ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 09/12/2013

ClinicalTrials.gov ID: NCT01129531

Study Identification

Unique Protocol ID:	214868-002
Brief Title:	A Study of the Safety and Efficacy of AGN-214868 in Patients With Postherpetic Neuralgia
Official Title:	
Secondary IDs:	

Study Status

Record Verification:	September 2013
Overall Status:	Completed
Study Start:	June 2010
Primary Completion:	October 2011 [Actual]
Study Completion:	January 2012 [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: 101,532 Serial Number: Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	Yes
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	This study will evaluate the safety and efficacy of AGN-214868 in patients with postherpetic neuralgia (PHN) - nerve pain.
Detailed Description:	

Conditions

Conditions:	Neuralgia, Postherpetic
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	3
Masking:	Double Blind (Subject, Investigator)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study

Enrollment: 294 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: AGN-214868 3.25 µg AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 3.25 µg per treatment.	Drug: AGN-214868 AGN-214868 injected into areas of postherpetic neuralgia pain for total dose per treatment.
Experimental: AGN-214868 16.25 µg AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 16.25 µg per treatment.	Drug: AGN-214868 AGN-214868 injected into areas of postherpetic neuralgia pain for total dose per treatment.
Placebo Comparator: Placebo Placebo to AGN-214868 injected into areas of postherpetic neuralgia pain per treatment.	Drug: Placebo to AGN-214868 Placebo to AGN-214868 injected into areas of postherpetic neuralgia pain per treatment.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 80 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Persistent postherpetic neuralgia (PHN) with nerve pain present for at least 9 months after onset of herpes zoster skin rash

Exclusion Criteria:

- Female patients with reproductive potential
- Active herpes zoster skin rash
- Current or anticipated treatment with acupuncture, TNS, or steroids
- Current or anticipated use of topical analgesic agents with PHN
- Treatment with botulinum toxin therapy of any serotype within the prior 12 weeks

Contacts/Locations

Study Officials: Medical Director

Study Director
Allergan, Inc.

Locations: United States, Florida
Orlando, Florida, United States

Germany
Kiel, Kiel, Germany

Czech Republic
Hradec kralove, Czech Republic

Poland
Katowice, Poland

Czech Republic
Brno, Czech Republic

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Pre-Assignment Details	There were two Treatment Cycles in this study 12 weeks apart. In Treatment Cycle 1 participants were randomized to AGN-214868 3.25 µg, AGN-214868 16.25 µg or Placebo. In Treatment Cycle 2 participants were re-randomized to AGN-214868 3.25 µg, AGN-214868 16.25 µg or Placebo.

Reporting Groups

	Description
AGN-214868 3.25 µg	AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 3.25 µg per treatment.
AGN-214868 16.25 µg	AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 16.25 µg per treatment.
Placebo	Placebo to AGN-214868 injected into areas of postherpetic neuralgia pain per treatment.

Treatment Cycle 1

	AGN-214868 3.25 µg	AGN-214868 16.25 µg	Placebo
Started	84	84	126
Completed	80	78	110
Not Completed	4	6	16

Treatment Cycle 2

	AGN-214868 3.25 µg	AGN-214868 16.25 µg	Placebo
Started	94 [1]	95 [1]	79 [1]
Completed	88	92	74
Not Completed	6	3	5

[1] Participants who completed Treatment Cycle 1 were re-randomized.

Baseline Characteristics

Reporting Groups

	Description
AGN-214868 3.25 µg	AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 3.25 µg per treatment.
AGN-214868 16.25 µg	AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 16.25 µg per treatment.
Placebo	Placebo to AGN-214868 injected into areas of postherpetic neuralgia pain per treatment.

