Sponsor

Alcon Research, Ltd.

Generic Drug Name

Travoprost ophthalmic solution, 0.004%

Trial Indication(s)

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

Protocol Number

C-01-78

Protocol Title

A Multicenter Study of the Pigmentation in the Trabecular Meshwork after 2 Years of Treatment with TRAVATAN 0.004% Ophthalmic Solution

Clinical Trial Phase

Phase 4

Study Start/End Dates

07 July 2004 to 23 February 2012

Reason for Termination

Study objectives were met.

Study Design/Methodology

This was a multicenter, observer-masked, active-controlled, parallel-group, safety trial. Qualified patients underwent trabeculectomy and a tissue sample of the trabecular meshwork was collected.

Centers

Subjects were recruited from 10 investigational sites located in the United States (9) and Spain (1).

Objectives

The primary objective of this study was to assess the pigmentation in the trabecular meshwork in patients that had been treated for at least 2 years with travoprost compared with patients without exposure (or less than 1 month) to a prostaglandin analogue (PGA).

Test Product, Dose, and Mode of Administration

No test articles were utilized in the conduct of this study. Study patients were grouped according to their prior use of travoprost 0.004% or no prior use of any topical ocular PGA.

Statistical Methods

Descriptive statistics - planned variables are descriptive in nature and not intended to imply efficacy.
The intent-to-treat (ITT) data set included all patients who had a trabecular meshwork sample taken and a melanin granule count assessed under a 450x magnification.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion criteria:

- Diagnosis of open-angle glaucoma without pseudoexfoliation or pigment dispersion component;
- Either two or more years of dosing with Travatan, or no prior exposure (less than 1 month) to a topical ocular prostaglandin;
- Requires a trabeculectomy;
- Other protocol-defined inclusion criteria may apply.

Exclusion Criteria:

- Pseudoexfoliation or pigment dispersion;
- History of chronic or recurrent severe inflammatory eye disease;
- History of or current ocular infection or ocular inflammation within the past 3 months in either eye;
- Greater than one month but less than two years of exposure to TRAVATAN;
- Pregnant, breast-feeding, not using highly effective birth control;

- Other protocol-defined exclusion criteria may apply.

Participant Flow Table

Patient Status
(All Patients Enrolled)

	Total		Travoprost (N=51)		None (N=37)	
	N	(%)	N	(%)	N	(%)
Completed Study	86	(97.7)	51	(59.3)	35	(40.7)
Discontinued	2	(2.3)	0	(0.0)	2	(100.0)

Travoprost = exposed to travoprost ophthalmic solution 0.004% for at least 2 years
None = no prior exposure (or <1 month) to any topical, ocular prostaglandin
One patient in the Travoprost group is counted twice in the summary since the patient participated twice in the study; once for each eye.

Baseline Characteristics

Demographic Statistics by Treatment Group
(Intent-to-Treat Population)

	Total		Travoprost (N=51)		None (N=37)	
	N	(%)	N	(%)	N	(%)
Age (Years)						
<65	7	(17.1)	3	(13.0)	4	(22.2)
≥65	34	(82.9)	20	(87.0)	14	(77.8)
Age (≥65 Years)						
≥65 to <75	14	(41.2)	7	(35.0)	7	(50.0)
≥75 to <85	17	(50.0)	10	(50.0)	7	(50.0)
≥85 to <95	3	(8.8)	3	(15.0)	0	(0.0)

Sex						
Male	20	(48.8)	13	(56.5)	7	(38.9)
Female	21	(51.2)	10	(43.5)	11	(61.1)

Travoprost = exposed to travoprost ophthalmic solution 0.004% for at least 2 years
None = no prior exposure (or <1 month) to any topical, ocular prostaglandin
One patient in the Travoprost group is counted twice in the summary since the patient participated twice in the study; once for each eye

Summary of Efficacy

Primary Outcome Measure

Trabecular Meshwork Assessment from Pathologist

(Intent-to-Treat Data)

	Total		**Travoprost**		**None**	
	N	%	**N**	%	**N**	%
Total	41	100.0	23	100.0	18	100.0
Identified Pigmentation						
Marginal	10	24.4	8	34.8	2	11.1
Obvious	8	19.5	1	4.3	7	38.9
Present	23	56.1	14	60.9	9	50.0

Travoprost = exposed to travoprost ophthalmic solution 0.004% for at least 2 years
None = no prior exposure (or <1 month) to any topical, ocular prostaglandin

Secondary Outcome Measures

None reported.

Summary of Safety

No adverse events reported in this study.

Other Relevant Findings

No other relevant findings to disclose.

Date of Clinical Trial Report

21 February 2013