

## Service Alert: Planned Maintenance on July 26th

Most services will be unavailable for 12+ hours starting 6 AM EDT.

[Learn more about the maintenance](#)



Record 1 of 1



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Terminated

Safety

# A Study Evaluating Safety and Pharmacokinetics of ABBV-221 in Subjects With Advanced Solid Tumor Types Likely to Exhibit Elevated Levels of Epidermal Growth Factor Receptor

ClinicalTrials.gov ID NCT02365662

Sponsor AbbVie

Information provided by AbbVie (Responsible Party)

Last Update Posted 2018-03-30

## Study Details Tab

### Study Overview

#### Brief Summary

This is an open-label, Phase I, dose escalation study to determine the recommended Phase 2 dose, maximum tolerated dose, and evaluate the safety and pharmacokinetic profile of ABBV-221 in participants with advanced solid tumors likely to exhibit elevated levels of Epidermal Growth Factor Receptor (EGFR).



**Official Title**

A Phase 1 Study of **ABBV-221** in Subjects With Advanced Solid Tumor Types Likely to Exhibit Elevated Levels of Epidermal Growth Factor Receptor

**Conditions** ⓘ

Head and Neck Squamous Cell Carcinoma

Non-small Cell Lung Cancer

Triple Negative Breast Cancer

Colorectal Carcinoma

Glioblastoma Multiforme

**Intervention / Treatment** ⓘ

- Drug: **ABBV-221**

**Other Study ID Numbers** ⓘ

- 2014-003557-34 ( EudraCT Number )

**Study Start (Actual)** ⓘ

2015-01-09

**Primary Completion (Actual)** ⓘ

2018-03-15

**Study Completion (Actual)** ⓘ

2018-03-15

**Enrollment (Actual)** ⓘ

46

**Study Type** ⓘ

Interventional

**Phase** ⓘ

Phase 1

**Resource links provided by the National Library of Medicine**

[MedlinePlus Genetics](https://medlineplus.gov/genetics/) (<https://medlineplus.gov/genetics/>), related topics: [Head and neck squamous cell carcinoma](https://medlineplus.gov/genetics/condition/head-and-neck-squamous-cell-carcinoma) (<https://medlineplus.gov/genetics/condition/head-and-neck-squamous-cell-carcinoma>), [Breast cancer](https://medlineplus.gov/genetics/condition/breast-cancer) (<https://medlineplus.gov/genetics/condition/breast-cancer>).

[Genetic and Rare Diseases Information Center](https://rarediseases.info.nih.gov/gard) (<https://rarediseases.info.nih.gov/gard>), resources: [Glioblastoma](https://rarediseases.info.nih.gov/diseases/2491/glioblastoma) (<https://rarediseases.info.nih.gov/diseases/2491/glioblastoma>)

[Glioma](https://rarediseases.info.nih.gov/diseases/6513/glioma) (<https://rarediseases.info.nih.gov/diseases/6513/glioma>)

[Neuroepithelioma](https://rarediseases.info.nih.gov/diseases/3963/neuroepithelioma) (<https://rarediseases.info.nih.gov/diseases/3963/neuroepithelioma>)

[Drug Information](https://dailymed.nlm.nih.gov/dailymed/) (<https://dailymed.nlm.nih.gov/dailymed/>) available for:

[Urogastrone](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Urogastrone) (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Urogastrone>)

[FDA Drug and Device Resources](https://clinicaltrials.gov/fda-links) (<https://clinicaltrials.gov/fda-links>)

## Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.