Baseline Measures

	AGN-214868 3.25 µg	AGN-214868 16.25 µg	Placebo	Total
Number of Participants	84	84	126	294
Age, Customized [units: Participants]				
18 to < 40 Years	2	2	2	6
40 to < 65 Years	18	29	38	85
65 to < 75 Years	42	33	57	132
≥ 75 Years	22	20	29	71

	AGN-214868 3.25 µg	AGN-214868 16.25 µg	Placebo	Total
Gender, Male/Female [units: Participants]				
Female	44	47	73	164
Male	40	37	53	130

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline in the Average Pain Intensity Score at Week 12
Measure Description	Participants rated the severity of their daily pain in the previous 7 days using a 10 point scale where 0=no pain to 10=pain as bad as you can imagine. A negative change from Baseline indicated improvement.
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Modified intent to treat population included all randomized participants who received treatment and had at least 1 post-baseline pain intensity score.

Reporting Groups

	Description
AGN-214868 3.25 µg	AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 3.25 µg per treatment.
AGN-214868 16.25 µg	AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 16.25 µg per treatment.
Placebo	Placebo to AGN-214868 injected into areas of postherpetic neuralgia pain per treatment.

Measured Values

	AGN-214868 3.25 µg	AGN-214868 16.25 µg	Placebo
Number of Participants Analyzed	84	82	124
Change From Baseline in the Average Pain Intensity Score at Week 12 [units: Score on a scale] Mean (Standard Deviation)			
Baseline	6.13 (1.248)	6.04 (1.324)	6.05 (1.334)
Change from Baseline at Week 12	-1.42 (1.876)	-1.35 (1.996)	-1.27 (2.036)

2. Secondary Outcome Measure:

Measure Title	Change From Baseline in Area of Spontaneous Pain
Measure Description	A tracing of the area of spontaneous pain was made and sent to an independent central reading center for measurement. The area of spontaneous pain was measured in centimeters squared (cm^2) at Baseline and Week 12. A negative change from Baseline indicated improvement.
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Modified intent to treat population included all randomized participants who received treatment and had at least 1 post-baseline pain intensity score.

Reporting Groups

	Description
AGN-214868 3.25 µg	AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 3.25 µg per treatment.
AGN-214868 16.25 µg	AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 16.25 µg per treatment.
Placebo	Placebo to AGN-214868 injected into areas of postherpetic neuralgia pain per treatment.

Measured Values

	AGN-214868 3.25 µg	AGN-214868 16.25 µg	Placebo
Number of Participants Analyzed	84	82	124
Change From Baseline in Area of Spontaneous Pain [units: cm^2] Mean (Standard Deviation)			
Baseline	87.44 (51.312)	118.17 (74.858)	98.27 (62.866)
Change from Baseline at Week 12 (N=81, 79, 117)	-4.83 (62.374)	-17.18 (62.694)	-6.13 (68.990)

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in Area of Allodynia
Measure Description	A tracing of the area of allodynia (pain to touch) was made and sent to an independent central reading center for measurement. The area of allodynia was measured in centimeters squared (cm^2) at Baseline and Week 12. A negative change from Baseline indicated improvement.

Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Modified intent to treat population included all randomized participants who received treatment and had at least 1 post-baseline pain intensity score.

Reporting Groups

	Description
AGN-214868 3.25 µg	AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 3.25 µg per treatment.
AGN-214868 16.25 µg	AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 16.25 µg per treatment.
Placebo	Placebo to AGN-214868 injected into areas of postherpetic neuralgia pain per treatment. Participants received two treatments 12 weeks apart.

Measured Values

	AGN-214868 3.25 µg	AGN-214868 16.25 µg	Placebo
Number of Participants Analyzed	84	82	124
Change From Baseline in Area of Allodynia [units: cm^2] Mean (Standard Deviation)			
Baseline	184.28 (145.259)	195.11 (149.355)	174.17 (134.132)
Change from Baseline at Week 12 (N=81, 79, 117)	-32.40 (89.849)	-43.56 (107.183)	-15.27 (116.338)

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in Evoked Pain Score in the Area of Allodynia
Measure Description	Participants were asked to rate the unpleasantness (pain to touch) after 3 brush strokes in the area of allodynia on a 100 point scale where 0=no pain to 100=worst pain imaginable. A negative change from Baseline indicated improvement.
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Modified intent to treat population included all randomized participants who received treatment and had at least 1 post-baseline pain intensity score.

