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Trial record **1 of 1** for: m13-813

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A Study of ABT-414 in Subjects With Newly Diagnosed Glioblastoma (GBM) With Epidermal Growth Factor Receptor (EGFR) Amplification (Intellance 1)

This study is currently recruiting participants. (see Contacts and Locations)

Verified October 2015 by AbbVie

Sponsor:
AbbVie

Collaborator:
Radiation Therapy Oncology Group

Information provided by (Responsible Party):
AbbVie

ClinicalTrials.gov Identifier:
NCT02573324

First received: September 28, 2015
Last updated: October 8, 2015
Last verified: October 2015
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

This study seeks to determine whether the addition of ABT-414 to concomitant radiotherapy and temozolomide (TMZ) prolongs progression free survival (PFS) and overall survival (OS) in participants with newly diagnosed glioblastoma (GBM) with epidermal growth factor receptor (EGFR) amplification.

Condition	Intervention	Phase
Glioblastoma Gliosarcoma	Drug: ABT-414 Radiation: Radiation Drug: Temozolomide Drug: Placebo for ABT-414	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator)
Primary Purpose: Treatment

Official Title: A Randomized, Placebo Controlled Phase 2b/3 Study of ABT-414 With Concurrent Chemoradiation and Adjuvant Temozolomide in Subjects With Newly Diagnosed Glioblastoma (GBM) With Epidermal Growth Factor Receptor (EGFR) Amplification (Intellance 1)

Resource links provided by NLM:

Drug Information available for: Temozolomide

Genetic and Rare Diseases Information Center resources: Glioblastoma Glioma Gliosarcoma Neuroepithelioma

U.S. FDA Resources

Further study details as provided by AbbVie:

Primary Outcome Measures:

- Progression Free Survival (PFS) for Phase 2b [Time Frame: At Baseline, then every 8 weeks, at follow up visits and at the final study drug visit, for an average of up to 2 years.] [Designated as safety issue: No]

Time to PFS is defined as the number of days from the date of randomization to the date of earliest disease progression based on Response Assessment in Neuro Oncology (RANO) criteria (as determined by the Investigator) or to the date of death, if disease progression does not occur.

- Overall Survival (OS) for Phase 3 [Time Frame: Quarterly after treatment discontinuation for approximately 4 years] [Designated as safety issue: No]

  Time to OS is defined as the number of days from the date of randomization to the date of death due to any cause.

Secondary Outcome Measures:

- Progression Free Survival (PFS) for Phase 3 [Time Frame: At Baseline, then every 8 weeks, at follow up visits and at the final study drug visit, for an average of up to 2 years.] [Designated as safety issue: No]

  Time to PFS is defined as the number of days from the date of randomization to the date of earliest disease progression based on Response Assessment in Neuro Oncology (RANO) criteria (as determined by the Investigator) or to the date of death, if disease progression does not occur.

- Overall Survival (OS) for Phase 2b [Time Frame: Quarterly after treatment discontinuation for approximately 4 years] [Designated as safety issue: No]

  Time to OS is defined as the number of days from the date of randomization to the date of death due to any cause.

- OS for the EGFRvIII-mutated tumor subgroup [Time Frame: Quarterly after treatment discontinuation for approximately 4 years] [Designated as safety issue: No]

  Time to OS is defined as the number of days from the date of randomization to the date of death due to any cause.

- PFS for EGFRvIII-mutated tumor subgroup [Time Frame: At Baseline, then every 8 weeks, at follow up visits and at the final study drug visit, for an average of up to 2 years.] [Designated as safety issue: No]

  Time to PFS is defined as the number of days from the date of randomization to the date of earliest disease progression based on Response Assessment in Neuro Oncology (RANO) criteria (as determined by the Investigator) or to the date of death, if disease progression does not occur.

- Number of days to deterioration in neurocognitive functioning [Time Frame: At Screening, every 8 weeks until disease progression, and post-progression, for an average of up to 2 years.] [Designated as safety issue: No]

  Number of days from baseline to 0.5 SD or greater deterioration from baseline on the composite score of the Clinical Trial Battery.

- Number of days to deterioration in symptom severity score M.D. Anderson Symptom Inventory Brain Tumor Module (MDASI-BT) [Time Frame: At Screening, every 8 weeks until disease progression, and post-progression, for an average of up to 2 years.] [Designated as safety issue: No]

  Number of days from baseline to 1 point or greater increase in MDASI-BT symptom severity score.

- Number of days to deterioration in symptom interference score (MDASI-BT) [Time Frame: At Screening, every 8 weeks until disease progression, at post-progression, for an average of up to 2 years.] [Designated as safety issue: No]

  Number of days from baseline to 1 point or greater increase in MDASI-BT symptom interference score.

