Efficacy and Safety Trial of Conbercept Intravitreal Injection for Neovascular AMD (PANDA-2)

ClinicalTrials.gov Identifier: NCT03630952

Recruitment Status : Terminated (desired primary endpoint was not met)
First Posted : August 15, 2018
Last Update Posted : June 23, 2021

Sponsor:
Chengdu Kanghong Biotech Co., Ltd.

Information provided by (Responsible Party):
Chengdu Kanghong Biotech Co., Ltd.

Study Description

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Brief Summary:
The purpose of this clinical study is to evaluate the efficacy and safety of two different levels of conbercept intravitreal (IVT) injection as compared to the approved vascular endothelial growth factor (VEGF) antagonist active control, aflibercept intravitreal injection (2.0 mg/eye, Eylea®), in subjects with neovascular AMD.

Condition or disease	Intervention/treatment	Phase
Neovascular Age-related Macular Degeneration	Biological: 0.5 mg Conbercept Intravitreal Injection Biological: 1.0 mg Conbercept Intravitreal Injection Biological: 2.0 mg Aflibercept Intravitreal Injection	Phase 3

Detailed Description:
A multicenter, multinational, double-masked, parallel-group, dose-ranging, active-controlled, randomized trial, which will randomize approximately 1140 subjects in a ratio of 1:1:1 to receive IVT injections of 0.5 mg conbercept, 1.0 mg conbercept, or 2.0 mg aflibercept. The trial includes a screening period of less than or equal to 14 days, followed by a treatment period of 92 weeks (last assessment at 96 weeks) with primary efficacy analysis at 36 weeks.

Study Design

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Study Type :
Interventional (Clinical Trial)

Actual Enrollment :
1157 participants

Allocation:
Randomized

Intervention Model:
Parallel Assignment

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

Primary Purpose:
Treatment

Official Title:

A Multicenter, Double-Masked, Randomized, Dose-Ranging Trial to Evaluate the Efficacy and Safety of Conbercept Intravitreal Injection in Subjects With Neovascular Age-Related Macular Degeneration (AMD) (PANDA-2)

Actual Study Start Date :

December 21, 2018

Actual Primary Completion Date :

September 10, 2020

Actual Study Completion Date :

May 19, 2021

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: Aflibercept Ziv-aflibercept

Genetic and Rare Diseases Information Center resources: PANDAS

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: 0.5 mg Conbercept Subjects received 0.5 mg conbercept intravitreal injection at Day 1, Week 4 and Week 8 (three injection loading dose), and treated every eight weeks thereafter (0.5 mg, q8w) through Week 36. At the Week 40 visit, the criteria-based pro re nata (PRN) approach will begin through the end of the treatment period at Week 92, for a total of 92 weeks treatment in the study eye.	Biological: 0.5 mg Conbercept Intravitreal Injection Subjects received 0.5 mg conbercept intravitreal injection at Day 1, Week 4 and Week 8 (three injection loading dose), and treated every eight weeks thereafter (0.5 mg, q8w) through Week 36. At the Week 40 visit, the criteria-based pro re nata (PRN) approach will begin through the end of the treatment period at Week 92, for a total of 92 weeks treatment in the study eye.

Arm	Intervention/treatment
Experimental: 1.0 mg Conbercept Subjects received 1.0 mg conbercept intravitreal injection at Day 1, Week 4 and Week 8 (three injection loading dose), and treated every twelve weeks thereafter (1.0 mg, q12w) through Week 36. At the Week 40 visit, the criteria-based PRN approach will begin through the end of the treatment period at Week 92, for a total of 92 weeks treatment in the study eye.	Biological: 1.0 mg Conbercept Intravitreal Injection Subjects received 1.0 mg conbercept intravitreal injection at Day 1, Week 4 and Week 8 (three injection loading dose), and treated every twelve weeks thereafter (1.0 mg, q12w) through Week 36. At the Week 40 visit, the criteria-based PRN approach will begin through the end of the treatment period at Week 92, for a total of 92 weeks treatment in the study eye.
Active Comparator: Aflibercept Subjects received 2.0 mg aflibercept intravitreal injection at Day 1, Week 4 and Week 8 (three injection loading dose), and treated every eight weeks thereafter (2.0 mg, q8w) through Week 36. At the Week 40 visit, the criteria-based PRN approach will begin through the end of the treatment period at Week 92, for a total of 92 weeks treatment in the study eye.	Biological: 2.0 mg Aflibercept Intravitreal Injection Subjects received 2.0 mg aflibercept intravitreal injection at Day 1, Week 4 and Week 8 (three injection loading dose), and treated every eight weeks thereafter (2.0 mg, q8w) through Week 36. At the Week 40 visit, the criteria-based PRN approach will begin through the end of the treatment period at Week 92, for a total of 92 weeks treatment in the study eye. Other Name: Eylea®

Outcome Measures

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Primary Outcome Measures :

1. Mean change from baseline in best corrected visual acuity (BCVA) at Week 36 in the study eye [Time Frame: Baseline to Week 36]

   BCVA was assessed by Early Treatment of Diabetic Retinopathy Study (ETDRS) method

Secondary Outcome Measures :

1. Proportion of subjects maintaining vision (i.e., losing <15 ETDRS BCVA letters) from baseline to Week 36 [Time Frame: Baseline to Week 36]

   To Assess Proportion of subjects maintaining vision (i.e., losing <15 ETDRS BCVA letters) from baseline to Week 36

2. Proportion of subjects gaining ≥15 ETDRS BCVA letters from baseline to Week 36
   [Time Frame: Baseline to Week 36]

   To Assess Proportion of subjects gaining ≥15 ETDRS BCVA letters from baseline to Week 36

3. Mean change from baseline in central retinal thickness (μm) by spectral domain optical coherence tomography (SD-OCT) at Week [Time Frame: Baseline and Week 36]

   To Assess Mean change from baseline in central retinal thickness (μm) by spectral domain optical coherence tomography (SD-OCT) at Week

4. Proportion of subjects maintaining vision (i.e. losing <15 ETDRS BCVA letters) from baseline to Week 48 [Time Frame: Baseline to Week 48]

   To Assess Proportion of subjects maintaining vision (i.e. losing <15 ETDRS BCVA letters) from baseline to Week 48

5. Mean change from baseline in ETDRS BCVA letter score at Week 96 [Time Frame: Baseline and Week 96]

   To Assess Mean change from baseline in ETDRS BCVA letter score at Week 96

6. Number of participants with adverse events as measure of safety and tolerability
   [Time Frame: Baseline to Week 96]

   To Assess Number of participants with adverse events as measure of safety and tolerability

7. Blood concentration of conbercept doses conducted in a subgroup of subjects, when feasible
   [Time Frame: Baseline to Week 96]

   To Assess Blood concentration of conbercept doses conducted in a subgroup of subjects, when feasible

8. Half-life (t1/2) of conbercept doses conducted in a subgroup of subjects, when feasible
   [Time Frame: Baseline to Week 96]

   To Assess Half-life (t1/2) of conbercept doses conducted in a subgroup of subjects, when feasible

9. Presence of anti-drug antibody of conbercept doses conducted in a subgroup of subjects, when feasible [Time Frame: Baseline to Week 96]

   To Assess Presence of anti-drug antibody of conbercept doses conducted in a subgroup of subjects, when feasible

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