ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 08/21/2012

ClinicalTrials.gov ID: NCT00907426

Study Identification

Unique Protocol ID:	192024-038
Brief Title:	Safety and Efficacy Study of Bimatoprost to Treat Hypotrichosis of the Eyelashes After Application to the Eyelid Margin
Official Title:	
Secondary IDs:	

Study Status

Record Verification:	August 2012
Overall Status:	Completed
Study Start:	August 2009
Primary Completion:	November 2010 [Actual]
Study Completion:	May 2011 [Actual]

Sponsor/Collaborators

Sponsor:	Allergan
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No

IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 48929 Serial Number: Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	This one-year study evaluates the long-term safety and effectiveness of bimatoprost solution application to the eyelid margin (where the eyelashes meet the skin) to treat hypotrichosis of the eyelashes (inadequate or not enough eyelashes). There will be two different types of subjects participating in the study 1)those with inadequate eyelashes due to natural causes or 2) those with inadequate eyelashes following a complete course of chemotherapy treatment. There will be two treatment periods of six months each. Subjects will receive either the study medication or vehicle in either of the two treatment periods.
Detailed Description:	

Conditions

Conditions:	Hypotrichosis
Keywords:	eyelashes

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	3

Masking:	Double Blind (Subject, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	368 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Bimatoprost 0.03% Followed by Bimatoprost 0.03% Treatment period one (0-6 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). For treatment period two (6-12 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin.	Drug: Bimatoprost 0.03% solution Once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). Other Names: • LATISSE™
Bimatoprost 0.03% Followed by Vehicle Treatment period one (0-6 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). For treatment period two (6-12 months), once daily, one drop of vehicle solution using a single-use per eye applicator will be applied to the upper eyelid margin.	Drug: Bimatoprost 0.03% solution Once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). Other Names: • LATISSE™ Drug: Vehicle solution Once daily, one drop of vehicle solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). Other Names: • LATISSE™
Vehicle Followed by Bimatoprost 0.03% Treatment period one (0-6 months), once daily, one drop of vehicle solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). For treatment period two (6-12 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin.	Drug: Bimatoprost 0.03% solution Once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). Other Names: • LATISSE™ Drug: Vehicle solution Once daily, one drop of vehicle solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). Other Names:

Arms	Assigned Interventions
	• LATISSE™

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Subjects who have inadequate eyelashes due to natural causes and are not satisfied with their eyelash appearance.
- For the post-chemotherapy population: subjects who have inadequate eyelashes following a complete course of chemotherapy treatment and are not satisfied with their eyelash appearance, are considered free of cancer and are well enough to complete the study.

Exclusion Criteria:

- Subjects with unequal right and left eyelashes, any eye disease or abnormality, eye surgery, permanent eyeliner, eyelash implants, eyelash extension application.
- Any use of over the counter or prescription use eyelash growth products.
- Subjects requiring eye drop medications for glaucoma.
- Females who are pregnant, nursing or planning a pregnancy during the study or who are of childbearing potential and not using a reliable method of contraception.

Contacts/Locations

Study Officials: Medical Director
Study Director
Allergan, Inc.

Locations: United States, California
San Diego, California, United States

United Kingdom
London, England, United Kingdom

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Bimatoprost 0.03% Followed by Bimatoprost 0.03%	Treatment period one (0-6 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). For treatment period two (6-12 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin.
Bimatoprost 0.03% Followed by Vehicle	Treatment period one (0-6 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). For treatment period two (6-12 months), once daily, one drop of vehicle solution using a single-use per eye applicator will be applied to the upper eyelid margin.
Vehicle Followed by Bimatoprost 0.03%	Treatment period one (0-6 months), once daily, one drop of vehicle solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). For treatment period two (6-12 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin.

Treatment Period 1 (0 to 6 Months)

	Bimatoprost 0.03% Followed by Bimatoprost 0.03%	Bimatoprost 0.03% Followed by Vehicle	Vehicle Followed by Bimatoprost 0.03%
Started	215	60	93
Completed	195	55	84
Not Completed	20	5	9

Treatment Period 2 (6 to 12 Months)

	Bimatoprost 0.03% Followed by Bimatoprost 0.03%	Bimatoprost 0.03% Followed by Vehicle	Vehicle Followed by Bimatoprost 0.03%
Started	195	55	84
Completed	184	52	77
Not Completed	11	3	7

Baseline Characteristics

Reporting Groups

	Description
Bimatoprost 0.03% Followed by Bimatoprost 0.03%	Treatment period one (0-6 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). For treatment period two (6-12 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin.
Bimatoprost 0.03% Followed by Vehicle	Treatment period one (0-6 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). For treatment period two (6-12 months), once daily, one drop of vehicle solution using a single-use per eye applicator will be applied to the upper eyelid margin.
Vehicle Followed by Bimatoprost 0.03%	Treatment period one (0-6 months), once daily, one drop of vehicle solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). For treatment period two (6-12 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin.

