Abbreviated Novartis Clinical Trials Result Template

Sponsor

Alcon Research, Ltd.

Generic Drug Name

Brinzolamide 1%/brimonidine tartrate 0.2% ophthalmic suspension

Trial Indication(s)

Open-Angle Glaucoma, Ocular Hypertension

Protocol Number

C-10-040

Protocol Title

Safety and IOP-Lowering Efficacy of Brinzolamide 10 mg/mL/Brimonidine 2 mg/mL Fixed Combination Eye Drops, Suspension Compared to Brinzolamide 10 mg/mL Eye Drops, Suspension and Brimonidine 2 mg/mL Eye Drops, Solution in Patients With Open-Angle Glaucoma or Ocular Hypertension

Clinical Trial Study Phase

Phase 3

Study Start/End Dates

May 2011 to January 2013

Centers

Subjects were recruited from 63 investigational centers in the Asia-Pacific region, the European Union, Latin America and Caribbean nations, and the United States.

Objectives

The purpose of this study is to evaluate the safety and efficacy of Brinzolamide/Brimonidine in lowering intraocular pressure (IOP) relative to each of its individual active components in patients with open-angle glaucoma or ocular hypertension.

Test Product (s), Dose(s), and Mode(s) of Administration

Brinzolamide 1%/brimonidine tartrate 0.2% ophthalmic suspension, 1 drop instilled in each eye 2 times a day for 6 months

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:

- Diagnosed with open angle glaucoma or ocular hypertension, and, in the opinion of the Investigator, are insufficiently controlled on monotherapy or are currently on multiple IOP-lowering medications.
- At least 18 years of age.
- Meet qualifying IOP entry criteria.
- Able to understand and sign an informed consent form.
- Other protocol-specified inclusion criteria may apply.

Exclusion Criteria:

- Women of childbearing potential if pregnant, test positive for pregnancy at Screening Visit, breastfeeding, or not in agreement to use adequate birth control methods to prevent pregnancy throughout the study.
- Severe central visual field loss.
- Best corrected visual acuity (BCVA) score worse than 55 ETDRS letters (20/80 Snellen equivalent).
- Chronic, recurrent or severe inflammatory eye disease.
- Ocular trauma within the preceding 6 months.
- Ocular infection or ocular inflammation within the preceding 3 months.

- Clinically significant or progressive retinal disease.
- Other ocular pathology.
- Intraocular surgery within the 6 months prior to entry.
- Ocular laser surgery within the 3 months prior to entry.
- Any abnormality preventing reliable applanation tonometry.
- Any other conditions, including severe illness, which would make the subject, in the opinion of the Investigator, unsuitable for the study.
- Recent use of high-dose (>1 gram daily) salicylate therapy.
- Recent, current, or anticipated treatment with any medication that augments adrenergic responses, or precludes use of an alpha-adrenergic agonist.
- Concurrent use of glucocorticoid medications administered by any route.
- Other protocol-specified exclusion crtieria may apply.

For study results, refer to www.clinicaltrials.gov, NCT01310777.