To learn more, please see the [Contacts and Locations section in How to Read a Study Record](https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations) (<https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations>)


This study has 5 locations

### United States


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#### Massachusetts Locations

 **Boston, Massachusetts, United States, 02114**  
Massachusetts General Hospital

 **Boston, Massachusetts, United States, 02215**  
Dana-Farber Cancer Institute

#### Texas Locations

 **San Antonio, Texas, United States, 78229**  
South Texas Accelerated Research  
Therapeutics

### Spain

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 **Madrid, Spain, 28040**  
Fundacion Jimenez Diaz

 **Madrid, Spain, 28050**  
Hosp Univ Madrid Sanchinarro

## Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](#) (<https://clinicaltrials.gov/study-basics/learn-about-studies>)

### Eligibility Criteria

#### Description

##### Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 2.
- Has a solid tumor likely to exhibit elevated levels of EGFR (e.g. head and neck squamous cell carcinoma, non-small cell lung cancer, triple negative breast cancer ,colorectal carcinoma and glioblastoma multiforme).
- Has an archived, diagnostic tumor tissue available for analysis.
- Has adequate hematologic, renal, cardiac and hepatic function.
- Expanded Safety Cohort participants must have confirmed metastatic lung cancer and progressed after receiving prior platinum-containing chemotherapy.

##### Exclusion Criteria:

- Previously received an EGFR-directed monoclonal antibody within the past 4 weeks.
- Has unresolved, clinically significant toxicities from prior anti-cancer therapy defined as > Grade 1 on Common Terminology Criteria for Adverse Events.
- History of major immunologic reaction to any IgG containing agent.
- Any medical condition which in the opinion of the investigator places the participant at an unacceptably high risk for toxicities.

#### Ages Eligible for Study <sup>1</sup>

18 Years to 99 Years(Adult, Older Adult)

#### Sexes Eligible for Study <sup>1</sup>

All

#### Accepts Healthy Volunteers <sup>1</sup>

No

## Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

### How is the study designed?

#### Design Details

**Primary Purpose** ⓘ : Treatment

**Allocation** ⓘ : N/A

**Interventional Model** ⓘ : Single Group Assignment

**Masking** ⓘ : None (Open Label)

#### Arms and Interventions

Participant Group/Arm ⓘ	Intervention/Treatment ⓘ
Experimental: Arm 1  Solid Tumor Types Likely to Exhibit Elevated Levels of Epidermal Growth Factor Receptor	Drug: <b>ABBV-221</b> <ul style="list-style-type: none"> <li>• <b>ABBV-221</b> will be given either every 3 weeks or 2 weeks on, 1 week off or weekly dosing by intravenous infusion approximately over 30 minutes to 3 hours. This is a dose escalation study, therefore the dose of <b>ABBV-221</b> will change throughout the study.</li> </ul>

### What is the study measuring?

#### Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame

Number of participants with adverse events	Adverse event monitoring will be performed during the study	Measured for approximately 4 years
Maximum Plasma Concentration (C <sub>max</sub> ) of <b>ABBV-221</b>	The maximum plasma concentration (C <sub>max</sub> ; measured in ng/mL) is the highest concentration that a drug achieves in the plasma after administration in a dosing interval.	Blood samples will be collected before infusion (0 hour, pre-dose) on Cycle 1 Day 1 (C1D1), C1D2, C1D3, C1D5, C1D8, C1D15, C2D1, C3D1, C3D2, C3D3, C3D5, C3D8, C3D15, every 2 cycles starting with Cycle 5, and at

		the final visit (approximately 2 years).
Area Under the Plasma Concentration-time Curve from 0 to the Time of the Last Measurable Concentration (AUC <sub>t</sub> ) of <b>ABBV-221</b>	The area under the plasma concentration-time curve (AUC; measured in ng*hr/mL) is a method of measurement of the total exposure of a drug in blood plasma.	Blood samples will be collected before infusion (0 hour, pre-dose) on Cycle 1 Day 1 (C1D1), C1D2, C1D3, C1D5, C1D8, C1D15, C2D1, C3D1, C3D2, C3D3, C3D5, C3D8, C3D15, every 2 cycles starting with Cycle 5,

		and at the final visit (approximately 2 years).
Maximum tolerated dose of <b>ABBV-221</b>	The highest dose level at which less than 2 of 6 participants or less than 33% of (if cohort is expanded beyond 6) participants experience a dose limiting toxicity.	Up to 2 years from first dose of study drug.
Area Under the Plasma Concentration-time Curve of <b>ABBV-221</b>	The area under the plasma concentration-time curve (AUC; measured in ng*hr/mL) is a method of measurement of the total exposure of a drug in blood plasma.	Blood samples will be collected before infusion (0 hour, pre-dose) on Cycle 1 Day 1 (C1D1), C1D2, C1D3, C1D5, C1D8, C1D15, C2D1, C3D1,