Baseline Measures

	Bimatoprost 0.03% Followed by Bimatoprost 0.03%	Bimatoprost 0.03% Followed by Vehicle	Vehicle Followed by Bimatoprost 0.03%	Total
Number of Participants	215	60	93	368
Age, Customized [units: Participants]				
<45 Years	56	18	31	105
Between 45 and 65 years	151	35	53	239
>65 Years	8	7	9	24

	Bimatoprost 0.03% Followed by Bimatoprost 0.03%	Bimatoprost 0.03% Followed by Vehicle	Vehicle Followed by Bimatoprost 0.03%	Total
Gender, Male/Female [units: Participants]				
Female	214	58	92	364
Male	1	2	1	4

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Treatment Responders at Month 4
Measure Description	Percentage of Treatment Responders at Month 4 defined by: a) at least a 1-grade improvement from baseline in the Global Eyelash Assessment (GEA) score, AND b) at least a 3-point improvement from baseline in the total score for Domain 2 of the Eyelash Symptom Questionnaire (ESQ). The GEA 4-point scale assessed eyelash prominence from 1 (minimal) to 4 (very marked). Domain 2 of the ESQ assessed subjective attributes of confidence, attractiveness, and professionalism rated on a 5-point scale from 1 (very much disagree) to 5 (very much agree) for a total score between 3 and 15.
Time Frame	Month 4
Safety Issue?	No

Analysis Population Description

Intent-to-Treat: All randomized subjects

Reporting Groups

	Description
Bimatoprost 0.03%	Once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin).
Vehicle	Once daily, one drop of vehicle solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin).

Measured Values

	Bimatoprost 0.03%	Vehicle
Number of Participants Analyzed	275	93
Percentage of Treatment Responders at Month 4 [units: Percentage of Subjects]	39.3	10.9

2. Secondary Outcome Measure:

Measure Title	Change From Baseline in Upper Eyelash Length at Month 4
Measure Description	Change from Baseline to in upper eyelash length at Month 4, measured in millimeters (mm). Data from both eyes were averaged for each subject for analysis. Changes from baseline represented by positive values indicated longer length, and changes from baseline represented by negative values indicated shorter length.
Time Frame	Baseline, Month 4
Safety Issue?	No

Analysis Population Description

Intent-to-Treat: All randomized subjects who had baseline and Month 4 data collected for this outcome measure

Reporting Groups

	Description
Bimatoprost 0.03%	Once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin).
Vehicle	Once daily, one drop of vehicle solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin).

Measured Values

	Bimatoprost 0.03%	Vehicle
Number of Participants Analyzed	271	89
Change From Baseline in Upper Eyelash Length at Month 4 [units: Millimeters (mm)] Mean (Standard Deviation)		
Baseline	5.40 (1.085)	5.42 (1.138)
Change from Baseline at Month 4	1.33 (1.110)	0.07 (1.015)

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in Average Progressive Upper Eyelash Thickness at Month 4

Measure Description	Change from baseline in average progressive upper eyelash thickness at Month 4 was measured within 3 preset areas. Eyelash thickness was assessed across both eyes as an average of the 3 preset areas measured in millimeters squared (mm^2). Changes from baseline at Month 4 represented by positive values indicated increased eyelash thickness, and changes from baseline represented by negative values indicated thinner eyelash thickness.
Time Frame	Baseline, Month 4
Safety Issue?	No

Analysis Population Description

Intent-to-Treat: All randomized subjects who had baseline and Month 4 data collected for this outcome measure

Reporting Groups

	Description
Bimatoprost 0.03%	Once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin).
Vehicle	Once daily, one drop of vehicle solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin).

