Alcon

a Novartis company

Sponsor

Alcon Research, Ltd.

Generic Drug Name

Travoprost/Brinzolamide

Trial Indications

Open-angle glaucoma (with or without pseudoexfoliation or pigment dispersion component) or ocular hypertension

Protocol Number

C-07-63

Protocol Title

A Three-Month, Multicenter, Double-Masked Study Comparing the Safety and Efficacy of the Fixed Combination Travoprost/Brinzolamide Eye Drops, Suspension vs TRAVATAN vs AZOPT in Patients with Open-Angle Glaucoma or Ocular Hypertension

Clinical Trial Phase

Phase III

Study Start/End Dates

22 October 2008 / 17 February 2009 (Study Completion Date) / 26 February 2009 (Date of Early Termination)

Reason for Termination

This study was terminated early in the enrollment phase due to the cancellation of the TravBrinz QD development program.

Study Design/Methodology

The design was double-masked, randomized, parallel-group.

Alcon

a Novartis company

Centers

Subjects were recruited from 6 investigational sites located in Australia (4), Taiwan (1), and Belgium (1).

Objectives

The primary objective of this study was to compare the intraocular pressure (IOP)-lowering efficacy of morning or evening instillations of Travoprost/Brinzolamide, versus TRAVATAN dosed in the evening, versus AZOPT dosed in the morning and in the evening, in patients with open-angle glaucoma or ocular hypertension.

Test Product, Dose, and Mode of Administration

Test Product: Travoprost 40 micrograms/ml/Brinzolamide 10 mg/ml Eye Drops, Suspension
Dose: Once daily
Mode of Administration: Topical ocular

Statistical Methods

The primary statistical objective of this study was to demonstrate that the IOP-lowering efficacy of Trav/Brinz was superior to that of AZOPT, and to that of TRAVATAN. The primary efficacy variable, mean IOP, was to be performed using a repeated measures analysis of variance model, and was assessed at Week 2, Week 6, and Week 12 at the 9 A.M, 11 A.M., and 4 P.M. time points with primary inference based upon the assessments at Week 12.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion criteria:

- 18 years of age or older
- Either gender or any race
- Glaucoma (OAG) or ocular hypertension (OHT)
- Currently on stable (at least 4 weeks) IOP lowering medication
- Mean IOP in same eye (at both eligibility and 1&2 visits)
    - 24 and 36 mmHG at 9 A.M.
    - 21 and 36 mm HG at 11 A.M. and 4 P.M.
- Able to discontinue use of IOP lowering medication for a minimum wash out period of 5 to 28 days prior to eligibility visit 1

Exclusion criteria:

- Related to disease condition being investigated (OAG or OHT) in either eye
  - Severe central visual field loss
  - Angle Shaffer grade <2
  - C/D ratio >0.8 (horizontal and vertical measurement)
- Related to ocular patient history or current ocular condition in either eye
  - BCVA worse than 55 ETDRS letters read (equivalent to approximately 20/80 Snellen or 0.25 decimal)
  - Ocular infection or inflammation or laser surgery within the last 3 months
  - Intraocular surgery or trauma within the last 6 months
  - Any abnormality preventing reliable applanation tonometry
  - History of or chronic, recurrently or current severe inflammatory disease
  - History of or current clinically significant or progressive retinal disease
  - History of or current ocular pathology (including severe dry eye) that would affect the conduct of the study
- Related to systemic or ocular medication in either eye
  - Allergy/hypersensitivity to study medications
  - Unable to discontinue glucocorticoid at least 4 weeks prior to the study or unable to remain off these medications during the study period
  - Use of oral CAIs during the study
  - Recent use (<4 weeks prior to the study) of Aspirin (>1 gram)
  - Less than 30 days stable dosing regimen of medications used on a chronic basis that may affect IOP
  - Therapy with another investigational agent within 30 days prior to the Screening Visit

Participant Flow Table

	Overall Participants
Started	17
Completed	6
Discontinued	11

Reason for discontinued	
Study termination	9
Reason not specified	2

Baseline Characteristics

Gender Demographic Statistics for ITT Population

Gender	Overall participants
Male	8
Female	9

Categorical Age Demographic Statistics for ITT Population

Age (years)	Overall participants
<65	9
≥65	8

Summary of Efficacy

Due to the early cancellation of the TravBrinz QD development program and subsequently the termination of the C-07-63 clinical study, the analyses outlined in the Biostatistics Efficacy Analysis Plan were not conducted.

Primary Outcome Results

The primary outcome, mean IOP, was not analyzed due to early termination of the TravBrinz QD development program.

Secondary Outcome Results

The key secondary outcome, mean diurnal IOP, was not analyzed due to early termination of the TravBrinz QD development program.

Summary of Safety

Serious Adverse Events

No serious adverse events were reported during the study.

Other Adverse Events

No other adverse events were reported during the study.

Other Relevant Findings

No other relevant findings to disclose.

Date of Clinical Trial Report

20-Jul-2011