View of NCT00637377 on 2008_03_17

ClinicalTrials Identifier: NCT00637377
Updated: 2008_03_17

Descriptive Information

Brief title	VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).
Official title	A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration (AMD).

Brief summary

This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed description

Phase	Phase 3
Study type	Interventional
Study design	Treatment
Study design	Randomized
Study design	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Study design	Active Control
Study design	Parallel Assignment
Study design	Safety/Efficacy Study
Primary outcome	Measure: The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss) Time Frame: week 52 Safety Issue? Yes
Secondary outcome	Measure: Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52 Time Frame: week 52 Safety Issue? Yes
Secondary outcome	Measure: The proportion of subjects who gain at least 15 letters of vision at Week 52 Time Frame: week 52 Safety Issue? No
Secondary outcome	Measure: Mean change from baseline in total NEI VFQ-25 score at Week 52

	Time Frame: week 52 Safety Issue? No
Secondary outcome	Measure: Mean change from baseline in CNV area at Week 52 Time Frame: week 52 Safety Issue? Yes
Enrollment	1200 (Anticipated)
Condition	Macular Degeneration
Arm/Group	Arm Label: Arm 3 Experimental n/a
Arm/Group	Arm Label: Arm 1 Experimental n/a
Arm/Group	Arm Label: Arm 2 Experimental n/a
Arm/Group	Arm Label: Arm 4 Active Comparator n/a
Intervention	Drug: VEGF Trap-Eye Arm Label: Arm 1 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Intervention	Drug: VEGF Trap-Eye Arm Label: Arm 2 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Intervention	Drug: VEGF Trap-Eye Arm Label: Arm 3 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Intervention	Drug: Ranibizumab Arm Label: Arm 4 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
URL	http://www.fda.gov/cder/drug/DrugSafety/DrugIndex.htm
URL	http://www.fda.gov/medwatch/safety.htm
URL	http://www.clinicalstudyresults.org
See also	Click here and search for drug information provided by the FDA
See also	Click here and search for information on any recalls, market or product safety alerts by the FDA which might have occurred with this product
See also	

Click here to find results for studies related to marketed products

Recruitment Information

Status	Not yet recruiting
Start date	2008-03
Last follow-up date	2011-09 (Anticipated)

Criteria

Inclusion Criteria:

1. Signed informed consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size >12 disc areas (30.5 mm^2, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
6. Scar or fibrosis making up >50% of the total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. Prior vitrectomy in the study eye.
12. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
13. Any history of macular hole of stage 2 and above in the study eye.
14. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
15. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Gender	Both
Minimum age	50 Years
Healthy volunteers	No

Administrative Data

Organization name	Bayer
Organization study ID	91689
Secondary ID	EurdaCT No.: 2007-000583-25
Secondary ID	311523
Secondary ID	VIEW 2
Sponsor	Bayer
Collaborator	Regeneron Pharmaceuticals
Health Authority	Switzerland: Ethikkommision