its imaging biodistribution with FAP expression by IHC in patients with sarcomas or GIT cancers. The study will be conducted in 2 parts (Part 1 and Part 2).

Contact(s): - cancer@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE1
IRB Number:
System ID: NCT06298916
