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Trial record **2 of 3** for: lampalizumab | Phase 3

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



The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT02247531

[Recruitment Status](#) ⓘ : Terminated

[First Posted](#) ⓘ : September 25, 2014

[Results First Posted](#) ⓘ : March 14, 2019

[Last Update Posted](#) ⓘ : October 15, 2019

Sponsor:

Hoffmann-La Roche

Information provided by (Responsible Party):

Mylan v. Regeneron
IPR2021-00881
U.S. Pat. 9,254,338
Exhibit 2020

Hoffmann-La Roche

[Study Details](#)[Tabular View](#)[Study Results](#)[Disclaimer](#)[How to Read a Study Record](#)

Study Description

Go to

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 Comparator	Phase 3

Study Design

Go to

[Study Type](#) ⓘ :

Interventional (Clinical Trial)

[Actual Enrollment](#) ⓘ :

975 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](#) ⓘ :

October 6, 2014

Actual Primary Completion Date ⓘ :

January 23, 2018

Actual Study Completion Date ⓘ :

January 23, 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**Go to

Arm ⓘ	Intervention/treatment ⓘ
<p>Experimental: Lampalizumab once in every 4 weeks (Q4W)</p> <p>Participants will receive 10 mg (milligrams) dose of lampalizumab by intravitreal injection, Q4W, starting at the Day 1 visit for approximately 92 weeks.</p>	<p>Drug: Lampalizumab</p> <p>10 mg dose of lampalizumab administered intravitreally.</p> <p>Other Name: RO5490249</p>
<p>Experimental: Lampalizumab once in every 6 weeks (Q6W)</p> <p>Participants will receive 10 mg dose of lampalizumab by intravitreal injection, Q6W, starting at the Day 1 visit for approximately 90 weeks.</p>	<p>Drug: Lampalizumab</p> <p>10 mg dose of lampalizumab administered intravitreally.</p> <p>Other Name: RO5490249</p>
<p>Sham Comparator: Sham Comparator</p> <p>Participants will receive sham comparator, Q4W, starting at the Day 1 visit for approximately 92 weeks or Q6W, starting at the Day 1 visit for approximately 90 weeks.</p>	<p>Other: Sham Comparator</p> <p>A sham injection is a procedure that mimics an intravitreal injection of lampalizumab.</p>

Outcome MeasuresGo to

Primary Outcome Measures :

1. Change From Baseline in Geographic Atrophy (GA) Area, as Assessed by Fundus Autofluorescence (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 Assessed by Mesopic Microperimetry 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. Mesopic microperimetry assessments were performed post-dilation on the study eye only, and the data was forwarded to the central reading center. A positive change from baseline indicates an increase in the number of absolute scotomatous points (more lack of retinal sensitivity); disease worsening. Data were collected up to Week 48 instead of Week 96, due to early termination of the study.

2. Change From Baseline in 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. Data were 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). A decrease in the VA score indicates a worsening in visual acuity. BCVA score testing was performed prior to dilating the eyes. The data was collected up to Week 48 instead of Week 96, due to early termination of the study. 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.

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). Data were 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 low luminance visual acuity 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. A negative change from baseline indicates a decrease in the visual acuity; disease worsening. Data were 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. Data were 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 negative change from baseline indicates a decrease in the binocular reading speed; disease

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