History of Changes for Study: NCT01148615

A Study of Intravenous Aflibercept With Docetaxel in Chinese Patients With Sc

Latest version (submitted January 12, 2012) on ClinicalTrials.gov

- 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 S
  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 v
- 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	A	B	Submitted Date	Changes
1	◉	◉	June 21, 2010	None (earliest Version on record)
2	○	○	June 22, 2010	Sponsor/Collaborators and Study Status

Version	A	B	Submitted Date	Changes
4	○	○	August 24, 2010	Contacts/Locations and Study Status
5	○	○	September 10, 2010	Study Status and Study Identification
6	○	○	March 14, 2011	Contacts/Locations, Study Status and Sponsor/Collaborators
7	○	○	October 3, 2011	Study Status and Sponsor/Collaborators
8	○	○	January 12, 2012	Recruitment Status, Study Status, Contacts/Locations and Study Design

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT01148615
Submitted Date: June 21, 2010 (v1)

Study Identification

Unique Protocol ID: TCD11382

Brief Title: A Study of Intravenous Aflibercept With Docetaxel in Chinese Patients With Solid

Official Title: A Phase I, Dose Escalation Study of the Safety, Tolerability, and Pharmacokinetic Aflibercept in Combination With Intravenous Docetaxel Administrated Every 3 We With Advanced Solid Malignancies

Secondary IDs:

Study Status

Record Verification:	June 2010
Overall Status:	Not yet recruiting
Study Start:	July 2010
Primary Completion:	July 2011 [Anticipated]
Study Completion:	January 2012 [Anticipated]
First Submitted:	June 21, 2010
First Submitted that Met QC Criteria:	June 21, 2010
First Posted:	June 22, 2010 [Estimate]
Last Update Submitted that Met QC Criteria:	June 21, 2010
Last Update Posted:	June 22, 2010 [Estimate]

Sponsor/Collaborators

Sponsor:	Sanofi
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: No

Study Description

Brief Summary: Primary Objective:

- To confirm the dose of aflibercept in western studies by assessing the dose intravenous (IV) aflibercept when administered in combination with docetax every 3 weeks in Chinese patients with solid tumors.

Secondary Objectives:

- To assess the safety profile of intravenous (IV) aflibercept when administer docetaxel
- To determine the pharmacokinetics of IV aflibercept and docetaxel when ad combination
- To make a preliminary assessment of antitumor effects of the combination o aflibercept in patients with evaluable disease
- To evaluate the immunogenicity of IV aflibercept
- To measure endogenous free Vascular Endothelial Growth Factor (VEGF)

Detailed Description: The duration of screening, treatment, and follow-up are within 21 days, 3 weeks/c the last aflibercept administration. Patients will be administered aflibercept in com until when/if a definitive treatment discontinuation criterion is met such as progres unacceptable toxicity or patient refusal to continue.

Conditions

Conditions: Neoplasm Malignant

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 1

Interventional Study Model: Single Group Assignment

Number of Arms: 1

Masking: None (Open Label)

Allocation: N/A

Enrollment: 22 [Anticipated]

Arms and Interventions

Arms	Assigned Inte
Experimental: Aflibercept/ docetaxel Patients with advanced cancer will receive different doses of aflibercept in combination with approved dose of docetaxel. Aflibercept 4 or 6mg/kg over 1 hour IV immediately followed by Docetaxel 75mg/m2 IV over 1 hour on Day 1, every 3 weeks	Drug: Aflibercept (AVE0005) Pharmaceutical form: so Route of administration: Drug: Docetaxel (XRP6976) Pharmaceutical form: so Route of administration:

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