NIH U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00644124

Aflibercept and Standard Chemotherapy (R-CHOP) in First Line of Non Hodgkin B-

Latest version (submitted May 5, 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 sapplies 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.

Mylan IPR2 U.S. P Ex

Study Record Versions

Version	Α	В	Submitted Date	Changes
1			<u>March 21, 2008</u>	None (earliest Version on record)
2	\bigcirc	\bigcirc	<u>April 25, 2008</u>	Study Status

Find authenticated court documents without watermarks at docketalarm.com.

Version	Α	В	Submitted Date	Changes
4	\bigcirc	0	<u>September 19, 2008</u>	Study Status, Outcome Measures and Study Identification
5	0	0	<u>March 3, 2009</u>	Study Status
6	\bigcirc	\bigcirc	<u>March 10, 2009</u>	Recruitment Status, Contacts/Locations and Study Status
7	\bigcirc	\bigcirc	<u>August 30, 2011</u>	Sponsor/Collaborators, Study Status, Study Identification and References
8	\bigcirc	\bigcirc	<u>January 3, 2012</u>	Recruitment Status, Study Status and Study Design
9	\bigcirc	\bigcirc	<u>May 5, 2016</u>	Arms and Interventions, Study Status, Study Design and Study Identification
Comp	are)	Comparison Form	● Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00644124 Submitted Date: March 21, 2008 (v1)

	Study Identification	
	Unique Protocol ID:	TCD10173
	Brief Title:	Aflibercept and Standard Chemotherapy (R-CHOP) in First Line of Non Hodgkin
	Official Title:	A Phase I Open-Label Dose-Escalation Study of Intravenous Aflibercept (AVE000 Combination With R-CHOP Administered Every 2 Weeks or Every 3 Weeks in Pa Hodgkin's B-Cell Lymphoma
	Secondary IDs:	AVE0005 EudraCT 2007-003737-16
D	OCKET	f

Find authenticated court documents without watermarks at docketalarm.com.

ALARM

Study Status

Record Verification: March 2008

Overall Status: Recruiting

Study Start: March 2008

Primary Completion:

Study Completion:

First Submitted: March 21, 2008

First Submitted that March 21, 2008 Met QC Criteria:

First Posted: March 26, 2008 [Estimate]

Last Update Submitted that March 21, 2008 Met QC Criteria:

Last Update Posted: March 26, 2008 [Estimate]

Sponsor/Collaborators

DOCKET

Δ

Sponsor: Sanofi

Responsible Party:

Collaborators: Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: No

Study Description

Brief Summary: The purpose of this study is to determine the selected dose of aflibercept when it CHOP treatment (Rituximab/Cyclophosphamide/Doxorubicin/Vincristine/Prednisc Methotrexate) administered every 2 weeks or every 3 weeks, in non Hodgkin B-c determine how the body handles aflibercept when it is administered with R-CHOP

Detailed Description:

Conditions

DOCKE

Δ

Conditions: Lymphoma, Non-Hodgkin Keywords: Non-Hodgkin's lymphoma

angiogenesis inhibitors CHOP protocol

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 1

Interventional Study Model: Parallel Assignment

Number of Arms:

Masking: None (Open Label)

Allocation: Non-Randomized

Enrollment: 50 [Anticipated]

Arms and Interventions

Intervention Details:

Drug: aflibercept in combination with standard treatment R-CHOP



Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

DOCKET A L A R M



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.