Safety Study Extension of Iloprost Power 15 in Pulmonary Arterial Hypertension (PROWESS 15 Ext)

This study has been completed.

Sponsor:
Actelion

Information provided by (Responsible Party):
Actelion

ClinicalTrials.gov Identifier:
NCT00709098

First received: July 1, 2008
Last updated: September 10, 2015
Last verified: March 2015
History of Changes

Results First Received: September 27, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Pulmonary Arterial Hypertension
Intervention:	Drug: iloprost

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
The double-blind period of the study was conducted at 20 centers in the US and Germany, and the following open-label period of the study was conducted at 17 centers in the US only. First patient, first visit was 4 September 2008 and the last patient, last visit was 17 June 2010.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Out of the 63 patients who completed the core study of AC-063A301, 49 gave informed consent and enrolled into this extension study.

Reporting Groups

	Description
Iloprost Power 6 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb® adaptive aerosol delivery (AAD®) System utilizing a power setting 6 disc
Iloprost Power 15 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc
Iloprost Power 15 (Open-label Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc

Participant Flow for 2 periods

Period 1: Double-blind Period

	Iloprost Power 6 (Double-blind Period)	Iloprost Power 15 (Double-blind Period)	Iloprost Power 15 (Open-label Period)
STARTED	25	24	0
COMPLETED	19	16	0

NOT COMPLETED	6	8	0
Withdrawal of consent	3	3	0
Administrative reason	1	3	0
Death	1	1	0
Lost to Follow-up	1	1	0

Period 2: Open-label Period

	Iloprost Power 6 (Double-blind Period)	Iloprost Power 15 (Double-blind Period)	Iloprost Power 15 (Open-label Period)
STARTED	0	0	32 [1]
COMPLETED	0	0	18
NOT COMPLETED	0	0	14
Withdrawal of consent	0	0	7
Administrative reason	0	0	5
Death	0	0	1
Lost to Follow-up	0	0	1

[1] The open-label period was only made available to patients in US centers

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Iloprost Power 6 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb® adaptive aerosol delivery (AAD®) System utilizing a power setting 6 disc
Iloprost Power 15 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc
Iloprost Power 15 (Open-label Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc
Total	Total of all reporting groups

Baseline Measures

	Iloprost Power 6 (Double-blind Period)	Iloprost Power 15 (Double-blind Period)	Iloprost Power 15 (Open-label Period)	Total
Number of Participants [units: participants]	**25**	**24**	**0**	**49**
Age [units: years] Mean (Full Range)	**58.3 (25 to 87)**	**55.4 (29 to 79)**		**56.9 (25 to 87)**
Gender [units: participants]				
Female	**19**	**19**		**38**
Male	**6**	**5**		**11**

Region of Enrollment [units: participants]				
United States	**23**	**22**		**45**
Germany	**2**	**2**		**4**

Outcome Measures

Hide All Outcome Measures

1. Primary: Treatment-emergent Adverse Events [Time Frame: Double-blind period: from first inhalation of study drug to end of 12-week treatment period. Open-label period: from the start to end of open-label medication, mean duration of exposure was 284.5 days.]

Measure Type	Primary
Measure Title	Treatment-emergent Adverse Events
Measure Description	Number of adverse events
Time Frame	Double-blind period: from first inhalation of study drug to end of 12-week treatment period. Open-label period: from the start to end of open-label medication, mean duration of exposure was 284.5 days.
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Safety population

Reporting Groups

	Description
Iloprost Power 6 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb® adaptive aerosol

	delivery (AAD®) System utilizing a power setting 6 disc
Iloprost Power 15 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc
Iloprost Power 15 (Open-label Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc

Measured Values

	Iloprost Power 6 (Double-blind Period)	Iloprost Power 15 (Double-blind Period)	Iloprost Power 15 (Open-label Period)
Number of Participants Analyzed [units: participants]	**25**	**24**	**32**
Treatment-emergent Adverse Events [units: adverse events]	**148**	**139**	**126**

No statistical analysis provided for Treatment-emergent Adverse Events

2. Primary: Treatment-emergent Serious Adverse Events [Time Frame: Double-blind period: from first inhalation of study drug to end of 12-week treatment period. Open-label period: from the start to end of open-label medication, mean duration of exposure was 284.5 days.]

