Sponsor

Alcon Research, Ltd.

Generic Drug Name

Travoprost/timolol

Trial Indications

Open-angle glaucoma or ocular hypertension

Protocol Number

C-09-032

Protocol Title

A Twelve-Month Open-Label Safety Study of Polyquaternium-Preserved DuoTrav APS Dosed Once Daily in Patients With Open-Angle Glaucoma or Ocular Hypertension

Clinical Trial Phase

Phase III

Study Start/End Dates

09 July 2009 / 01 November 2010

Reason for Termination

Not applicable

Study Design/Methodology

The design was multi-center, single-arm, open-label.

Centers

Subjects were recruited from 12 investigational sites located in Germany (2), Belgium (1), Latvia (1), Australia (1), and the United States (7).

Objectives

The primary objective was to describe the long-term safety of travoprost 40 µg/mL/timolol 5 mg/mL (POLYQUAD-preserved [DuoTrav PQ]) dosed once daily for 12 months, in patients with open-angle glaucoma or ocular hypertension.

Test Product, Dose, and Mode of Administration

Test Product: DuoTrav (POLYQUAD-preserved)
Dose: 1 drop in the study eye(s) once daily, at 9 AM
Mode of Administration: Topical ocular

Statistical Methods

Safety variables were analyzed using descriptive statistics.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion criteria:

- Willing and able to sign an informed consent document
- Open-angle glaucoma or ocular hypertension who would benefit from a fixed combination medication, in the opinion of the investigator
- Stable treatment of an IOP-lowering medication
- Other protocol-defined inclusion criteria may apply

Exclusion criteria:

- Pregnant, breastfeeding, or not using adequate birth control
- Best-corrected visual acuity (BCVA) worse than 55 ETDRS letters
- Other protocol-defined exclusion criteria may apply

Participant Flow Table

	DuoTrav PQ
Started	154
Safety Analysis Set	154
Completed	135
Discontinued	19
Reason for discontinued	
Adverse event	17
Patient's decision unrelated to an adverse event	1
Noncompliance	1

Baseline Characteristics

Gender Demographic Statistics for Safety Population

Gender	DuoTrav PQ
Male	60
Female	94

Categorical Age Demographic Statistics for Safety Population

Age	DuoTrav PQ
<65	74
≥65	80

Summary of Efficacy

Primary Outcome Measure

Not applicable. No efficacy evaluations were planned or conducted in this safety study.

Secondary Outcome Measures

Not applicable. No efficacy evaluations were planned or conducted in this safety study.

Summary of Safety

Serious Adverse Events

No deaths or serious adverse events assessed as related to the use of DuoTrav PQ were reported during the study. Twelve participants reported serious adverse events assessed as unrelated to the use of DuoTrav PQ.

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Summary of Treatment-Emergent Adverse Events

Adverse Event Category	N = 154	
	N	%
Deaths	**0**	**0.0**
Patients experiencing non-fatal serious adverse events[a]	**12**	**7.8**
Patients discontinued due to an adverse event	**17**	**11.0**
Discontinued due to non-fatal serious adverse events	1	0.6
Discontinued due to non-serious adverse events	16	10.4
Treatment-related	6	3.9
Not related to treatment	10	6.5
Patients with at least 1 treatment-emergent adverse event (related and not related combined)	**94**	**61.0**
Most frequent treatment-emergent adverse events (incidence of 5.0% or greater)		
Hypertension	13	8.4
Ocular hyperaemia	11	7.1
Eye pruritus	10	6.5
Cataract	8	5.2
Eye irritation	8	5.2
Patients with at least 1 treatment-emergent adverse event related to treatment (ADR; adverse drug reaction)	**31**	**20.1**
Most frequent adverse drug reactions (incidence of 1.0% or greater)		
Ocular hyperaemia	10	6.5
Eye pruritus	7	4.5
Eye irritation	5	3.2
Dry eye	3	1.9
Eye pain	3	1.9
Hypersensitivity	2	1.3
Heart rate decreased	2	1.3

[a]All non-fatal serious adverse events were assessed as unrelated to the use of DuoTrav (POLYQUAD-preserved)

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Most Common (2% or greater) Treatment-Emergent Adverse Events

	N = 154		Onset (in days)		Pt. D/C due to ADR	
	N	%	Min	Max	N	%
Eye disorders						
Ocular hyperaemia	11	7.1	1	264	1	0.6
Eye pruritus	10	6.5	1	166	0	0.0
Cataract	8	5.2	178	369	0	0.0
Eye irritation	8	5.2	1	259	0	0.0
Eye pain	6	3.9	1	114	0	0.0
Dry eye	6	3.9	1	264	0	0.0
Conjunctivitis	5	3.2	2	285	0	0.0
Foreign body sensation in eyes	4	2.6	1	252	0	0.0
Immune system disorders						
Seasonal allergies	7	4.5	1	259	0	0.0

	N = 154		Onset (in days)		Pt. D/C due to ADR	
	N	%	Min	Max	N	%
Investigations						
Increased intraocular pressure	7	4.5	91	280	5	3.2
Musculoskelatel and connective tissue disorders						
Back pain	4	2.6	36	278	0	0.0
Nervous system disorders						
Visual field defect	7	4.5	167	366	0	0.0
Vascular disorders						
Hypertension	13	8.4	9	308	0	0.0

Coded Adverse Event = MedDRA Preferred Term (version 12.0) presented by System Organ Class
Pt. D/C = patient discontinued

Other Relevant Findings

No other relevant findings to disclose.

Date of Clinical Trial Report

09-Dec-2010