

History of Changes for Study: NCT01148615

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

[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.

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Study Record Versions

Version	A	B	Submitted Date	Changes
1	<input checked="" type="radio"/>	<input checked="" type="radio"/>	June 21, 2010	None (earliest Version on record)
2	<input type="radio"/>	<input type="radio"/>	June 22, 2010	Sponsor/Collaborators and Study Status

Version	A	B	Submitted Date	Changes
4	<input type="radio"/>	<input type="radio"/>	August 24, 2010	Contacts/Locations and Study Status
5	<input type="radio"/>	<input type="radio"/>	September 10, 2010	Study Status and Study Identification
6	<input type="radio"/>	<input type="radio"/>	March 14, 2011	Contacts/Locations, Study Status and Sponsor/Collaborators
7	<input type="radio"/>	<input type="radio"/>	October 3, 2011	Study Status and Sponsor/Collaborators
8	<input type="radio"/>	<input type="radio"/>	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 June 21, 2010

Met QC Criteria:

First Posted: June 22, 2010 [Estimate]

Last Update Submitted that June 21, 2010

Met QC Criteria:

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 of intravenous (IV) aflibercept when administered in combination with docetaxel every 3 weeks in Chinese patients with solid tumors.

Secondary Objectives:

- To assess the safety profile of intravenous (IV) aflibercept when administered with docetaxel
- To determine the pharmacokinetics of IV aflibercept and docetaxel when administered in combination
- To make a preliminary assessment of antitumor effects of the combination of 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/3 months after the last aflibercept administration. Patients will be administered aflibercept in combination with docetaxel until when/if a definitive treatment discontinuation criterion is met such as progression of disease, 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 Interventions
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: solution Route of administration: intravenous Drug: Docetaxel (XRP6976) Pharmaceutical form: solution Route of administration: intravenous



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