Measure Type	Primary
Measure Title	Treatment-emergent Serious Adverse Events
Measure Description	Number of serious adverse events
Time Frame	Double-blind period: from first inhalation of study drug to end of 12-week treatment period. Open-label period: from the start to end of open-label medication, mean duration of exposure was 284.5 days.
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Safety population

Reporting Groups

	Description
Iloprost Power 6 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb® adaptive aerosol delivery (AAD®) System utilizing a power setting 6 disc
Iloprost Power 15 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc
Iloprost Power 15 (Open-label Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc

Measured Values

	Iloprost Power 6 (Double-blind Period)	**Iloprost Power 15 (Double-blind Period)**	**Iloprost Power 15 (Open-label Period)**
Number of Participants Analyzed [units: participants]	**25**	**24**	**32**
Treatment-emergent Serious Adverse Events [units: serious adverse events]	**11**	**11**	**10**

No statistical analysis provided for Treatment-emergent Serious Adverse Events

3. Primary: Adverse Events Leading to Premature Discontinuation of Study Drug [Time Frame: Double-blind period: from the first inhalation of study drug to discontinuation. Open-label period: from the start of open-label medication to discontinuation, mean duration of

exposure was 284.5 days.]

Measure Type	Primary
Measure Title	Adverse Events Leading to Premature Discontinuation of Study Drug
Measure Description	Number of adverse events leading to discontinuation of study treatment
Time Frame	Double-blind period: from the first inhalation of study drug to discontinuation. Open-label period: from the start of open-label medication to discontinuation, mean duration of exposure was 284.5 days.
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Safety population

Reporting Groups

	Description
Iloprost Power 6 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb® adaptive aerosol delivery (AAD®) System utilizing a power setting 6 disc
Iloprost Power 15 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc
Iloprost Power 15 (Open-label Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc

Measured Values

	Iloprost Power 6 (Double-blind Period)	**Iloprost Power 15 (Double-blind Period)**	**Iloprost Power 15 (Open-label Period)**
Number of Participants Analyzed [units: participants]	**25**	**24**	**32**

Adverse Events Leading to Premature Discontinuation of Study Drug [units: adverse events]	**3**	**10**	**7**

No statistical analysis provided for Adverse Events Leading to Premature Discontinuation of Study Drug

4. Primary: Patients With Adverse Events Leading to Premature Discontinuation of Study Drug [Time Frame: Double-blind period: from the first inhalation of study drug to discontinuation. Open-label period: from the start of open-label medication to discontinuation, mean duration of exposure was 284.5 days.]

Measure Type	Primary
Measure Title	Patients With Adverse Events Leading to Premature Discontinuation of Study Drug
Measure Description	Number of patients with adverse events leading to discontinuation of study treatment
Time Frame	Double-blind period: from the first inhalation of study drug to discontinuation. Open-label period: from the start of open-label medication to discontinuation, mean duration of exposure was 284.5 days.
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Iloprost Power 6 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb® adaptive aerosol delivery (AAD®) System utilizing a power setting 6 disc
Iloprost Power 15 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System

	utilizing a power setting 15 disc
Iloprost Power 15 (Open-label Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc

Measured Values

	Iloprost Power 6 (Double-blind Period)	Iloprost Power 15 (Double-blind Period)	Iloprost Power 15 (Open-label Period)
Number of Participants Analyzed [units: participants]	**25**	**24**	**32**
Patients With Adverse Events Leading to Premature Discontinuation of Study Drug [units: participants]	**2**	**6**	**7**

No statistical analysis provided for Patients With Adverse Events Leading to Premature Discontinuation of Study Drug

5. Other Pre-specified: Average Inhalation Time [Time Frame: 12 weeks]

Measure Type	Other Pre-specified
Measure Title	Average Inhalation Time
Measure Description	Average inhalation time of iloprost during the double-blind period (i.e., the sum of the duration of each inhalation divided by the number of inhalations during the double-blind period)
Time Frame	12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

All treated population

Reporting Groups

	Description
Iloprost Power 6 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 6 disc
Iloprost Power 15 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc

Measured Values

	Iloprost Power 6 (Double-blind Period)	Iloprost Power 15 (Double-blind Period)
Number of Participants Analyzed [units: participants]	**25**	**24**
Average Inhalation Time [units: minutes] Mean (Standard Deviation)	**10.9 (4.50)**	**5.8 (1.14)**

Statistical Analysis 1 for Average Inhalation Time

Groups [1]	All groups
Method [2]	t-test, 2 sided
P Value [3]	<0.0001
Mean group difference [4]	-5.1
95% Confidence Interval	-7.0 to -3.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.

