



The U.S. government does not review or approve the safety and science of all studies listed on this website.



Read our full [disclaimer](https://clinicaltrials.gov/about-site/disclaimer) (https://clinicaltrials.gov/about-site/disclaimer) for details.

Completed ⓘ

A Study of ABT-414 in Subjects With Solid Tumors

ClinicalTrials.gov ID ⓘ NCT01741727

Sponsor ⓘ AbbVie (prior sponsor, Abbott)

Information provided by ⓘ AbbVie (AbbVie (prior sponsor, Abbott)) (Responsible Party)

Last Update Posted ⓘ 2017-11-20

Study Details Tab

Study Overview

Brief Summary

A study of ABT-414 in subjects with solid tumors.

Official Title

A Phase 1/2 Study Evaluating the Safety, Pharmacokinetics and Efficacy of ABT-414 in Subjects With Advanced Solid Tumors Likely to Over-Express the Epidermal Growth Factor Receptor (EGFR)

Conditions ⓘ

Squamous Cell Tumors

Intervention / Treatment ⓘ

- Drug: ABT-414

Other Study ID Numbers ⓘ



- M13-379

Study Start ⓘ

2012-10

Primary Completion (Actual) ⓘ

2015-11

Study Completion (Actual) ⓘ

2015-11

Enrollment (Actual) ⓘ

57

Study Type ⓘ

Interventional

Phase ⓘ

Phase 1

Resource links provided by the National Library of Medicine

[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 6 locations

United States



Arizona Locations

-  **Scottsdale, Arizona, United States, 85258**
Site Reference ID/Investigator# 90333


Illinois Locations

-  **Chicago, Illinois, United States, 60637**
Site Reference ID/Investigator# 83156


Massachusetts Locations

-  **Boston, Massachusetts, United States, 02215**
Site Reference ID/Investigator# 117516
-  **Boston, Massachusetts, United States, 02215**
Site Reference ID/Investigator# 83154

Texas Locations

-  **San Antonio, Texas, United States, 78229**
Site Reference ID/Investigator# 83155

Canada

-  **Ottawa, Canada, K1H 8L6**
Site Reference ID/Investigator# 89035

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 \(https://clinicaltrials.gov/study-basics/learn-about-studies\)](https://clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion Criteria:

1. Subjects must have a solid tumor type likely to over-express Epidermal Growth Factor Receptor (EGFR) (Phase 1)
2. Subjects have an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-2
3. Subjects have available tumor tissue
4. Subjects have adequate bone marrow, renal, and hepatic function as follows: Bone marrow: Absolute neutrophil count (ANC) $\geq 1,500/\text{mm}^3$ Platelets $\geq 100,000/\text{mm}^3$; Hemoglobin ≥ 9.0 g/dL Renal function: Serum creatinine ≤ 1.5 times the upper limit of the institution's normal range Hepatic function: Bilirubin, aspartate aminotransferase (AST), and alanine aminotransferase (ALT) ≤ 1.5 times the upper limit of the institution's normal range. Subjects with liver metastasis may have an AST and ALT of ≤ 5.0 x the upper limit of normal.
5. Subjects in the Phase 2 portion must have squamous cell Non-Small Cell Lung Cancer (NSCLC)
6. Eligibility is restricted to subjects with confirmed EGFR amplification in the EGFR amplified cohort

Exclusion Criteria:

1. The subject has uncontrolled metastases to the central nervous system (CNS). Subjects with brain metastases are eligible provided they have shown clinical and radiographic stable disease for at least 28 days after definitive therapy and have not received prior whole brain radiation (Phase 1 only).
2. The subject has received anticancer therapy including chemotherapy, immunotherapy, radiotherapy, hormonal, biologic, or any investigational therapy within a period of 28 days prior to the first dose of ABT-414.
3. The subject has unresolved clinically significant toxicities from prior anticancer therapy, defined as any Common Terminology Criteria for Adverse Events (CTCAE) Grade 2 or higher.
4. The subject had had major surgery within 28 days prior to the first dose of ABT-414.
5. The subject has a history of immunologic reaction to any Immunoglobulin G (IgG) containing agent.
6. Phase 2 portion only: The subject has previous or concurrent cancer that is distinct in primary site or histology from NSCLC, except cervical carcinoma in situ, non-melanoma carcinoma of the skin or in situ carcinoma of the bladder. Any cancer curatively treated greater than 3 years prior to entry is permitted.

Ages Eligible for Study

18 Years to 99 Years (Adult, Older Adult)

Sexes Eligible for Study ⓘ

All

Accepts Healthy Volunteers ⓘ

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: ABT-414 Subjects with solid tumors (Phase 1) and squamous non-small cell lung cancer (NSCLC) (Phase 2)	Drug: ABT-414 • ABT-414 will be administered by intravenous infusion.

What is the study measuring?

Primary Outcome Measures 

Outcome Measure	Measure Description	Time Frame
Phase 1 - Safety (Number of subjects with adverse events and/or dose limiting toxicities)	Evaluation of vital signs, clinical lab testing, adverse event monitoring, physical exam and electrocardiogram (ECG) (periodic) under different dosing schedules, drug infusion times, and manufacturing processes.	Every 1-3 weeks for an average of 20 weeks
Phase 1 - Pharmacokinetic profile	Cmax, Cmin, and half-life	Multiple timepoints Week 1 and Week 7
Phase 2 - Efficacy	Objective response per Response Evaluation Criteria in Solid Tumors, version 1.1 (RECIST)	Every 6-9 weeks for an average of 20 weeks

Secondary Outcome Measures 

Outcome Measure	Measure Description	Time Frame
Phase 2- Safety (Scheduled study visits occurring on	Evaluation of vital signs, clinical lab testing, and adverse event monitoring, physical exam, and electrocardiogram (periodic)	Followed on average every 3 weeks

average every 3 weeks)		for approximately 20 weeks
Phase 2- Pharmacokinetic profile	Cmax, Cmin, and half-life	Multiple timepoints Week 1
Phase 1&2 - QT assessment	Triplicate electrocardiograms	Week 1

Collaborators and Investigators

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

Sponsor ⓘ

AbbVie (prior sponsor, Abbott)

Investigators ⓘ

- Study Director: Christopher Ocampo, MD, AbbVie

Publications

Study Results

These publications are provided voluntarily by the person who enters information about the study and are about the results of the study.

- [Munasinghe WP, Mittapalli RK, Li H, Hoffman DM, Holen KD, Menon RM, Xiong H. Evaluation of the effect of the EGFR antibody-drug conjugate ABT-414 on QT interval prolongation in patients with advanced solid tumors likely to over-express EGFR. Cancer Chemother Pharmacol. 2017](#)

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 ⓘ

2012-09-19

First Submitted that Met QC Criteria ⓘ

2012-12-03

First Posted (Estimated) ⓘ

2012-12-05

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2017-11-16

Last Update Posted ⓘ

2017-11-20

Last Verified ⓘ

2016-02

More Information

[Terms related to this study](#)

Additional Relevant MeSH Terms

ABT-414