# 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.<br><br>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<br>Neoplasm Metastasis |
| Keywords: | metastatic<br>prostate<br>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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