Measured Values

	Bimatoprost 0.03%	Vehicle
Number of Participants Analyzed	216	71
Change From Baseline in Average Progressive Upper Eyelash Thickness at Month 4 [units: Millimeters squared (mm^2)] Mean (Standard Deviation)		
Baseline	0.67 (0.376)	0.82 (0.598)
Change from Baseline at Month 4	0.59 (0.471)	-0.07 (0.520)

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in Upper Eyelash Darkness at Month 4
Measure Description	Change from baseline in upper eyelash darkness at Month 4 was determined by lash intensity within the spline (a narrow area approximately 5 pixels wide that bisects the area of interest). Upper eyelash darkness was measured in both eyes and averaged for analysis. Colors ranged from black=0 to white=255. Lower numbers on this continuum indicated darker colors. A negative number value change from baseline indicated increased eyelash darkening.
Time Frame	Baseline, Month 4

Safety Issue?	No

Analysis Population Description

Intent-to-Treat: All randomized subjects who had baseline and Month 4 data collected for this outcome measure

Reporting Groups

	Description
Bimatoprost 0.03%	Once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin).
Vehicle	Once daily, one drop of vehicle solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin).

Measured Values

	Bimatoprost 0.03%	Vehicle
Number of Participants Analyzed	215	70
Change From Baseline in Upper Eyelash Darkness at Month 4 [units: Eyelash Intensity Units] Mean (Standard Deviation)		
Baseline	151.36 (24.670)	148.82 (26.445)
Change from Baseline at Month 4	-23.55 (20.787)	-2.60 (18.592)

5. Other Pre-specified Outcome Measure:

Measure Title	Percentage of Subjects With at Least a 1-Grade Improvement in Global Eyelash Assessment (GEA) Score at Month 4
Measure Description	Percentage of subjects with at least a 1-grade improvement in GEA score at Month 4. The GEA scale is an investigator-graded 4-point scale of overall eyelash prominence where 1=minimal, 2=moderate, 3=marked, and 4=very marked prominence.
Time Frame	Month 4
Safety Issue?	No

Analysis Population Description

Intent-to-Treat: All randomized subjects who had baseline and Month 4 data collected for this outcome measure

Reporting Groups

	Description
Bimatoprost 0.03%	Once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin).
Vehicle	Once daily, one drop of vehicle solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin).

Measured Values

	Bimatoprost 0.03%	Vehicle
Number of Participants Analyzed	275	92
Percentage of Subjects With at Least a 1-Grade Improvement in Global Eyelash Assessment (GEA) Score at Month 4 [units: Percentage of Participants]	73.8	28.3

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	The Safety Population included all subjects who received at least one dose of study medication and was used to analyze serious adverse events (SAEs) and adverse events (AEs). SAEs/AEs are reported by arm randomized, not by treatment received.

Reporting Groups

	Description
Bimatoprost 0.03% Followed by Bimatoprost 0.03%	Treatment period one (0-6 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). For treatment period two (6-12 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin.
Bimatoprost 0.03% Followed by Vehicle	Treatment period one (0-6 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). For treatment period two (6-12 months), once daily, one drop of vehicle solution using a single-use per eye applicator will be applied to the upper eyelid margin.

	Description
Vehicle Followed by Bimatoprost 0.03%	Treatment period one (0-6 months), once daily, one drop of vehicle solution using a single-use per eye applicator will be applied to the upper eyelid margin (where the eyelashes meet the skin). For treatment period two (6-12 months), once daily, one drop of Bimatoprost 0.03% solution using a single-use per eye applicator will be applied to the upper eyelid margin.