[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Double-blind period: from first inhalation of study drug to end of 12-week treatment period. Open-label period: from the start to end of open-label medication
Additional Description	Treatment-emergent adverse events

Reporting Groups

	Description
Iloprost Power 6 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb® adaptive aerosol delivery (AAD®) System utilizing a power setting 6 disc
Iloprost Power 15 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc
Iloprost Power 15 (Open-label Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc

Serious Adverse Events

	Iloprost Power 6 (Double-blind Period)	Iloprost Power 15 (Double-blind Period)	Iloprost Power 15 (Open-label Period)
Total, serious adverse events			
# participants affected / at risk	6/25 (24.00%)	5/24 (20.83%)	8/32 (25.00%)
Cardiac disorders			
ATRIAL FIBRILLATION † 1			
# participants affected / at risk	0/25 (0.00%)	1/24 (4.17%)	0/32 (0.00%)
ATRIAL FLUTTER † 1			
# participants affected / at risk	0/25 (0.00%)	1/24 (4.17%)	0/32 (0.00%)
RIGHT VENTRICULAR FAILURE † 1			
# participants affected / at risk	1/25 (4.00%)	0/24 (0.00%)	0/32 (0.00%)
Gastrointestinal disorders			
COLITIS † 1			
# participants affected / at risk	0/25 (0.00%)	1/24 (4.17%)	0/32 (0.00%)
DIVERTICULUM † 1			
# participants affected / at risk	1/25 (4.00%)	0/24 (0.00%)	0/32 (0.00%)
General disorders			
SUDDEN CARDIAC DEATH † 1			
# participants affected / at risk	1/25 (4.00%)	0/24 (0.00%)	0/32 (0.00%)
NO THERAPEUTIC RESPONSE † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	1/32 (3.13%)
Hepatobiliary disorders			
CHOLECYSTITIS ACUTE † 1			
# participants affected / at risk	1/25 (4.00%)	0/24 (0.00%)	0/32 (0.00%)
Infections and infestations			

BRONCHITIS † 1			
# participants affected / at risk	1/25 (4.00%)	0/24 (0.00%)	1/32 (3.13%)
DIVERTICULITIS † 1			
# participants affected / at risk	1/25 (4.00%)	0/24 (0.00%)	0/32 (0.00%)
LOBAR PNEUMONIA † 1			
# participants affected / at risk	1/25 (4.00%)	0/24 (0.00%)	0/32 (0.00%)
SEPSIS † 1			
# participants affected / at risk	0/25 (0.00%)	1/24 (4.17%)	0/32 (0.00%)
URINARY TRACT INFECTION † 1			
# participants affected / at risk	0/25 (0.00%)	1/24 (4.17%)	0/32 (0.00%)
PNEUMONIA † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	1/32 (3.13%)
Investigations			
LIVER FUNCTION TEST ABNORMAL † 1			
# participants affected / at risk	0/25 (0.00%)	1/24 (4.17%)	0/32 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
PROSTATE CANCER † 1			
# participants affected / at risk	1/25 (4.00%)	0/24 (0.00%)	0/32 (0.00%)
Nervous system disorders			
CEREBROVASCULAR ACCIDENT † 1			
# participants affected / at risk	1/25 (4.00%)	0/24 (0.00%)	0/32 (0.00%)
SYNCOPE † 1			
# participants affected / at risk	1/25 (4.00%)	0/24 (0.00%)	1/32 (3.13%)
Renal and urinary disorders			

RENAL FAILURE ACUTE † 1			
# participants affected / at risk	0/25 (0.00%)	1/24 (4.17%)	0/32 (0.00%)
Respiratory, thoracic and mediastinal disorders			
CHRONIC OBSTRUCTIVE PULMONARY DISEASE † 1			
# participants affected / at risk	0/25 (0.00%)	1/24 (4.17%)	0/32 (0.00%)
HYPOXIA † 1			
# participants affected / at risk	0/25 (0.00%)	1/24 (4.17%)	1/32 (3.13%)
PULMONARY HYPERTENSION † 1			
# participants affected / at risk	1/25 (4.00%)	0/24 (0.00%)	1/32 (3.13%)
RESPIRATORY FAILURE † 1			
# participants affected / at risk	0/25 (0.00%)	1/24 (4.17%)	0/32 (0.00%)
PULMONARY ARTERIAL HYPERTENSION † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	3/32 (9.38%)
DYSPNOEA † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	1/32 (3.13%)
Vascular disorders			
PERIPHERAL VASCULAR DISORDER † 1			
# participants affected / at risk	0/25 (0.00%)	1/24 (4.17%)	0/32 (0.00%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (12.0)

Other Adverse Events

Hide Other Adverse Events

Time Frame	Double-blind period: from first inhalation of study drug to end of 12-week treatment period. Open-label period: from the start to end of open-label medication
Additional Description	Treatment-emergent adverse events

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Iloprost Power 6 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb® adaptive aerosol delivery (AAD®) System utilizing a power setting 6 disc
Iloprost Power 15 (Double-blind Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc
Iloprost Power 15 (Open-label Period)	The study medication was 5 µg iloprost delivered as an aerosol using the I-neb®AAD® System utilizing a power setting 15 disc