Estimated Enrollment:	720
Study Start Date:	October 2015
Estimated Study Completion Date:	March 2020
Estimated Primary Completion Date:	March 2020 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: ABT-414, radiation and TMZ ABT-414 is given on Day 1 of Week 1, 3 and 5 along with the standard therapy of TMZ and radiation during the chemoradiation phase. ABT-414 is given on Day 1 & 15 of each cycle along with TMZ (Days 1-5 of each cycle) per standard of care during the adjuvant phase.	Drug: ABT-414 intravenous infusion Radiation: Radiation Drug: Temozolomide oral
Placebo Comparator: Placebo, radiation and TMZ Placebo is given on Day 1 of Week 1, 3 and 5 along with the standard therapy of TMZ and radiation during the chemoradiation phase. Placebo is given on Day 1 & 15 of each cycle along with TMZ (Days 1-5 of each cycle) per standard of care during the adjuvant phase.	Radiation: Radiation Drug: Temozolomide oral

	Drug: Placebo for ABT-414 intravenous infusion

Eligibility

Ages Eligible for Study: 18 Years to 99 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria: 1. Must have a clinical diagnosis of Glioblastoma (GBM) 2. Must have a confirmed Epidermal growth factor receptor amplification in tumor tissue 3. Must have a Karnofsky Performance Status (KPS) performance score of 70 - 100.

4. Must have recovered from effects of surgery, postoperative infection and other complications of surgery.

5. Must have adequate bone marrow, renal, and hepatic function Exclusion Criteria: 1. Multifocal, recurrent or metastatic Glioblastoma (GBM) or gliomatosis cerebri 2. Prior chemo therapy or radiosensitizer for head and neck cancer. 3. Prior radiotherapy to the head or neck in overlap of radiation fields. 4. Prior therapy for glioblastoma or other invasive malignancy. 5. Prior, concomitant or planned treatment with Novo-TTF, EGFR-targeted therapy, bevacizumab, Gliadel wafers or other intratumoral or intracavity anti-neoplastic therapy.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02573324

Contacts

Contact: Kathy Kim, MS 847-938-0255 kathy.kim@abbvie.com

Contact: Kysa Meek 847-938-1090 kysa.a.meek@abbvie.com

Locations

United States, Arkansas

Site Reference ID/Investigator# 142050 **Recruiting**
Fayetteville, Arkansas, United States, 72703
Principal Investigator: Site Reference ID/Investigator# 142050, MD

Brazil

Site Reference ID/Investigator# 143876 **Not yet recruiting**
Barretos, Brazil, 14784-400
Principal Investigator: Site Reference ID/Investigator# 143876, MD

Site Reference ID/Investigator# 143878 **Not yet recruiting**
Natal, Brazil, 59075-740
Principal Investigator: Site Reference ID/Investigator# 143878, MD

Site Reference ID/Investigator# 143879 **Not yet recruiting**
Porto Alegre, Brazil, 90610-000
Principal Investigator: Site Reference ID/Investigator# 143879, MD

Site Reference ID/Investigator# 143877 **Not yet recruiting**
Rio de Janeiro, Brazil, 20230-130
Principal Investigator: Site Reference ID/Investigator# 143877, MD

Site Reference ID/Investigator# 144031 **Not yet recruiting**
Sao Paulo, Brazil, 01246-000
Principal Investigator: Site Reference ID/Investigator# 144031, MD

Mexico

Site Reference ID/Investigator# 143888 **Not yet recruiting**
Guadalajara, Jalisco, Mexico, 44280
Principal Investigator: Site Reference ID/Investigator# 143888, MD

Sponsors and Collaborators

AbbVie

Radiation Therapy Oncology Group

Investigators

Study Director: Earle Bain, MD AbbVie

More Information

No publications provided

Responsible Party:	AbbVie
ClinicalTrials.gov Identifier:	NCT02573324 History of Changes
Other Study ID Numbers:	**M13-813**, 2015-001166-26
Study First Received:	September 28, 2015
Last Updated:	October 8, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by AbbVie:

Newly Diagnosed Glioblastoma	ABT-414
Radiology Therapy Oncology Group	EGFRvIII
Brain Tumor	Antibody Drug Conjugate
Brain Tumor Group	Epithelial Growth Factor Receptor
Temozolomide	

Additional relevant MeSH terms:

Glioblastoma	Neuroectodermal Tumors
Gliosarcoma	Mitogens
Astrocytoma	Temozolomide
Glioma	Alkylating Agents
Neoplasms	Antineoplastic Agents
Neoplasms by Histologic Type	Antineoplastic Agents, Alkylating
Neoplasms, Germ Cell and Embryonal	Mitosis Modulators
Neoplasms, Glandular and Epithelial	Molecular Mechanisms of Pharmacological Action
Neoplasms, Nerve Tissue	Pharmacologic Actions
Neoplasms, Neuroepithelial	Therapeutic Uses

ClinicalTrials.gov processed this record on November 24, 2015