Serious Adverse Events

	Bimatoprost 0.03% Followed by Bimatoprost 0.03%	Bimatoprost 0.03% Followed by Vehicle	Vehicle Followed by Bimatoprost 0.03%
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	20/214 (9.35%)	3/60 (5%)	9/92 (9.78%)
Cardiac disorders			
Cardiac Arrest [A] [1] †	1/214 (0.47%)	0/60 (0%)	0/92 (0%)
Gastrointestinal disorders			
Gastrointestinal Inflammation [A] [1] †	1/214 (0.47%)	0/60 (0%)	0/92 (0%)
Retroperitoneal Haematoma [A] [1] †	1/214 (0.47%)	0/60 (0%)	0/92 (0%)
General disorders			
Chest Pain [A] [1] *	0/214 (0%)	1/60 (1.67%)	0/92 (0%)
Infections and infestations			
Breast Cellulitis [A] [1] †	0/214 (0%)	0/60 (0%)	1/92 (1.09%)
Bronchitis [A] [1] †	0/214 (0%)	0/60 (0%)	1/92 (1.09%)
Pneumonia [A] [1] †	0/214 (0%)	0/60 (0%)	1/92 (1.09%)
Staphylococcal Infection [A] [1] †	1/214 (0.47%)	0/60 (0%)	0/92 (0%)
Injury, poisoning and procedural complications			
Road Traffic Accident [A] [1] *	1/214 (0.47%)	0/60 (0%)	0/92 (0%)
Seroma [A] [1] *	0/214 (0%)	0/60 (0%)	1/92 (1.09%)
Wound [A] [1] *	1/214 (0.47%)	0/60 (0%)	0/92 (0%)
Wound Dehiscence [A] [1] *	1/214 (0.47%)	0/60 (0%)	0/92 (0%)

	Bimatoprost 0.03% Followed by Bimatoprost 0.03%	Bimatoprost 0.03% Followed by Vehicle	Vehicle Followed by Bimatoprost 0.03%
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Wrist Fracture [A] [1] *	1/214 (0.47%)	0/60 (0%)	0/92 (0%)
Musculoskeletal and connective tissue disorders			
Musculoskeletal Chest Pain [A] [1] *	1/214 (0.47%)	0/60 (0%)	0/92 (0%)
Musculoskeletal Pain [A] [1] *	1/214 (0.47%)	0/60 (0%)	0/92 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma [A] [1] †	0/214 (0%)	2/60 (3.33%)	0/92 (0%)
Breast Cancer [A] [1] †	0/214 (0%)	0/60 (0%)	2/92 (2.17%)
Breast Cancer Metastatic [A] [1] †	3/214 (1.4%)	0/60 (0%)	0/92 (0%)
Lung Carcinoma Cell Type Unspecified Stage IV [A] [1] †	0/214 (0%)	0/60 (0%)	1/92 (1.09%)
Ovarian Cancer [A] [1] †	1/214 (0.47%)	0/60 (0%)	0/92 (0%)
Thyroid Cancer [A] [1] †	1/214 (0.47%)	0/60 (0%)	0/92 (0%)
Nervous system disorders			
Migraine [A] [1] *	1/214 (0.47%)	0/60 (0%)	0/92 (0%)
Reproductive system and breast disorders			
Ovarian Cyst [A] [1] †	1/214 (0.47%)	0/60 (0%)	0/92 (0%)
Vaginal Prolapse [A] [1] †	1/214 (0.47%)	0/60 (0%)	0/92 (0%)
Respiratory, thoracic and mediastinal disorders			
Asthma [A] [1] †	0/214 (0%)	0/60 (0%)	1/92 (1.09%)
Pulmonary Embolism [A] [1] †	1/214 (0.47%)	0/60 (0%)	0/92 (0%)
Surgical and medical procedures			
Breast Reconstruction [A] [1] †	1/214 (0.47%)	0/60 (0%)	1/92 (1.09%)

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA Version 14.0

[1] Not related to study treatment

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Bimatoprost 0.03% Followed by Bimatoprost 0.03%	Bimatoprost 0.03% Followed by Vehicle	Vehicle Followed by Bimatoprost 0.03%
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	75/214 (35.05%)	21/60 (35%)	36/92 (39.13%)
Eye disorders			
Conjunctival Hyperaemia [A] *	26/214 (12.15%)	4/60 (6.67%)	6/92 (6.52%)
Erythema of Eyelid [A] *	9/214 (4.21%)	6/60 (10%)	5/92 (5.43%)
Eyelids Pruritus [A] *	10/214 (4.67%)	4/60 (6.67%)	5/92 (5.43%)
Punctate Keratitis [A] †	12/214 (5.61%)	3/60 (5%)	5/92 (5.43%)
Infections and infestations			
Nasopharyngitis [A] *	5/214 (2.34%)	4/60 (6.67%)	4/92 (4.35%)
Upper Respiratory Tract Infection [A] *	9/214 (4.21%)	0/60 (0%)	5/92 (5.43%)
Nervous system disorders			
Headache [A] *	4/214 (1.87%)	0/60 (0%)	6/92 (6.52%)

† Indicates events were collected by systematic assessment.

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA Version 14.0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

A disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 90 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo

Results Point of Contact:

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