A Study of the Efficacy and Safety of Ranibizumab Injection in Patients With Macular Edema Secondary to Branch Retinal Vein Occlusion (BRAVO) (BRAVO)

ClinicalTrials.gov Identifier: NCT00486018

Recruitment Status : Completed
First Posted : June 13, 2007
Results First Posted : February 25, 2011
Last Update Posted : May 10, 2017

Sponsor:
Genentech, Inc.

Information provided by (Responsible Party):
Genentech, Inc.

Study Description

Go to

Brief Summary:
This was a Phase III, multicenter, randomized, double-masked, sham injection-controlled study of the efficacy and safety of intravitreal ranibizumab compared with sham injections in patients with macular edema secondary to branch

retinal vein occlusion (BRVO); 397 patients with BRVO were enrolled at 93 investigational sites in the United States. The study included a treatment period (6 months) and an observation period (6 months).

Condition or disease	Intervention/treatment	Phase
Macular Edema Retinal Vein Occlusion	Drug: Ranibizumab injection 0.3 mg Drug: Ranibizumab injection 0.5 mg Drug: Sham injection	Phase 3

Study Design

Go to

Study Type :
Interventional (Clinical Trial)

Actual Enrollment :
397 participants

Allocation:
Randomized

Intervention Model:
Parallel Assignment

Masking:
Double (Participant, Investigator)

Primary Purpose:
Treatment

Official Title:
A Phase III, Multicenter, Randomized, Sham Injection-Controlled Study of the Efficacy and Safety of Ranibizumab Injection Compared With Sham in Subjects With Macular Edema Secondary to Branch Retinal Vein Occlusion

Study Start Date :
July 2007

Actual Primary Completion Date :
May 2009

Actual Study Completion Date :
November 2009

Resource links provided by the National Library of Medicine

Drug Information available for: Ranibizumab

U.S. FDA Resources

Arms and Interventions

Go to

Arm	Intervention/treatment
Sham Comparator: Sham injection	Drug: Sham injection Sham injection in a single-dose regimen given every month (Day 0 through the Month 5 visit), for a total of six sham injections.
Experimental: Ranibizumab injection 0.3 mg	Drug: Ranibizumab injection 0.3 mg Ranibizumab injection 0.3 mg in a single-dose regimen given every month (Day 0 through the Month 5 visit), for a total of six injections. Other Name: Lucentis
Experimental: Ranibizumab injection 0.5 mg	Drug: Ranibizumab injection 0.5 mg Ranibizumab injection 0.5 mg in a single-dose regimen given every month (Day 0 through the Month 5 visit), for a total of six injections. Other Name: Lucentis

Outcome Measures

Go to

Primary Outcome Measures :

1. Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) Score at 6 Months
   [Time Frame: Baseline and 6 months]

   BCVA score in the study eye was based on the Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity charts (number of correct letters) and assessed at a starting distance of 4 meters.

1. Percentage of Participants Who Gained ≥ 15 Letters in BCVA Score at Month 6 Compared With Baseline [Time Frame: Baseline and 6 months]

   BCVA score based on the ETDRS visual acuity charts (number of correct letters) and assessed at a starting distance of 4 meters.

2. Percentage of Participants Who Lost < 15 Letters in BCVA Score at Month 6 Compared With Baseline [Time Frame: Baseline and 6 months]

   BCVA score based on the ETDRS visual acuity charts (number of correct letters) and assessed at a starting distance of 4 meters. The percentage of subjects who lost <15 letters will be greater than the percentage of subjects who "gained >=15 letters" as "losing <15 letters" includes both those who gained >=15 letters and those who were "stable" (i.e. lost between 1 and 14 letters, had no change, or gained between 1 and 14 letters).

3. Percentage of Participants With a Central Foveal Thickness of ≤ 250 µm at Month 6 [Time Frame: 6 months]

   A central reading center assessed all optical coherence tomography (OCT) images. Central foveal thickness was defined as the center point thickness.

4. Mean Absolute Change From Baseline in Central Foveal Thickness at Month 6 [Time Frame: Baseline and 6 months]

   A central reading center assessed all OCT images. Central foveal thickness was defined as the center point thickness.

5. Mean Change From Baseline in the National Eye Institute Visual Functioning Questionnaire-25 (NEI VFQ-25) Near Activities Subscale Score at Month 6 [Time Frame: Baseline and 6 months]

   The NEI VFQ-25 (v. 2000; Interviewer Format) consisted of the base set of 25 questions, plus the optional additional questions (where questions A3, A4, and A5 pertained to the Near Activities Subscale). Scores ranged from 0 to 100; a higher score represented better functioning.

6. Mean Change From Baseline in the NEI VFQ-25 Distance Activities Subscale Score at Month 6 [Time Frame: Baseline and 6 months]

   The NEI VFQ-25 (v. 2000; Interviewer Format) consisted of the base set of 25 questions, plus the optional additional questions (where questions A6, A7, and A8 pertained to the Distance Activities Subscale). Scores ranged from 0 to 100; a higher score represented better functioning.

Eligibility Criteria

Go to

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Criteria

Inclusion Criteria:

- Willingness to provide signed Informed Consent Form
- Age ≥ 18 years
- For sexually active women of childbearing potential, use of an appropriate form of contraception (or abstinence) for the duration of the study
- Ability and willingness to return for all scheduled visits and assessments

Ocular Inclusion Criterion (Study Eye):

- Foveal center-involved macular edema secondary to BRVO
- BCVA using ETDRS charts of 20/40 to 20/400 (Snellen equivalent)
- Mean central subfield thickness ≥ 250 µm on two optical coherence tomography (OCT) measurements (at screening [confirmed by the central reading center] and Day 0 [confirmed by the evaluating physician])
- Media clarity, pupillary dilation, and participant cooperation sufficient to obtain adequate fundus photographs

Exclusion Criteria:

- History of cerebral vascular accident or myocardial infarction within 3 months prior to Day 0
- History of any anti-vascular endothelial growth factor (VEGF) treatment in fellow eye within 3 months prior

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.