Phase I/II Study of [225Ac]Ac-PSMA-R2 in PSMA-positive Prostate Cancer, With/Without Prior 177Lu-PSMA RLT

Last Update: Mar 05, 2025
SatisfACtion: Phase I/II, Open-label, Multi-center Study of [225Ac]Ac-PSMA-R2 in Men With mHSPC and Heavily Pre-treated PSMA-positive mCRPC, With/Without Prior 177Lu-labelled PSMA-targeted Radioligand Therapy
ClinicalTrials.gov Identifier:
NCT05983198
Novartis Reference Number:CAAA802A12101
See if you Pre-qualify
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

This is an open label, phase I/II, multi-center study in adult participants with metastatic hormone sensitive prostate cancer (mHSPC) and with metastatic castration resistant prostate cancer (mCRPC) who have received prior anti-cancer treatment and have a positive 68Ga-PSMA-11 PET scan. The purpose of this study is to learn if the study drug, \[225Ac\]Ac-PSMA-R2, is safe and tolerable, and has anti-tumor activity in treated patients. The study contains three groups (Group 1, Group 2, and Group 3). Each group has a dose escalation part at a specific dosing schedule followed by a dose expansion part. The dose escalation parts in each group within each dosing schedule will establish the maximum tolerated dose or the recommended dose for expansion (MTDs/RDEs) of the 225Ac-PSMA-R2. Dose escalation decisions will be made by the Investigators and Novartis during dose escalation meetings (DEMs) based on safety and tolerability information. The dose expansion parts in each group group/dosing schedule will assess the anti-tumor activity in the mHSPC and mCRPC populations.

Condition
Prostate Cancer
Phase
Phase1, Phase2
Overall Status
Recruiting
Number of Participants
200
Start Date
Nov 07, 2023
Completion Date
Nov 05, 2029
Gender

Male
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

225Ac-PSMA-R2

PSMA-R2 is a ligand coupled with 225Ac an alpha emitting radionuclide
Radiation

68Ga-PSMA-11

Kit for radiopharmaceutical preparation
Radiation

68Ga-PSMA-R2

Kit for radiopharmaceutical preparation

Eligibility Criteria

Key Inclusion Criteria:

* Evidence of PSMA-positive disease by 68Ga-PSMA-11 PET/CT and eligible as determined by central reading
* Documented progressive mCRPC or mHSPC
* Adequate organ function
* Prior orchiectomy or ongoing ADT and should have received prior 177Lu-PSMA-RLT (Group1 dose escalation \& expansion) or never received 177Lu-PSMA-RLT (Group 2 and Group 3 dose escalation \& expansion).

Key Exclusion Criteria:

* Any other investigational agents within 28 days of the anticipated C1D1 of 225Ac-PSMA-R2 therapy
* Any systemic anti-cancer therapy within 28 days of the anticipated C1D1 of 225Ac-PSMA-R2 therapy
* Uncontrolled pain or incompatibility that may result in participant's lack of ability to comply with imaging procedures
* History of CNS metastases and symptomatic cord compression, or clinical or radiologic findings indicative of impending cord compression
* History of myocardial infarction, angina pectoris, or coronary artery bypass graft within 6 months prior to ICF signature and/or clinically active significant cardiac disease
* Diagnosis of other malignancies in the past three years expected to alter life expectancy or may interfere with disease assessment

Other protocol-defined inclusion/exclusion criteria may apply.

Australia

Novartis Investigative Site

Recruiting

Darlinghurst,New South Wales,2010,Australia

Canada

Novartis Investigative Site

Recruiting

Montreal,Quebec,H2x 1r9,Canada

Novartis Investigative Site

Recruiting

Montreal,Quebec,H3t 1e2,Canada

France

Novartis Investigative Site

Recruiting

Vandoeuvre Les Nancy,54511,France

Novartis Investigative Site

Recruiting

Dijon,Cote D Or,21034,France

Novartis Investigative Site

Recruiting

Clermont-Ferrand,63011,France

Novartis Investigative Site

Recruiting

Lyon,69373,France

Novartis Investigative Site

Recruiting

Nantes Cedex 1,44093,France

Novartis Investigative Site

Recruiting

Saint Herblain,44805,France

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

Novartis Pharmaceuticals

Phone: +41613241111
Email:

Novartis Pharmaceuticals

Phone: 1-888-669-6682
Email: novartis.email@novartis.com

Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct05983198*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT05983198
2. #trial-eligibility
3. tel:+41613241111
4. mailto:
5. tel:1-888-669-6682
6. mailto:novartis.email@novartis.com