Reporting Groups

	Description
AGN-214868 3.25 µg	AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 3.25 µg per treatment.
AGN-214868 16.25 µg	AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 16.25 µg per treatment.
Placebo	Placebo to AGN-214868 injected into areas of postherpetic neuralgia pain per treatment.

Measured Values

	AGN-214868 3.25 µg	AGN-214868 16.25 µg	Placebo
Number of Participants Analyzed	84	82	124
Change From Baseline in Evoked Pain Score in the Area of Allodynia [units: Score on a scale] Mean (Standard Deviation)			
Baseline	60.8 (22.39)	58.4 (24.04)	60.0 (22.39)
Change from Baseline at Week 12 (N=82, 80, 118)	-11.7 (25.36)	-7.9 (28.61)	-11.1 (27.64)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	The safety population (all participants who received at least one dose of study medication) was used to calculate the number of participants at risk for Serious Adverse Events and Adverse Events.

Reporting Groups

	Description
AGN-214868 3.25 µg_Cycle 1	One treatment of AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 3.25 µg.
AGN-214868 16.25 µg_Cycle 1	One treatment of AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 16.25 µg.
Placebo_Cycle 1	One treatment of Placebo to AGN-214868 injected into areas of postherpetic neuralgia pain.
AGN-214868 3.25 µg_ Cycle 2	One treatment of AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 3.25 µg.
AGN-214868 16.25 µg_ Cycle 2	One treatment of AGN-214868 injected into areas of postherpetic neuralgia pain for a total dose of 16.25 µg.
Placebo_Cycle 2	One treatment of Placebo to AGN-214868 injected into areas of postherpetic neuralgia pain.

Serious Adverse Events

	AGN-214868 3.25 µg_Cycle 1	AGN-214868 16.25 µg_Cycle 1	Placebo_Cycle 1	AGN-214868 3.25 µg_ Cycle 2	AGN-214868 16.25 µg_ Cycle 2	Placebo_Cycle 2
	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)
Total	1/84 (1.19%)	2/83 (2.41%)	1/125 (0.8%)	5/94 (5.32%)	5/95 (5.26%)	3/79 (3.8%)
Cardiac disorders						
Angina pectoris [A] †	0/84 (0%)	0/83 (0%)	0/125 (0%)	1/94 (1.06%)	0/95 (0%)	0/79 (0%)
Cardiac failure chronic [A] †	1/84 (1.19%)	0/83 (0%)	0/125 (0%)	0/94 (0%)	0/95 (0%)	0/79 (0%)
Coronary artery disease [A] †	0/84 (0%)	0/83 (0%)	0/125 (0%)	1/94 (1.06%)	0/95 (0%)	0/79 (0%)
Myocardial infarction [A] †	0/84 (0%)	0/83 (0%)	0/125 (0%)	0/94 (0%)	0/95 (0%)	1/79 (1.27%)
Myocardial ischaemia [A] †	0/84 (0%)	0/83 (0%)	0/125 (0%)	1/94 (1.06%)	0/95 (0%)	0/79 (0%)
Gastrointestinal disorders						
Gastroduodenitis [A] †	0/84 (0%)	0/83 (0%)	0/125 (0%)	0/94 (0%)	0/95 (0%)	1/79 (1.27%)
Gastrointestinal haemorrhage [A] †	0/84 (0%)	0/83 (0%)	0/125 (0%)	1/94 (1.06%)	0/95 (0%)	0/79 (0%)
Haemorrhoidal haemorrhage [A] †	0/84 (0%)	0/83 (0%)	0/125 (0%)	0/94 (0%)	1/95 (1.05%)	0/79 (0%)
Vomiting [A] *	0/84 (0%)	0/83 (0%)	0/125 (0%)	0/94 (0%)	1/95 (1.05%)	0/79 (0%)
General disorders						
Chest pain [A] *	0/84 (0%)	1/83 (1.2%)	0/125 (0%)	0/94 (0%)	0/95 (0%)	0/79 (0%)
Infections and infestations						
Pneumonia [A] †	0/84 (0%)	0/83 (0%)	0/125 (0%)	1/94 (1.06%)	0/95 (0%)	0/79 (0%)
Sepsis [A] †	0/84 (0%)	0/83 (0%)	0/125 (0%)	1/94 (1.06%)	0/95 (0%)	0/79 (0%)
Metabolism and nutrition disorders						
Dehydration [A] †	0/84 (0%)	0/83 (0%)	0/125 (0%)	0/94 (0%)	0/95 (0%)	1/79 (1.27%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Basal cell carcinoma [A] †	0/84 (0%)	0/83 (0%)	0/125 (0%)	0/94 (0%)	2/95 (2.11%)	0/79 (0%)

