A Dose Finding Study of [177Lu]Lu-DOTA-TATE in Newly Diagnosed Glioblastoma in Combination With Standard of Care and in Recurrent Glioblastoma as a Single Agent.

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A Phase Ib Dose Finding Study Assessing Safety and Activity of [177Lu]Lu-DOTA-TATE in Newly Diagnosed Glioblastoma in Combination With Radiotherapy With or Without Temozolomide and in Recurrent Glioblastoma as Single Agent
ClinicalTrials.gov Identifier:
NCT05109728
Novartis Reference Number:CAAA601A52101
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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

A Dose Finding Study of \[177Lu\]Lu-DOTA-TATE in Newly Diagnosed Glioblastoma in Combination with Standard of Care and in Recurrent Glioblastoma as a Single Agent The study for each participant consists of a Screening period, a Treatment period and a 12-month Follow-up period.

During the screening period of up to 6 weeks before starting GBM treatment, each participant will be assessed for somatostatin receptor (SSTR) expression by \[68Ga\]Ga-DOTA-TATE imaging PET/scan.

Eligible participants with newly diagnosed glioblastoma will be assigned to Group 1 :

• Participants in Group 1 (concomitant radiotherapy + temozolomide and temozolomide maintenance) will receive treatment with \[177Lu\]Lu-DOTA-TATE every 4 weeks +/- 2 days, up to 6 administrations. Radiotherapy and temozolomide will be administered 7 to 10 days after the first administration of \[177Lu\]Lu-DOTA-TATE. Temozolomide will be administered orally at a dose of 75 mg/m2/day during the concomitant period, concurrently with radiotherapy. Radiotherapy will be delivered at a dose of 2 Gray (Gy)/day, 5 days per week followed by 2 days of rest, for 6 consecutive weeks with a total dose of 60 Gy (without interruption). During the maintenance period, there is an intra-patient dose escalation in temozolomide treatment. The dosage of temozolomide is 150 mg/m2 in Cycle 1 of maintenance period, and then to 200 mg/m2 in Cycle 2 and beyond in the maintenance period, if 150 mg/m2 temozolomide treatment is well tolerated in Cycle 1.

Eligible participants with recurrent glioblastoma will be assigned to Group 3 and will receive \[177Lu\]Lu-DOTA-TATE as single agent treatment every 3 weeks +/- 2 days.

An infusion of sterile 2.5% Lysine - Arginine amino acid (AA) solution will be co-administered with each \[177Lu\]Lu-DOTA-TATE dose for renal protection.

Condition
Glioblastoma
Phase
Phase1
Overall Status
Recruiting
Number of Participants
60
Start Date
May 10, 2022
Completion Date
Feb 25, 2026
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Other

Radiotherapy

2 Gy/day, 5 days per week followed by 2 days of rest, for 6 consecutive weeks
Other

Temozolomide

Concomitant Phase: Temozolomide 75mg/m2/d p.o until last day of EBRT. Maintenance Phase: Temozolomide p.o 150 mg/m2/d during cycle 1 then 200 mg/m2/d for the following cycles if tolerated well in Cycle 1. 6 cycles total (1 cycle = every 28 days)
Drug

[177Lu]Lu-DOTA-TATE

Group 1: \[177Lu\]Lu-DOTA-TATE, dose level 0 (150mCi) administered every 4 weeks. Three provisional dose levels (Dose level +2: 250 mCi; Dose level +1: 200 mCi; Dose level -1: 100 mCi) will be assessed. Group 3: \[177Lu\]Lu-DOTA-TATE, dose level 0 (150mCi) administered every 3 weeks. Three provisional dose levels (Dose level +2: 250 mCi; Dose level +1: 200 mCi; Dose level -1: 100 mCi) will be assessed.
Drug

[68Ga]Ga-DOTA-TATE

2 MBq/kg of body weight (0.054 mCi/kg), with a minimum dose of 100 MBq (2.7 mCi) and maximum dose of 200 MBq (5.4 mCi)

Eligibility Criteria

Key Inclusion Criteria:

Common Criteria:

* Participant is \>= 18 years on the day of signing informed consent form
* Histologically confirmed glioblastoma
* Adequate bone marrow, organ function and electrolyte values