Other Adverse Events

	Iloprost Power 6 (Double-blind Period)	**Iloprost Power 15 (Double-blind Period)**	**Iloprost Power 15 (Open-label Period)**
Total, other (not including serious) adverse events			
# participants affected / at risk	**23/25 (92.00%)**	**23/24 (95.83%)**	**25/32 (78.13%)**
Cardiac disorders			
PALPITATIONS † [1]			
# participants affected / at risk	**0/25 (0.00%)**	**0/24 (0.00%)**	**3/32 (9.38%)**
Gastrointestinal disorders			

NAUSEA † 1			
# participants affected / at risk	6/25 (24.00%)	5/24 (20.83%)	5/32 (15.63%)
DIARRHOEA † 1			
# participants affected / at risk	3/25 (12.00%)	4/24 (16.67%)	5/32 (15.63%)
ABDOMINAL PAIN † 1			
# participants affected / at risk	2/25 (8.00%)	2/24 (8.33%)	0/32 (0.00%)
VOMITING † 1			
# participants affected / at risk	4/25 (16.00%)	0/24 (0.00%)	3/32 (9.38%)
ABDOMINAL PAIN UPPER † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	2/32 (6.25%)
General disorders			
CHEST DISCOMFORT † 1			
# participants affected / at risk	6/25 (24.00%)	4/24 (16.67%)	0/32 (0.00%)
CHEST PAIN † 1			
# participants affected / at risk	2/25 (8.00%)	4/24 (16.67%)	2/32 (6.25%)
FATIGUE † 1			
# participants affected / at risk	1/25 (4.00%)	4/24 (16.67%)	2/32 (6.25%)
ASTHENIA † 1			
# participants affected / at risk	2/25 (8.00%)	1/24 (4.17%)	0/32 (0.00%)
OEDEMA PERIPHERAL † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	3/32 (9.38%)
Infections and infestations			
UPPER RESPIRATORY TRACT INFECTION † 1			
# participants affected / at risk	5/25 (20.00%)	3/24 (12.50%)	5/32 (15.63%)

NASOPHARYNGITIS † 1			
# participants affected / at risk	2/25 (8.00%)	1/24 (4.17%)	0/32 (0.00%)
ACUTE SINUSITIS † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	2/32 (6.25%)
BRONCHITIS † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	2/32 (6.25%)
EAR INFECTION † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	2/32 (6.25%)
INFLUENZA † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	2/32 (6.25%)
SINUSITIS † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	2/32 (6.25%)
URINARY TRACT INFECTION † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	2/32 (6.25%)
Musculoskeletal and connective tissue disorders			
PAIN IN JAW † 1			
# participants affected / at risk	3/25 (12.00%)	2/24 (8.33%)	2/32 (6.25%)
BACK PAIN † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	3/32 (9.38%)
Nervous system disorders			
HEADACHE † 1			
# participants affected / at risk	11/25 (44.00%)	13/24 (54.17%)	2/32 (6.25%)
DIZZINESS † 1			
# participants affected / at risk	8/25 (32.00%)	7/24 (29.17%)	4/32 (12.50%)

SYNCOPE † 1			
# participants affected / at risk	0/25 (0.00%)	3/24 (12.50%)	0/32 (0.00%)
Psychiatric disorders			
DEPRESSION † 1			
# participants affected / at risk	2/25 (8.00%)	2/24 (8.33%)	0/32 (0.00%)
ANXIETY † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	2/32 (6.25%)
INSOMNIA † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	2/32 (6.25%)
Respiratory, thoracic and mediastinal disorders			
COUGH † 1			
# participants affected / at risk	7/25 (28.00%)	10/24 (41.67%)	2/32 (6.25%)
DYSPNOEA † 1			
# participants affected / at risk	3/25 (12.00%)	4/24 (16.67%)	3/32 (9.38%)
OROPHARYNGEAL PAIN † 1			
# participants affected / at risk	2/25 (8.00%)	2/24 (8.33%)	0/32 (0.00%)
DYSPNOEA EXERTIONAL † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	2/32 (6.25%)
HYPOXIA † 1			
# participants affected / at risk	0/25 (0.00%)	0/24 (0.00%)	2/32 (6.25%)
Vascular disorders			
FLUSHING † 1			
# participants affected / at risk	6/25 (24.00%)	8/24 (33.33%)	0/32 (0.00%)

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA (12.0)

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There is **NOT** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

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Responsible Party: Actelion
ClinicalTrials.gov Identifier: NCT00709098 History of Changes
Other Study ID Numbers: **AC-063A302**
Study First Received: July 1, 2008
Results First Received: September 27, 2012

Last Updated:	September 10, 2015
Health Authority:	United States: Food and Drug Administration