A Phase II Study of AAA617 Alone and AAA617 in Combination With ARPI in Patients With PSMA PET Scan Positive CRPC

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An International Prospective Open-label, Multi-center, Randomized, Non-comparative Phase II Study of Lutetium [177Lu] Vipivotide Tetraxetan (AAA617) Alone and Lutetium [177Lu] Vipivotide Tetraxetan (AAA617) in Combination With Androgen Receptor Pathway Inhibitors in Patients With PSMA PET Scan Positive Castration-Resistant Prostate Cancer
ClinicalTrials.gov Identifier:
NCT05849298
Novartis Reference Number:CAAA617B12203
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

The purpose of this study is to evaluate the efficacy and safety of AAA617 alone (Lutetium \[177Lu\] vipivotide tetraxetan) and in combination with an Androgen Receptor Pathway Inhibitors (ARPI) in participants with PSMA-positive, castration-resistant prostate cancer and no evidence of metastasis in conventional imaging (CI) (i.e., CT/MRI and bone scans). Approximately 120 participants will be randomized.

Condition
Prostatic Neoplasm
Phase
Phase2
Overall Status
Recruiting
Number of Participants
120
Start Date
Jan 03, 2024
Completion Date
Dec 22, 2028
Gender
Male
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

AAA517

Single intravenous dose of approx. 150 Megabecquerel (MBq) prior PSMA-PET scans
Drug

AAA617

Administration intravenously once every 6 weeks (1 cycle) for 6 cycles
Drug

ADT

as prescribed by the local investigator
Drug

ARPI

Enzalutamide, Darolutamide, Apalutamide as prescribed by the local investigator
Other

Best supportive care

as prescribed by the local investigator
Drug

Piflufolastat F 18

Single intravenous dose of approx. 333 Megabecquerel (MBq) prior PSMA-PET scans

Eligibility Criteria

Key Inclusion criteria

* Participants must be adults ≥ 18 years of age with signed informed consent prior to participation to study
* Histologically or cytologically confirmed prostate cancer
* Participants must have ongoing androgen deprivation therapy with a GnRH agonist/antagonist or prior bilateral orchiectomy
* Castrate level of serum testosterone (\< 1.7 nmol/l \[50 ng/dl\]) on GnRH agonist or antagonist therapy or after bilateral orchiectomy
* Participants must have evidence of PSMA-positive disease as seen on a AAA517 or piflufolastat F 18 PET/CT scan at baseline as determined by Blinded Independent Central Review (BICR) based on the methodology proposed in the Prostate Cancer Molecular Imaging Standardized Evaluation (PROMISE) (Eiber et al 2018). Participants with M1 disease only on PSMA PET scan are allowed to participate
* Participants must have a negative conventional imaging for M1 disease.
* PSA Doubling Time (PSADT) of ≤ 10 months
* Participants must have adequate organ functions: bone marrow reserve, hepatic \& renal

Key Exclusion criteria

* Prior or present evidence of metastatic disease as assessed by CT/MRI locally for soft tissue disease and whole-body radionuclide bone scan for bone disease. Exception: Participants with soft tissue pelvic disease may be eligible (e.g., participants with enlarged lymph nodes below the aortic bifurcation (N1) are eligible if the short axis of the largest lymph node is \<20 mm)
* Unmanageable concurrent bladder outflow obstruction or urinary incontinence. Note: participants with bladder outflow obstruction or urinary incontinence, which is manageable with best available standard of care (incl. pads, drainage) are allowed
* Active clinically significant cardiac disease; history of seizure or condition that may pre-dispose to seizure which may require treatment with surgery or radiation therapy
* Prior therapy with: second generation anti-androgens (e.g., enzalutamide, apalutamide and darolutamide); CYP17 inhibitors (e.g., abiraterone acetate, orteronel, galeterone, ketoconazole; radiopharmaceutical agents (e.g., Strontium-89), PSMA-targeted radioligand therapy; immunotherapy (e.g., sipuleucel-T); chemotherapy, except if administered in the adjuvant/neoadjuvant setting, completed \> 2 years before randomization; any other investigational agents for CRPC; use of estrogens, 5-α reductase inhibitors (finasteride, dutasteride), other steroidogenesis inhibitors (aminoglutethimide) or first-generation anti-androgens (bicalutamide, flutamide, nilutamide, cyproterone) within 28 days before randomization; radiation therapy (external beam radiation therapy \[EBRT\] and brachytherapy within 28 days before randomization
* Other concurrent cytotoxicity chemotherapy, immunotherapy, radioligand therapy, poly adenosine diphosphate-ribose polymerase (PARP) inhibitor, biological therapy or investigational therapy

Other protocol-defined inclusion/exclusion criteria may apply.