	AGN-214868 3.25 µg_Cycle 1	AGN-214868 16.25 µg_Cycle 1	Placebo_Cycle 1	AGN-214868 3.25 µg_ Cycle 2	AGN-214868 16.25 µg_ Cycle 2	Placebo_Cycle 2
	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)
Malignant melanoma [A] †	0/84 (0%)	1/83 (1.2%)	0/125 (0%)	0/94 (0%)	0/95 (0%)	0/79 (0%)
Nervous system disorders						
Cerebrovascular accident [A] †	0/84 (0%)	0/83 (0%)	0/125 (0%)	0/94 (0%)	1/95 (1.05%)	0/79 (0%)
Dizziness [A] *	0/84 (0%)	0/83 (0%)	0/125 (0%)	0/94 (0%)	1/95 (1.05%)	0/79 (0%)
VIIth nerve paralysis [A] †	0/84 (0%)	0/83 (0%)	0/125 (0%)	1/94 (1.06%)	0/95 (0%)	0/79 (0%)
Psychiatric disorders						
Depression [A] †	0/84 (0%)	0/83 (0%)	0/125 (0%)	0/94 (0%)	0/95 (0%)	1/79 (1.27%)
Renal and urinary disorders						
Tubulointerstitial nephritis [A] †	0/84 (0%)	0/83 (0%)	0/125 (0%)	1/94 (1.06%)	0/95 (0%)	0/79 (0%)
Respiratory, thoracic and mediastinal disorders						
Chronic obstructive pulmonary disease [A] †	0/84 (0%)	0/83 (0%)	1/125 (0.8%)	0/94 (0%)	0/95 (0%)	0/79 (0%)
Respiratory failure [A] †	1/84 (1.19%)	0/83 (0%)	0/125 (0%)	0/94 (0%)	0/95 (0%)	0/79 (0%)
Vascular disorders						
Deep vein thrombosis [A] *	0/84 (0%)	0/83 (0%)	0/125 (0%)	1/94 (1.06%)	0/95 (0%)	0/79 (0%)

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA 14.1

Other Adverse Events

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

	AGN-214868 3.25 µg_Cycle 1	AGN-214868 16.25 µg_Cycle 1	Placebo_Cycle 1	AGN-214868 3.25 µg_ Cycle 2	AGN-214868 16.25 µg_ Cycle 2	Placebo_Cycle 2
	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)
Total	1/84 (1.19%)	1/83 (1.2%)	2/125 (1.6%)	6/94 (6.38%)	1/95 (1.05%)	3/79 (3.8%)
Musculoskeletal and connective tissue disorders						
Arthralgia [A] *	1/84 (1.19%)	1/83 (1.2%)	2/125 (1.6%)	6/94 (6.38%)	1/95 (1.05%)	3/79 (3.8%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA 14.1

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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