History of Changes for Study: NCT00519285

Aflibercept in Combination With Docetaxel in Metastatic Androgen Independent Prosta

Latest version (submitted June 21, 2016) 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	◉	◉	August 21, 2007	None (earliest Version on record)
2	○	○	December 31, 2007	Contacts/Locations, Study Status and Sponsor/Collaborators

Version	A	B	Submitted Date	Changes
4	○	○	June 2, 2008	Study Status
5	○	○	August 21, 2008	Arms and Interventions, Outcome Measures, Study Design and Study Status
6	○	○	January 12, 2009	Study Status and Study Identification
7	○	○	July 3, 2009	Contacts/Locations, Study Status and References
8	○	○	August 13, 2009	Contacts/Locations, Study Status and Study Identification
9	○	○	January 29, 2010	Contacts/Locations and Study Status
10	○	○	February 2, 2010	Study Status and Contacts/Locations
11	○	○	February 12, 2010	Recruitment Status, Study Status and Contacts/Locations
12	○	○	August 30, 2011	Sponsor/Collaborators, Study Status and Contacts/Locations
13	○	○	April 16, 2012	Recruitment Status, Study Status, Outcome Measures, Study Design and Study De
14	○	○	April 20, 2012	Study Status
15	○	○	August 2, 2013	Outcome Measures, Arms and Interventions, Study Status, Study Identification, Stu References, Eligibility and Oversight
16	○	○	June 21, 2016	Study Status and Baseline Characteristics

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study Identification

Unique Protocol ID:	EFC6546
Brief Title:	Aflibercept in Combination With Docetaxel in Metastatic Androgen Independent P (VENICE)
Official Title:	A Multicenter, Randomized, Double Blind Study Comparing the Efficacy and Safe Placebo Administered Every 3 Weeks in Patients Treated With Docetaxel/ Predni Androgen-Independent Prostate Cancer
Secondary IDs:	AVE0005

Study Status

Record Verification:	August 2007
Overall Status:	Recruiting
Study Start:	August 2007
Primary Completion:	
Study Completion:	
First Submitted:	August 21, 2007
First Submitted that Met QC Criteria:	August 21, 2007
First Posted:	August 22, 2007 [Estimate]
Last Update Submitted that Met QC Criteria:	August 21, 2007
Last Update Posted:	August 22, 2007 [Estimate]

Sponsor/Collaborators

Sponsor:	Sanofi
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	

Study Description

Brief Summary:	The primary objective of the study is to demonstrate an improvement of overall su with aflibercept versus placebo, in patients receiving docetaxel/ prednisone. Main secondary endpoints gather prostate-specific antigen (PSA) response, pain occurrence of skeletal related events and progression free survival (PFS), as well pharmacokinetics and immunogenicity.
Detailed Description:	

Conditions

Conditions:	Prostatic Neoplasms Neoplasm Metastasis
Keywords:	metastatic prostate cancer

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	
Masking:	Double (masked roles unspecified)
Allocation:	Randomized
Enrollment:	1200 [Anticipated]

Arms and Interventions

Intervention Details:	
	Drug: aflibercept (VEGF Trap)

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