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History of Changes for Study: NCT00794417

A Study of Aflibercept Administered in Combination With Pemetrexed and Cisplatin in Pa Carcinoma

<u>Latest version (submitted November 13, 2020) on ClinicalTrials.gov</u>

Myla

U.S.

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study versions.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in red.
- · Study additions are displayed in green.

Study Record Versions

Version	Α	В	Submitted Date	Changes
1			November 19, 2008	None (earliest Version on record)



Α	В	Submitted Date	Changes				
\circ	\circ	November 25, 2009	Study Status, Contacts/Locations, Conditions and Sponsor/Collaborators				
\circ	\circ	<u>January 6, 2010</u>	Contacts/Locations and Study Status				
0	0	July 19, 2010	Contacts/Locations and Study Status				
0	0	<u>January 5, 2011</u>	Study Status				
0	0	<u>January 21, 2011</u>	Recruitment Status, Study Status and Contacts/Locations				
0	0	February 11, 2011	Study Status				
0	0	February 16, 2011	Study Design and Study Status				
0	0	<u>April 17, 2011</u>	Study Status				
0	0	<u>May 27, 2011</u>	Arms and Interventions and Study Status				
0	0	<u>January 6, 2012</u>	Recruitment Status, Study Status, Sponsor/Collaborators and Contacts/Locations				
0	0	August 30, 2012	Study Status				
Results Submission Events							
0	0	November 13, 2020	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Mo Design, Study Description, Adverse Events, Baseline Characteristics, Participant Flo and Study Identification				
			○ November 25, 2009 ○ January 6, 2010 ○ July 19, 2010 ○ January 5, 2011 ○ January 21, 2011 ○ February 11, 2011 ○ April 17, 2011 ○ May 27, 2011 ○ January 6, 2012 ○ August 30, 2012 Results Submission Even				

Compare

Comparison Format:

Merged

 \bigcirc Side-by-Side

Scroll up to access the controls



Study NCT00794417

Submitted Date: November 19, 2008 (v1)

▼ Study Identification

Unique Protocol ID: VGFT-ST-0708

Brief Title: A Study of Aflibercept Administered in Combination With Pemetrexed and Cispla

Advanced Carcinoma

Official Title: A Phase 1/2 Study of Aflibercept Administered in Combination With Pemetrexed

With Advanced Carcinoma

Secondary IDs: TCD10767

Study Status

Record Verification: November 2008

Overall Status: Recruiting

Study Start: September 2008

Primary Completion: September 2010 [Anticipated]

Study Completion: October 2010 [Anticipated]

First Submitted: November 19, 2008

First Submitted that November 19, 2008

Met QC Criteria:

First Posted: November 20, 2008 [Estimate]

Last Update Submitted that November 19, 2008

Met QC Criteria:

Last Update Posted: November 20, 2008 [Estimate]



Sponsor/Collaborators

Sponsor: Regeneron Pharmaceuticals

Responsible Party:

Collaborators: Sanofi

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: No

Study Description

Brief Summary: The purpose of the study is to determine whether the combination of aflibercept,

is safe and effective.

Detailed Description: The study will be conducted in two phases. In phase 1, patients with advanced ca

doses of aflibercept in combination with approved doses of pemetrexed and cisple phase 1 is to determine the safest dose of the combined study medications. This

administered to patients with previously untreated non-small cell lung cancer in p portion of the study will determine if the combination is effective in treating non-sr



Conditions

Conditions: Advanced Carcinoma

Non-Small Cell Lung Cancer

Keywords: advanced cancer

lung cancer NSCLC

Non-small Cell Lung Cancer

aflibercept chemotherapy

▼ Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 1/Phase 2

Interventional Study Model: Single Group Assignment

Number of Arms: 1

Masking: None (Open Label)

Allocation: N/A

Enrollment: 100 [Anticipated]



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