NEPC Study: An Exploratory Safety and Efficacy Study With PSMA, SSTR2 and GRPR Targeted Radioligand Therapy in Metastatic Neuroendocrine Prostate Cancer.

Last Update: Jun 06, 2025
A Phase I, Open-label, Multi-center Exploratory Safety and Efficacy Study With PSMA, SSTR2 and GRPR Targeted Radioligand Therapy in Metastatic Neuroendocrine Prostate Cancer.
ClinicalTrials.gov Identifier:
NCT06379217
Novartis Reference Number:CAAA617H12101
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All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this study is to evaluate the change in the expression of treatment targets on the surface of tumor cells (Prostate Specific Membrane Antigen (PSMA), Somatostatin Receptor 2 (SSTR2), and Gastrin Releasing Peptide Receptor (GRPR) between the start and after the completion of radioligand therapy (RLT). Study will use radioligand imaging (RLI) to determine predominantly expressed target on the surface of tumor cells. Based on predominant expression of target, corresponding RLT targeting PSMA, SSTR2, or GRPR RLT will be given for up to 6 cycles every 6 weeks as intravenous (i.v.) injection in participants with metastatic neuroendocrine prostate cancer (mNEPC). The screening period for each subject includes imaging with 3 radioligand imaging (RLI) compounds to assess expression level of PSMA, SSTR2 and GRPR. Participants will be assigned to the radioligand treatment (RLT) corresponding to their predominantly expressed target based on blinded independent central review (BICR). During the treatment period, participants will receive up to 6 cycles of the assigned RLT, corresponding to a total dose of 44.4 GBq (+/-10%) for \[177Lu\]Lu-PSMA-617 or \[177Lu\]Lu-DOTA-TATE , and 55.5 GBq (+/-10%) for \[177Lu\]Lu-NeoB. No crossover to a different type of RLT is allowed.

At end of treatment (EoT) with RLT, participants will be scanned again with the 3 RLIs. All EoT PET/CT scans should be performed using the same PET/CT camera, acquisition and reconstruction protocols as used for screening PET/CT for the participant.

The post-treatment follow-up period consists of a 42-days post EoT safety follow-up visit and long-term follow-up until radiographic disease progression, death, lost to follow-up or withdrawal of consent, whichever occurs first.

The planned duration of treatment is up to 36 weeks for all treatment arms in this study, with treatment given every 6 weeks. Participants may be discontinued from treatment earlier due to unacceptable toxicity or disease progression, and/or at the discretion of the Investigator or the participant.

Condition
Metastatic Neuroendocrine Prostate Cancer
Phase
Phase1
Overall Status
Recruiting
Number of Participants
36
Start Date
Jul 29, 2024
Completion Date
Jun 22, 2027
Gender
Male
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Antiemetics & antinauseants

ATC code A04A
Drug

GnRH antagonists

abarelix, degarelix, or relugolix
Drug

Gonadotropin-releasing hormone (GnRH) analogues

Anatomical Therapeutic Chemical \[ATC\] code L02AE
Drug

L-Lysine HCl-L-Arginine HCl, 2.5 %,

sterile solution for infusion Lysine HCl-Arginine HCl, 2.5 % (1L)
Drug

Metoclopramide

ATC code A03FA01
Drug

[177Lu]Lu-DOTA-TATE

\[177Lu\]Lu-DOTA-TATE will be administered as an intravenous infusion at a dose of 7.4 GBq (200mCi) (+/- 10%) every 6 weeks for 6 cycles.

Drug

[177Lu]Lu-NeoB

\[177Lu\]Lu-NeoB will be administered as an intravenous infusion at a dose of 9.25 GBq (250mCi) every 6 weeks for 6 cycles
Drug

[177Lu]Lu-PSMA-617

\[177Lu\]Lu-PSMA-617 will be administered as an intravenous infusion at a dose of 7.4 GBq (200mCi) (+/- 10%), every 6 weeks for 6 cycles.
Drug

[68Ga]GA-DOTA-TATE

\[68Ga\]Ga-DOTA-TATE will be administered as a single intravenous dose to be administered during baseline imaging and approximately 7 weeks after last RLT dose, within a range of 100-200MBq (2.7-5.4 mCi)
Drug

[68Ga]Ga-NeoB

\[68Ga\]Ga-NeoB will be administered as a single intravenous dose to be administered during baseline imaging and approximately 7 weeks after last RLT dose.within a range of 150-250 MBq (4.1-6.8 mCi).
Drug

[68Ga]Ga-PSMA-11

\[68Ga\]Ga-PSMA-11 will be administered as a single intravenous dose of approximately 150 MBq (4 mCi) to be administered during baseline imaging and approximately 7 weeks after last RLT dose. Administered dose should not be lower than 111 MBq (3 mCi) or higher than 259 MBq (7 mCi)

Eligibility Criteria

Key Inclusion criteria:

* Participants must have metastatic prostate cancer with neuroendocrine differentiation as determined by at least one of the following:

1. Histologically small cell or neuroendocrine cancer from a primary prostate or metastatic biopsy confirmed by local laboratory.
2. Expression of NEPC markers (e.g., chromogranin or synaptophysin) in tumor tissue by IHC confirmed by local laboratory
3. Progression of visceral metastases in the absence of PSA progression
4. Serum chromogranin A \> 5x normal limit, or neuron-specific enolase \> 2x normal limit with control for proton-pump inhibitors (PPI) drugs among concomitant treatment
5. Prostate adenocarcinoma with molecular features of neuroendocrine differentiated cancer (e.g., 2 of the following 3: PTEN, TP53, or RB loss)

* PSMA and/or SSTR2 and/or GRPR PET-positive participants, with at least one measurable lesion per RECIST 1.1 with moderate target expression in at least one of the 3 PET scans

* Castrate level of serum/plasma testosterone (\< 50 ng/dl, or \< 1.7 nmol/L) for participants with adenocarcinoma component or stable testosterone level for participants with pure neuroendocrine carcinoma
* Recovered to ≤ Grade 2 from all clinically significant toxicities related to prior therapy
* Participant has adequate bone marrow and organ function (as assessed by central laboratory for eligibility)
* ECOG status =\< 2

Key Exclusion criteria:

* Previous treatment with any of the following within 6 months prior to Screening: Strontium-89, Samarium-153, Rhenium-186, Rhenium-188, Radium-223, hemi-body irradiation
* Previous PSMA, SSTR2, or GRPR targeted radioligand therapy
* Other concurrent cytotoxic chemotherapy, immunotherapy, radioligand therapy or investigational therapy
* History of CNS metastases that are neurologically unstable, symptomatic, or receiving corticosteroids for the purpose of maintaining neurologic integrity
* Symptomatic cord compression, or clinical or radiologic findings indicative of impending cord compression
* History or current diagnosis of ECG abnormalities indicating significant risk of safety for study participants

Other protocol-defined inclusion/exclusion criteria may apply.

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