COMPLETED

Phase 1 Study of VEGF Trap in Patients With Diabetic Macular Edema

ClinicalTrials.gov ID NCT00320814

Sponsor Regeneron Pharmaceuticals

Information provided by Regeneron Pharmaceuticals

Last Update Posted 2011-06-10

Table View Tab

Trial Contacts

Contacts	ICMJE
Contact information is only displayed when the study is recruiting subjects	

Study Record Dates

First Submitted	ICMJE
2006-04-28	

First Posted	ICMJE

Last Update Posted
2011-06-10

Last Verified
2011-06

Outcome Measures

Change History
See all versions of this study

Primary (Current) ICMJE
(Submitted 2009 01 05)

- To assess the ocular and systemic safety and tolerability of a single intravitreal (IVT) injection of VEGF Trap-Eye in patients with diabetic macular edema (DME) [Time Frame: Assessments for safety and tolerablity are performed at each visit (Visit 1 - Visit 10)]

Primary (Original) ICMJE
(Submitted: 2006-04-28)

- Safety and tolerability, Bioeffect

Secondary (Current) ICMJE
(Submitted: 2009-01-05)

- To obtain a preliminary assessment of the effect of a single dose of VEGF Trap-Eye on central retinal thickness (CRT) at the center point as determined by optical coherence tomography (OCT) [Time Frame: Assessments for CRT are performed at each visit (Visit 1 - Visit 10) by means of OCT.]
- To obtain a preliminary assessment of the effect of a single IVT administration of VEGF Trap-Eye on visual acuity [Time Frame: Assessments for visual acuity are performed at each visit (Visit 1 - Visit 10).]

Secondary (Original) ICMJE
(Submitted: 2006-04-28)

- The effect of VEGF Trap administration on central retinal thickness visual acuity and anti VEGF Trap antibodies in the systemic circulation

Other Pre-specified (Current)
Not provided

Other Pre-specified (Original)
Not provided

Trial Description

Brief Title	ICMJE
Phase 1 Study of VEGF Trap in Patients With Diabetic Macular Edema	

Official Title	ICMJE
An Exploratory Study of the Safety, Tolerability and Biological Effect of a Single Intravitreal Administration of VEGF Trap in Patients With Diabetic Macular Edema	

Brief Summary
To assess the ocular and systemic safety and tolerability of a single intravitreal injection of VEGF Trap in patients with diabetic macular edema

Detailed Description
This is an open label study. Initially, 5 patients with DME will receive an ITV injection of VEGF Trap into the study eye. Additional patients may be enrolled at the same or additional dose levels. Patients will be observed for six weeks following the injection for assessments of ocular and systemic safety.

Study Type	ICMJE
Interventional	

Study Phase	ICMJE
Phase 1	

Study Design	ICMJE
Allocation: Non-Randomized Interventional Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment	

Condition ICMJE

- Diabetic Macular Edema

Intervention ICMJE

- Drug: VEGF Trap-Eye
  - single IVT injection of 4.0 mg of VEGF Trap-Eye into the study eye on Day 1

Study Arms ICMJE

- Experimental: VEGF Trap-Eye
  - single IVT injection of 4.0 mg of VEGF Trap-Eye into the study eye on Day 1
  - Interventions:
    - Drug: VEGF Trap-Eye

Publications *

Not provided

* Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.

Recruitment Information

Recruitment Status ICMJE

Completed

Enrollment (Actual) ICMJE
(Submitted: 2006-04-28)

5

Original Enrollment ICMJE

Same as current

Study Start Date ICMJE

2006-04

Primary Completion Date (Actual)

2006-08 (Final data collection date for primary outcome measure)

Study Completion Date (Actual) ICMJE

2007-08

Eligibility Criteria ICMJE

Inclusion Criteria:

- Diagnosis of diabetes mellitus (type 1 or type 2).
- Best corrected E-ETDRS visual acuity score of ≥ 24 letters (i.e., 20/320 or better) and ≤ 73 letters (i.e., 20/40 or worse).
- On clinical exam, definite retinal thickening due to diabetic macular edema involving the center of the macula.
- Retinal Thickness at the center point ≥ 250 microns.
- Media clarity, pupillary dilation, and patient cooperation sufficient for adequate fundus photographs.

Exclusion Criteria

- History of any vitreous hemorrhage within 4 weeks prior to Visit 2 (Day 1).
- Macular edema due to causes other than diabetic macular edema. An eye should be considered ineligible: (1) if the macular edema is considered to be related to cataract extraction or (2) clinical exam and/or OCT suggests that vitreoretinal interface disease (e.g., a taut posterior hyaloid or epiretinal membrane) is the primary cause of the macular edema.
- An ocular condition is present such that, in the opinion of the investigator, visual acuity would not improve from resolution of macular edema (e.g., foveal atrophy, pigmentary changes, dense subfoveal hard exudates, nonretinal condition).
- An ocular condition is present (other than diabetes) that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the course of the study (e.g., vein occlusion, age-related macular degeneration, uveitis or other ocular inflammatory disease, neovascular glaucoma, Irvine-Gass Syndrome, etc.).
- Presence of any other condition or laboratory abnormality which in the opinion of the Investigator would interfere with the assessment of disease status/progression or jeopardize the patient s appropriate participation in this Phase 1 study

Sex/Gender ICMJE

Sexes Eligible for the Study
All

Ages ICMJE

18 Years and older (Adult Older Adult)

Accepts Healthy Volunteers ICMJE

No

Location Countries ICMJE

DOCKET ALARM

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.