Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO) (GALILEO)

ClinicalTrials.gov Identifier: NCT01012973

Recruitment Status : Completed
First Posted : November 13, 2009
Results First Posted : November 22, 2012
Last Update Posted : November 2, 2014

Sponsor:
Bayer

Regeneron Pharmaceuticals

Information provided by (Responsible Party):

Bayer

Study Description

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Brief Summary:

To determine the efficacy of vascular endothelial growth factor (VEGF) Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion

Condition or disease	Intervention/treatment	Phase
Retinal Vein Occlusion	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Other: Sham treatment	Phase 3

Study Design

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Study Type :

Interventional (Clinical Trial)

Actual Enrollment :

177 participants

Allocation:

Randomized

Intervention Model:

Parallel Assignment

Masking:

Triple (Participant, Investigator, Outcomes Assessor)

Primary Purpose:

Treatment

Official Title:

A Randomized, Double-masked, Sham-controlled Phase 3 Study of the Efficacy, Safety and Tolerability of Repeated Intravitreal Administration of VEGF Trap-Eye in Subjects With Macular Edema Secondary to

Study Start Date :

October 2009

Actual Primary Completion Date :

February 2011

Actual Study Completion Date :

February 2012

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Edema

Drug Information available for: Aflibercept Ziv-aflibercept

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2 mg dose of Intravitreal Aflibercept Injection (IAI) administered every 4 weeks from Day 1 through Week 20, later as often as every 4 weeks depending on the study retreatment criteria from Week 24 through Week 48. Follow-up phase: Participants on IAI, who continued the study, received 2 mg dose of IAI depending on the study retreatment criteria at Week 60 and 68.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Intravitreal injection. Weeks 0 to 20 of Aflibercept Injection every 4 weeks; Weeks 24 to 52 every 4 weeks PRN (pro re nata, on demand); plus additional on Week 60 and 68. Other: Sham treatment Sham treatment. Weeks 0 to 52 sham treatment every 4 weeks; plus additional on Week 60 and 68.

Arm	Intervention/treatment
Sham Comparator: Sham treatment Participants received sham treatment administered every 4 weeks from Day 1 through Week 52. Follow-up phase: Participants on sham treatment, who switched to Intravitreal Aflibercept Injection (IAI), received a 2 mg dose of IAI at week 52 and depending on the study retreatment criteria at Week 60 and 68.	Other: Sham treatment Sham treatment. Weeks 0 to 52 sham treatment every 4 weeks; plus additional on Week 60 and 68.

Outcome Measures

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Primary Outcome Measures :

1. Percentage of Participants Who Gained at Least 15 Letters in BCVA as Measured by ETDRS Letter Score Compared With Baseline at Week 24 With Discontinued Participants Before Week 24 Evaluated as Failures [Time Frame: Baseline and Week 24]

   Defined study baseline range of Early Treatment Diabetic Retinopathy Study (ETDRS) Best Corrected Visual Acuity (BCVA) letter score of 73 to 24 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.

Secondary Outcome Measures :

1. Change From Baseline in BCVA as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 24 - Last Observation Carried Forward (LOCF)
   [Time Frame: Baseline and Week 24]

   Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 24 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. However, because this was assessed at the screening visit, subjects may have had a higher BCVA recorded at the baseline visit and would not have been excluded from the study.

2. Change From Baseline in Central Retinal Thickness (CRT) at Week 24 - LOCF
   [Time Frame: Baseline and Week 24]
3. Percentage of Participants Who Developed Neovascularization During the First 24 Weeks
   [Time Frame: From baseline until Week 24]

Formation of blood vessels in the anterior segment, optic disc, or elsewhere in the fundus up to Week 24

4. Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 24 - LOCF [Time Frame: Baseline and Week 24]

   The NEI VFQ-25 total score ranges from 0-100 with a score of 0 being the worst outcome and 100 being the best outcome. The NEI VFQ questionnaire is organized as a collection of subscales which are all scored from 0-100. To reach the overall composite score, each sub-scale score is averaged in order to give each sub-scale equal weight

5. Change From Baseline in European Five-dimensional Health Scale (EQ-5D) Score at Week 24 - LOCF [Time Frame: Baseline and Week 24]

   EQ-5D is a quality of life questionnaire based on a scale from -0.594 (worst) to 1.00 (best).

Eligibility Criteria

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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:

- Center-involved macular edema secondary to central retinal vein occlusion (CRVO) for no longer than 9

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