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Trial record **1 of 1** for: NCT03577899

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Efficacy and Safety Trial of Conbercept Intravitreal Injection for Neovascular AMD (PANDA-1)



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: NCT03577899

[Recruitment Status](#) ⓘ : Terminated (desired primary endpoint was not met)

[First Posted](#) ⓘ : July 5, 2018

[Last Update Posted](#) ⓘ : June 24, 2021

Sponsor:

Chengdu Kanghong Biotech Co., Ltd.

Information provided by (Responsible Party):

Chengdu Kanghong Biotech Co., Ltd.

Samsung v. Regeneron
IPR2023-00442
U.S. Pat. 10,130,681
Exhibit 2307

[Study Details](#)[Tabular View](#)[No Results Posted](#)[Disclaimer](#)[How to Read a Study Record](#)

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-1)

Actual Study Start Date ⓘ :

September 25, 2018

Actual Primary Completion Date ⓘ :

September 25, 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) 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) for a total of 92 weeks treatment in the study eye.

Arm 	Intervention/treatment 
<p>Experimental: 1.0 mg Conbercept</p> <p>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) for a total of 92 weeks treatment in the study eye.</p>	<p>Biological: 1.0 mg Conbercept Intravitreal Injection</p> <p>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) for a total of 92 weeks treatment in the study eye.</p>
<p>Active Comparator: Aflibercept</p> <p>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) for a total of 92 weeks of treatment in the study eye.</p>	<p>Biological: 2.0 mg Aflibercept Intravitreal Injection</p> <p>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) for a total of 92 weeks of treatment in the study eye.</p> <p>Other Name: Eylea®</p>

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 36 [Time Frame: Baseline and Week 36]

To assess mean change from baseline in central retinal thickness (μm) by spectral

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 the 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 the blood concentration of conbercept doses conducted in a subgroup of subjects, when feasible

8. Half-life ($t_{1/2}$) of conbercept doses conducted in a subgroup of subjects, when feasible [Time Frame: Baseline to Week 96]

To assess half-life ($t_{1/2}$) 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 the presence of anti-drug antibody of conbercept doses conducted in a subgroup of subjects, when feasible

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:**

1. Men and women ≥ 50 years of age at the Screening visit;
2. Females must be at least 1 year postmenopausal, or surgically sterilized, or, if of childbearing potential, must have a negative pregnancy test at the Screening visit;
 - o Women of childbearing potential must agree to use a highly effective method of contraception throughout the study.
3. Have received no previous treatment for neovascular AMD, including laser photocoagulation and/or photodynamic therapy (PDT) and/or IVT VEGF antagonists (treatment naïve) and;
4. Have active subfoveal choroidal neovascularization (CNV) lesions secondary to AMD (including polypoidal choroidal vasculopathy (PCV)) evidenced by subfoveal fluorescein angiography (FA) leakage, or definite subfoveal fluid by SD-OCT in the study eye at Screening;
5. Have a ETDRS BCVA letter score of 78 to 25 in the study eye at Screening;
6. Are willing and able to sign the study written informed consent form (ICF).

Exclusion Criteria:

1. Have had any prior ocular or systemic treatment (investigational or approved) or surgery for the treatment of neovascular AMD in the study eye except dietary supplements or vitamins;
2. Have participated as a subject in any interventional clinical trial within one month (30 days) prior to Baseline visit;
3. Have a subretinal hemorrhage that is either 50% or more of the total lesion area, or blood is under the fovea and is one or more disc areas in size (greater than 2.5 mm²) in the study eye at Screening;

4. Have any retinal pigment epithelial tears or rips in the study eye at Screening or upon examination at Baseline;
5. Have any vitreous hemorrhage in the study eye upon examination at Baseline or history of vitreous hemorrhage within eight weeks prior to Screening;
6. Have any other cause of CNV;
7. Have had prior pars plana vitrectomy in the study eye;
8. Have presence of a full thickness macular hole at Screening or upon examination at Baseline or a history of a full thickness macular hole in the study eye;
9. Have prior trabeculectomy or other filtration surgery in the study eye;
10. Have uncontrolled glaucoma;
11. Have active intraocular inflammation in either eye at Screening or upon examination at Baseline or a history of uveitis in either eye;
12. Have aphakia or pseudophakia with absence of posterior capsule (unless it occurred as a result of yttrium aluminum garnet (YAG) posterior capsulotomy) in the study eye;
13. Significant media opacities, including cataract, in the study eye that, in the opinion of the Investigator, could require either medical or surgical intervention during the study period;
14. Have any use of long acting intraocular steroids, including implants, within six months prior to Day 1, Baseline;
15. Have any known allergy to povidone iodine or known serious allergy to the fluorescein sodium for injection in angiography;
16. Any history of known contraindications indicated in the Food and Drug Administration (FDA)-approved label for the active control;
17. If female, be pregnant (positive urine pregnancy test at Screening) or breastfeeding.

Contacts and Locations

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Information from the National Library of Medicine



To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

*Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT03577899***

Locations

► Show 179 study locations

Sponsors and Collaborators

Chengdu Kanghong Biotech Co., Ltd.

Investigators

Study Director: Yan Cheng, MD, PhD Chengdu Kanghong Biotechnology Co.,Ltd.

More Information

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Responsible Party:

Chengdu Kanghong Biotech Co., Ltd.

ClinicalTrials.gov Identifier:

[NCT03577899](#) [History of Changes](#)

Other Study ID Numbers:

KHB-1801

First Posted:

July 5, 2018 [Key Record Dates](#)

Last Update Posted:

June 24, 2021

Last Verified:

June 2021

Individual Participant Data (IPD) Sharing Statement:**Plan to Share IPD:**

No

Studies a U.S. FDA-regulated Drug Product:

Yes

Studies a U.S. FDA-regulated Device Product:

No

Additional relevant MeSH terms:

Macular Degeneration

Wet Macular Degeneration

Retinal Degeneration

Retinal Diseases

Eye Diseases