Newly diagnosed glioblastoma (Group 1):

* Presence of Gadolinium enhancing tumor in pre-surgery magnetic resonance imaging (MRI)
* Karnofsky Performance Score (KPS) \>= 70 %

Recurrent glioblastoma (Group 3 dose Escalation only):

• Participant has experienced first or second recurrence of their glioblastoma, after standard or experimental therapy that includes prior EBRT

Recurrent glioblastoma (Group 3 dose escalation and expansion):

* Evidence of recurrent disease demonstrated by disease progression using modified Response Assessment in Neuro-Oncology (mRANO) criteria
* KPS \>= 60 %
* \[68Ga\]Ga-DOTA-TATE uptake by positron emission tomography/computed tomography (PET/CT) or PET/MRI at the tumor region
* Presence of Gadolinium enhancement in the tumor region in MRI at the time of diagnosis of tumor recurrence
* A second surgery for glioblastoma is allowed provided that the following criteria are met:

1. Residual and measurable disease post-surgery is not required but surgery must have confirmed the diagnosis of recurrence
2. Surgery completed at least 2 weeks prior to study treatment initiation, with post-surgery recovery without any complications related to surgical procedure

Recurrent glioblastoma (Group 3 Dose Expansion only):
* Patients experiencing first recurrence of their glioblastoma, after standard or experimental therapy that includes prior EBRT

Key Exclusion Criteria:

Common Criteria:

* Participant is receiving additional, concurrent, active therapy for glioblastoma outside of the trial
* Extensive leptomeningeal disease
* History of another active malignancy in the previous 3 years prior to study entry
* Prior administration of a radiopharmaceutical unless 10 or more effective half-lives have elapsed before injection of \[68Ga\]Ga-DOTA-TATE or \[177Lu\]Lu-DOTA-TATE

Newly diagnosed glioblastoma (Group 1):

• Any prior treatment for glioma of any grade

Recurrent glioblastoma (Group 3 dose escalation and expansion):

* Early disease progression prior to 3 months from the completion of radiotherapy

* Previous treatment with bevacizumab for the treatment of glioblastoma with therapeutic intent, or with bevacizumab as supportive therapy (e.g. edema reduction) within 60 days of initiation of study treatment

Recurrent glioblastoma (Group 3 dose escalation only):

• More than 2 prior lines for systemic therapy

Recurrent glioblastoma (Group 3 dose expansion only):

• More than 1 prior line for systemic therapy

France

Novartis Investigative Site

Recruiting

Bron,69677,France

Spain

Novartis Investigative Site

Recruiting

Granada,Andalucia,18014,Spain

Novartis Investigative Site

Recruiting

Barcelona,Catalunya,08035,Spain

Novartis Investigative Site

Recruiting

Barcelona,Catalunya,08036,Spain

Novartis Investigative Site

Recruiting

Madrid,28041,Spain

Novartis Investigative Site

Recruiting

Madrid,28050,Spain

Switzerland

Novartis Investigative Site

Recruiting

Zuerich,8091,Switzerland

United States

University of Pittsburgh

Recruiting

Pittsburgh,Pennsylvania,15213,United States

Natasha Bennett

Phone: 412-648-6575
Email: bennettn10@upmc.edu

Jan Drappatz

MD Anderson Cancer Center Uni of Te

Recruiting

Houston,Texas,77030,United States

Nazanin K Majd

Sahar Khan

Email: sakhan8@mdanderson.org

Dana Farber Cancer Institute

Recruiting

Boston,Massachusetts,02215,United States

Elisa Aquilanti

Rasha Baig

Email: rasha_baig@dfci.harvard.edu

University of Wisconsin School of Medicine and Public Health

Recruiting

Madison,Wisconsin,53792-1615,United States

Ankush Bhatia

Ashley Parr

Phone: 608-262-5024
Email: aparr@wisc.edu

Col Uni Med Center New York Presby

Recruiting

New York,New York,10032,United States

Mikhail Doubrovin

Millie Metchick

Phone: 212-304-5684
Email: mm6733@cumc.columbia.edu

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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