		C3D2, C3D3, C3D5, C3D8, C3D15, every 2 cycles starting with Cycle 5, and at the final visit (approximately 2 years).
Recommended Phase 2 dose of <b>ABBV-221</b>	If a maximum tolerated dose (MTD) is reached, the recommended Phase 2 dose (RPTD) of <b>ABBV-221</b> will not be a dose higher than the defined MTD, and will be selected based on the type(s) and occurrence(s) of dose limiting toxicities which occur in addition to the MTD. If a MTD is not reached, then the RPTD will be defined based on the safety and pharmacokinetic data.	1 day of study drug administration within the 21-day cycle at the designated cohort dose

Secondary Outcome Measures 

Outcome Measure	Measure Description	Time Frame
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<p>Assess the effect of systemic <b>ABBV-221</b> administration on QT prolongation</p>	<p>ECG parameters will be descriptively summarized, and the relationship between change of baseline of QT interval corrected for heart rate and concentration of three analytes will be explored.</p>	<p>At Days 1, 2, 3, 5, 8 of Cycle 1; Day 1 of every cycle starting at Cycle 2, and Final Visit (approximately 2 years from first dose of study drug)</p>
<p>Objective Response Rate (ORR)</p>	<p>ORR is the proportion of participants with objective response per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 (complete or partial objective response) will be calculated for all dosed participants with at least one measurable lesion at baseline.</p>	<p>At screening; at the end of Cycle 2 and the end of every 3 cycles for approximately 2 years from first dose of</p>

study drug
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## Collaborators and Investigators

This is where you will find people and organizations involved with this study.

### Sponsor

**AbbVie**

### Investigators

- Study Director: AbbVie Inc., AbbVie

## Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

### Study Registration Dates

#### First Submitted

2015-02-05

#### First Submitted that Met QC Criteria

2015-02-16

#### First Posted (Estimated)

2015-02-19

## Study Record Updates

### Last Update Submitted that met QC Criteria ⓘ

2018-03-28

### Last Update Posted ⓘ

2018-03-30

### Last Verified ⓘ

2018-03

## More Information

### Terms related to this study

#### Keywords Provided by AbbVie

Oncology

Cancer

Solid Tumor types likely to exhibit elevated levels of Epidermal Growth Factor Receptor

Solid Tumors

#### Additional Relevant MeSH Terms

Neoplasms, Glandular and Epithelial

Neoplasms by Histologic Type

Neoplasms

Neoplasms by Site

Carcinoma, Squamous Cell

Astrocytoma

Glioma

Neoplasms, Neuroepithelial

Neuroectodermal Tumors

Neoplasms, Germ Cell and Embryonal

Neoplasms, Nerve Tissue

Breast Neoplasms

Breast Diseases

Skin Diseases

Head and Neck Neoplasms

Intestinal Neoplasms

Gastrointestinal Neoplasms

Digestive System Neoplasms

Digestive System Diseases

Gastrointestinal Diseases  
Colonic Diseases  
Intestinal Diseases  
Rectal Diseases  
Carcinoma  
Glioblastoma  
Triple Negative Breast Neoplasms  
Squamous Cell Carcinoma of Head and Neck  
Colorectal Neoplasms

## Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Undecided

## Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies a U.S. FDA-Regulated Device Product

No

Product Manufactured in and Exported from the U.S.

No