COMPLETED

DME And VEGF Trap-Eye [Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321)] INvestigation of Clinical Impact (DA VINCI)

ClinicalTrials.gov ID NCT00789477

Sponsor Regeneron Pharmaceuticals

Information provided by Regeneron Pharmaceuticals (Responsible Party)

Last Update Posted 2014-09-09

Table View Tab

Trial Contacts

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

Study Record Dates

First Submitted	ICMJE
2008-11-07	

First Posted	ICMJE

2008-11-11

Results First Submitted ICMJE

2014-08-28

Results First Posted ICMJE

2014-09-09

Last Update Posted

2014-09-09

Last Verified

2014-08

Outcome Measures

Change History

See all versions of this study

Primary (Current) ICMJE
(Submitted 2014 08 28)

- Change in BCVA From Baseline to Week 24 - Last Observation Carried Forward (LOCF) [Time Frame: At week 24]
  - Visual function of the study eye was assessed using the Early Treatment Diabetic Retinopathy Study (ETDRS) protocol at 4 meters. Measurements were taken at every study visit.

    Missing values were imputed with post-baseline values during on-treatment period by using last observation carried forward (LOCF).

Primary (Original) ICMJE
(Submitted 2008 11 07)

- Change in best corrected visual acuity

Secondary (Current) ICMJE
(Submitted: 2014-08-28)

- Change in BCVA From Baseline to Week 52 - LOCF [Time Frame: At week 52]
  - Visual function of the study eye was assessed using the Early Treatment Diabetic Retinopathy Study (ETDRS) protocol at 4 meters. Missing values were imputed with post-baseline values

- Participants With Gains in ETDRS Letter Score of at Least 15 Letters - LOCF [Time Frame: At week 24 and week 52]
  - Missing values were imputed with post-baseline values during on-treatment period by using last observation carried forward (LOCF).
- Change From Baseline in Central Retinal Thickness (CRT) as Assessed by Optical Coherence Tomography (OCT) - LOCF [Time Frame: At week 24 and week 52]
  - Retinal thickness was evaluated using OCT at every visit except week 1. Missing values were imputed with post-baseline values during on-treatment period by using last observation carried forward (LOCF).
- Number of Focal Laser Treatments [Time Frame: Week 1 to week 48]

Secondary (Original) ICMJE
(Submitted: 2008-11-07)

- Change from baseline in foveal thickness

Other Pre-specified (Current)

Not provided

Other Pre-specified (Original)

Not provided

Trial Description

Brief Title ICMJE

DME And VEGF Trap-Eye [Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321)] INvestigation of Clinical Impact

Official Title ICMJE

A Double Masked Randomized Controlled Study of the Safety Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap Eye in Patients With Diabetic Macular Edema (DME)

Brief Summary

This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) in subjects with diabetic macular edema (DME). Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.

Detailed Description

Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Study Type ICMJE

Interventional

Study Phase ICMJE

Phase 2

Study Design ICMJE

Allocation:
Randomized

Interventional Model:
Parallel Assignment

Masking:
Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose:
Treatment

Condition ICMJE

- Diabetic Macular Edema

Intervention ICMJE

- Procedure: Laser Photocoagulation
  - laser every 16 weeks as needed
  - Other Names:
    - macular laser therapy
- Drug: Intravitreal Aflibercept Injection
  - Other Names:
    - IAI; EYLEA®; BAY86-5321; VEGF Trap-Eye

Study Arms ICMJE

- Experimental: Intravitreal Aflibercept Injection .5Q4
  - Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) .5 mg every 4 weeks
  - Interventions:
    - Drug: Intravitreal Aflibercept Injection
- Experimental: Intravitreal Aflibercept Injection 2Q4
  - Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2 mg every 4 weeks
  - Interventions:
    - Drug: Intravitreal Aflibercept Injection
- Experimental: Intravitreal Aflibercept Injection 2Q8

- Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2mg every 4 weeks for 3 visits followed by every 8 weeks
- Interventions:
  - Drug: Intravitreal Aflibercept Injection

- Experimental: Intravitreal Aflibercept Injection 2PRN
  - Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2mg every 4 weeks for 3 visits followed by PRN (as-needed) dosing according to the re-treatment criteria
  - Interventions:
    - Drug: Intravitreal Aflibercept Injection
- Active Comparator: Laser Photocoagulation
  - Focal laser at week 1, and one week after visits at which the participant met laser re-treatment criteria to the end of the study (week 52) starting at week 16; laser re-treatment was permitted no more than once every 16 weeks.
  - Interventions:
    - Procedure: Laser Photocoagulation

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: 2014-08-28)

221

Original Enrollment (Estimated) ICMJE
(Submitted: 2008-11-07)

200

Study Start Date ICMJE

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