Brazil

Novartis Investigative Site

Recruiting

Sao Paulo,SP,01308-050,Brazil

Novartis Investigative Site

Recruiting

Sao Paulo,SP,05652-000,Brazil

Canada

Novartis Investigative Site

Recruiting

Toronto,Ontario,M5g 2m9,Canada

Novartis Investigative Site

Recruiting

Montreal,Quebec,H2x 1r9,Canada

Novartis Investigative Site

Recruiting

Montreal,Quebec,H3t 1e2,Canada

China

Novartis Investigative Site

Recruiting

Nanjing,Jiangsu,210029,China

Novartis Investigative Site

Recruiting

Beijing,100028,China

Czechia

Novartis Investigative Site

Recruiting

Olomouc,779 00,Czechia

France

Novartis Investigative Site

Recruiting

Caen,14021,France

Novartis Investigative Site

Recruiting

Paris,75014,France

Novartis Investigative Site

Recruiting

Strasbourg,67200,France

Novartis Investigative Site

Recruiting

Brest,29609,France

Novartis Investigative Site

Recruiting

Angers 02,49055,France

Germany

Novartis Investigative Site

Recruiting

Berlin,10249,Germany

Novartis Investigative Site

Recruiting

Koeln,50937,Germany

Italy

Novartis Investigative Site

Recruiting

Genova,GE,16132,Italy

Novartis Investigative Site

Recruiting

Roma,RM,00128,Italy

Novartis Investigative Site

Recruiting

Milano,MI,20141,Italy

Novartis Investigative Site

Recruiting

Napoli,80131,Italy

Korea, Republic of

Novartis Investigative Site

Recruiting

Seoul,03080,Korea, Republic of

Novartis Investigative Site

Recruiting

Seoul,05505,Korea, Republic of

Netherlands

Novartis Investigative Site

Recruiting

Arnhem,Gelderland,6815 ad,Netherlands

Poland

Novartis Investigative Site

Recruiting

Kielce,25-640,Poland

Novartis Investigative Site

Recruiting

Krakow,31-501,Poland

Singapore

Novartis Investigative Site

Recruiting

Singapore,119228,Singapore

Novartis Investigative Site

Recruiting

Singapore,169608,Singapore

Spain

Novartis Investigative Site

Recruiting

Barcelona,Catalunya,08036,Spain

Novartis Investigative Site

Recruiting

Valencia,Comunidad Valenciana,46010,Spain

Novartis Investigative Site

Recruiting

Vigo,Galicia,36204,Spain

Novartis Investigative Site

Recruiting

Madrid,28040,Spain

Novartis Investigative Site

Recruiting

Terrassa,Catalunya,08221,Spain

Novartis Investigative Site

Recruiting

Granada,Andalucia,18014,Spain

Novartis Investigative Site

Recruiting

Hospitalet de Llobregat,Barcelona,08907,Spain

United States

Rio Grande Urology

Recruiting

El Paso,Texas,79912,United States

Jameson Travis Mendel

Cynthia Cordero

Email: ccordero@riograndeurology.com

Urology Clinic of North Texas

Recruiting

Dallas,Texas,75231,United States

Alexia Demitsas

Phone: 214-271-9971

Email: ademitsas@urologyclinics.com

Wilson Hernandez

UT Health San Antonio Mays Cancer Center

Recruiting

San Antonio,Texas,78229,United States

Leslie Vega Garcia

Phone: 210-450-1950
Email: vegagarcia@uthscsa.edu

Chul Ha

Urology Associates of Mobile

Recruiting

Mobile,Alabama,36608,United States

Charles F White

Letoya Craig

Email: lcraig@uampa.com

Oregon Urology Institute

Recruiting

Springfield,Oregon,97477,United States

Victoria Evans

Email: vevans@oregonurology.com

Bryan Mehlhaff

Univ of Texas Southwest Med Center

Recruiting

Dallas,Texas,75390-9034,United States

Anna Manning Mortimer

Phone: 214-645-7728
Email: anna.manning-mortimer@utsouthwestern.edu

Orhan Oz

Rocky Mountain Cancer Centers

Recruiting

Longmont,Colorado,80501,United States

Allen Cohn

Lee Dimopoulos

Phone: 303-338-4876
Email: Lee.Dimopoulos@usoncology.com

Urology Cancer Center PC

Recruiting

Omaha,Nebraska,68130,United States

Luke Nordquist

Stephanie Vaughn

Phone: 402-697-2229
Email: stephaniev@xcancer.com

Houston Methodist Hospital

Recruiting

Houston,Texas,77030,United States

Brian Miles

Vivian MacDonnell

Email: vmmacdonnell@houstonmethodist.org

University Cancer and Blood Center LLC

Recruiting

Athens,Georgia,30607,United States

Laurie Bridges

Phone: 706-353-2990
Email: laurie.bridges@universitycancer.com

Petros Nikolinakos

Carolina Urologic Research Center, LLC

Recruiting

Myrtle Beach,South Carolina,29572,United States

Lindsey Rabon

Phone: 843-839-1679
Email: lrabon@curcmb.com

Neal D Shore

Wellspan York Hospital

Recruiting

York,Pennsylvania,17403,United States

Denise Tuleya

Email: dtuleya@wellspan.org

Navesh Sharma

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

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8. mailto:lcraig@uampa.com

9. mailto:vevans@oregonurology.com
10. tel:214-645-7728
11. mailto:anna.manning-mortimer@utsouthwestern.edu
12. tel:303-338-4876
13. mailto:Lee.Dimopoulos@usoncology.com
14. tel:402-697-2229
15. mailto:stephaniev@xcancer.com
16. mailto:vmmacdonnell@houstonmethodist.org
17. tel:706-353-2990
18. mailto:laurie.bridges@universitycancer.com
19. tel:843-839-1679
20. mailto:lrabon@curcmb.com
21. mailto:dtuleya@wellspan.org
22. tel:+41613241111
23. mailto:
24. tel:1-888-669-6682
25. mailto:novartis.email@novartis.com