A Phase 3 Safety and Efficacy Study of Fovista® (E10030) Intravitreous Administration in Combination With Lucentis® Compared to Lucentis® Monotherapy

ClinicalTrials.gov Identifier: NCT01944839

Recruitment Status : Terminated
First Posted : September 18, 2013
Results First Posted : August 10, 2018
Last Update Posted : August 10, 2018

Sponsor:
Ophthotech Corporation

Information provided by (Responsible Party):

Ophthotech (Ophthotech Corporation)

Study Description

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Brief Summary:

The objectives of this study are to evaluate the safety and efficacy of intravitreal administration of **Fovista®** administered in combination with Lucentis® compared to Lucentis® monotherapy in subjects with subfoveal choroidal neovascularization secondary to age-related macular degeneration (AMD).

Condition or disease	Intervention/treatment	Phase
Age-Related Macular Degeneration	Drug: E10030 Drug: ranibizumab Drug: E10030 sham intravitreal injection	**Phase 3**

Detailed Description:

Subjects will be randomized in a 1:1 ratio to the following dose groups:

- Fovista® 1.5 mg/eye + Lucentis® 0.5 mg/eye
- Fovista® sham + Lucentis® 0.5 mg/eye

Subjects will be treated for a total of 24 months with active Fovista® or sham in combination with Lucentis® with the primary endpoint at 12 months.

Primary Efficacy Endpoint:

The primary efficacy endpoint is the mean change in visual acuity (ETDRS letters) from baseline at the month 12 visit.

Safety Endpoints:

Safety endpoints include adverse events, vital signs, ophthalmic variables [ophthalmic examination, intraocular pressure (IOP), fluorescein angiogram (FA), optical coherence tomography (OCT)], ECG, and laboratory variables.

Approximately 622 subjects will be randomized into one of the two treatment cohorts (311 patients per dose group).

Study Design

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Study Type :

Interventional (Clinical Trial)

Actual Enrollment :

619 participants

Allocation:

Randomized

Intervention Model:

Parallel Assignment

Masking:

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

Primary Purpose:

Treatment

Official Title:

A Phase 3 Randomized, Double-masked, Controlled Trial to Establish the Safety and Efficacy of Intravitreous Administration of **Fovista®** (Anti PDGF-B Pegylated Aptamer) Administered in Combination With Lucentis® Compared to Lucentis® Monotherapy in Subjects With Subfoveal Neovascular Age-related Macular Degeneration.

Study Start Date :

August 2013

Actual Primary Completion Date :

December 2016

Actual Study Completion Date :

December 2016

Resource links provided by the National Library of Medicine

MedlinePlus Genetics related topics: Age-related macular degeneration

MedlinePlus related topics: Macular Degeneration

Drug Information available for: Ranibizumab

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment

Arm	Intervention/treatment
Experimental: E10030 + ranibizumab E10030 1.5 mg intravitreal injection + ranibizumab 0.5 mg intravitreal injection	Drug: E10030 Other Name: **Fovista®** Drug: ranibizumab Other Name: Lucentis®
Active Comparator: Sham + ranibizumab E10030 sham intravitreal injection + ranibizumab 0.5 mg intravitreal injection	Drug: ranibizumab Other Name: Lucentis® Drug: E10030 sham intravitreal injection Pressure on the eye with a syringe with no needle Other Name: Sham

Outcome Measures

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Primary Outcome Measures :

1. Mean Change in Visual Acuity From Baseline to 12 Months [Time Frame: 12 Months]

   The primary efficacy endpoint is the mean change in visual acuity (ETDRS letters) from baseline to the month 12 visit. Higher ETDRS letters represents higher vision and a higher change in ETDRS letters represents better functioning.

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:

50 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Criteria

Inclusion Criteria:

- Subjects of either gender aged ≥ 50 years
- Active subfoveal choroidal neovascularization (CNV) secondary to AMD
- Presence of sub-retinal hyper-reflective material (SD-OCT)

Exclusion Criteria:

- Any prior treatment for AMD in the study eye prior to the Day 1 visit, except oral supplements of vitamins and minerals
- Any prior intravitreal treatment in the study eye prior to the Day 1 visit, regardless of indication (including intravitreal corticosteroids)
- Any intraocular surgery or thermal laser within three (3) months of trial entry. Any prior thermal laser in the macular region, regardless of indication
- Subjects with subfoveal scar or subfoveal atrophy are excluded
- Diabetes mellitus

Contacts and Locations

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Information from the National Library of Medicine

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT01944839***

Locations

▸ Show 115 study locations

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