Trial record **3 of 3** for: lampalizumab | Phase 3

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A Study Investigating the Efficacy and Safety of Lampalizumab Intravitreal Injections in Participants With Geographic Atrophy Secondary to Age-Related Macular Degeneration (CHROMA)

ClinicalTrials.gov Identifier: NCT02247479

Recruitment Status : Terminated
First Posted : September 25, 2014
Results First Posted : April 23, 2019
Last Update Posted : June 26, 2019

Sponsor:
Hoffmann-La Roche

Information provided by (Responsible Party):

Hoffmann-La Roche

Study Description

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Brief Summary:
This study is a Phase III, double-masked, multicenter, randomized, sham injection-controlled study evaluating the efficacy and safety of **lampalizumab** administered by intravitreal injections in participants with geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

Condition or disease	Intervention/treatment	Phase
Geographic Atrophy	Drug: **Lampalizumab** Other: Sham	**Phase 3**

Study Design

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Study Type :
Interventional (Clinical Trial)

Actual Enrollment :
906 participants

Allocation:
Randomized

Intervention Model:
Parallel Assignment

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

Primary Purpose:
Treatment

Official Title:
A Phase III, Multicenter, Randomized, Double-Masked, Sham-Controlled Study to Assess the Efficacy and Safety of **Lampalizumab** Administered Intravitreally to Patients With Geographic Atrophy Secondary to Age-Related Macular Degeneration

Actual Study Start Date :
September 18, 2014

Actual Primary Completion Date :

January 29, 2018

Actual Study Completion Date :

January 29, 2018

Resource links provided by the National Library of Medicine

MedlinePlus Genetics related topics: Age-related macular degeneration

MedlinePlus related topics: Macular Degeneration

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: **Lampalizumab** Once in Every 4 Weeks (Q4W) Participants will receive 10 milligrams (mg) dose of **lampalizumab** administered by intravitreal injections for approximately 96 weeks.	Drug: **Lampalizumab** Participants will receive 10 mg dose of **lampalizumab** administered intravitreally. Other Name: RO5490249
Experimental: **Lampalizumab** Once in Every 6 Weeks (Q6W) Participants will receive 10 mg dose of **lampalizumab** administered by intravitreal injections for approximately 96 weeks.	Drug: **Lampalizumab** Participants will receive 10 mg dose of **lampalizumab** administered intravitreally. Other Name: RO5490249
Sham Comparator: Sham Comparator Participants will receive sham comparator Q4W or Q6W for 96 weeks.	Other: Sham A sham injection is a procedure that mimics an intravitreal injection of **lampalizumab**.

Outcome Measures

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Primary Outcome Measures :

1. Change From Baseline in Geographic Atrophy (GA) Area, as Assessed by Fundus Autofluoresence (FAF) at Week 48 [Time Frame: Baseline, Week 48]

The change in GA lesion area was measured by FAF and analysis of FAF images was performed by the central reading center. A positive change from baseline indicates an increase in size of GA lesion area (worsening; disease progression).

2. Change From Baseline in GA Area in Complement Factor I (CFI) Positive and Negative Participants at Week 48 [Time Frame: Baseline, Week 48]

   For CFI profile, positive or negative biomarker status refers to the presence (carrier) or absence of the risk allele at CFI and at least one risk allele at complement factor H (CFH) or risk locus containing both complement component 2 and complement factor B (C2/CFB).The change in GA lesion area was measured by FAF and analysis of FAF images was performed by the central reading center. A positive change from baseline indicates an increase in size of GA lesion area (worsening; disease progression).

Secondary Outcome Measures :

1. Change From Baseline in Number of Absolute Scotomatous Points as Assessed by Mesopic Micrometry at Week 48 [Time Frame: Baseline, Week 48]

   Scotomatous points were the testing points on microperimetry examination that were centered on the macula and reported a lack of retinal sensitivity within the range tested, a maximum of 68 points were tested within this range. Higher results indicate expansion of absolute scotoma and higher number of abolute scotomatous points. Mesopic microperimetry assessments were performed post-dilation on the study eye only, and the data was forwarded to the central reading center. The data was collected up to Week 48 instead of Week 96, due to early termination of the study. A positive change from baseline indicates an increase in the number of absolute scotomatous points (more lack of retinal sensitivity); disease worsening.

2. Change From Baseline in Mean Macular Sensitivity as Assessed by Mesopic Microperimetry at Week 48 [Time Frame: Baseline, Week 48]

   Mesopic microperimetry was used to assess macular sensitivity and assessments were performed post-dilation on the study eye only, and the data was forwarded to the central reading center. A negative change from baseline indicates a decrease in the mean macular sensitivity; disease worsening. The data was collected up to Week 48 instead of Week 96, due to early termination of the study.

3. Change From Baseline in Best Corrected Visual Acuity (BCVA) Score as Assessed by Early Treatment Diabetic Retinopathy Study (ETDRS) Chart at Week 48 [Time Frame: Baseline, Week 48]

BCVA score was based on the number of letters read correctly on the ETDRS visual acuity chart assessed at a starting distance of 4 meters (m). BCVA score testing was performed prior to dilating the eyes. BCVA score ranges from 0 to 100 letters in the study eye. The lower the number of letters read correctly on the eye chart, the worse the vision (or visual acuity). A negative change from baseline indicates a decrease in the visual acuity; disease worsening. The data was collected up to Week 48 instead of Week 96, due to early termination of the study.

4. Percentage of Participants With Less Than 15 Letters Loss From Baseline in BCVA Score at Week 48 [Time Frame: Week 48]

   Loss of less than 15 letters from baseline was assessed by the ETDRS chart at a starting distance of 4 meters (m). BCVA was measured using an eye chart and was reported as the number of letters read correctly (ranging from 0 to 100 letters). The lower the number of letters read correctly on the eye chart, the worse the vision (or visual acuity). The data was collected up to Week 48 instead of Week 96, due to early termination of the study.

5. Change From Baseline in Low Luminance Visual Acuity (LLVA) as Assessed by ETDRS Chart Under Low Luminance Conditions at Week 48 [Time Frame: Baseline, Week 48]

   The LLVA was measured by placing a 2.0-log-unit neutral density filter over the best correction for that eye and having the participant read the normally illuminated ETDRS chart. The assessment was performed prior to dilating the eyes. LLVA score ranges from 0 to 100 letters in the study eye. The lower the number of letters read correctly on the eye chart, the worse the vision (or visual acuity). The data was collected up to Week 48 instead of Week 96, due to early termination of the study.

6. Percentage of Participants With Less Than 15 Letters Loss From Baseline in LLVA Score at Week 48 [Time Frame: Week 48]

   Loss of less than 15 letters from baseline was assessed by the ETDRS chart at a starting distance of 4 m. The data was collected up to Week 48 instead of Week 96, due to early termination of the study.

7. Change From Baseline in Binocular Reading Speed as Assessed by Minnesota Low-Vision Reading Test (MNRead) Charts or Radner Reading Charts at Week 48 [Time Frame: Baseline, Week 48]

   MNRead acuity cards were continuous-text reading-acuity cards suitable for measuring the reading acuity and reading speed of normal and low-vision participants. The MNRead acuity cards consisted of single, simple sentences with equal numbers of characters. A stopwatch was used to record time to a tenth of a second. Sentences that could not be read or were not attempted due to vision should be recorded as 0 for time and 10 for errors. The Radner Reading Cards were suitable for measuring reading speed, reading visual acuity, and critical print size. The reading test was stopped when the reading time was longer than 20 seconds or when the participant was making severe errors. A

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