ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 08/25/2015

ClinicalTrials.gov ID: NCT00445705

Study Identification

Unique Protocol ID:	203818-503
Brief Title:	Safety and Efficacy of AGN 203818 for Pain Associated With Fibromyalgia Syndrome
Official Title:	
Secondary IDs:	

Study Status

Record Verification:	August 2015
Overall Status:	Terminated [This study was terminated early due to company decision. Part B was never conducted.]
Study Start:	March 2007
Primary Completion:	January 2008 [Actual]
Study Completion:	January 2008 [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: 70,859 Serial Number: Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	This study will explore the safety and effectiveness of different doses of AGN 203818 in treating the pain associated with fibromyalgia syndrome. The study is being conducted in 2 parts. Part A enrolled 211 pts dosed with either 3, 20, 60 mg BID AGN 203818 or placebo over 4 week treatment duration. Part B will enroll 440 pts and dose with either 20, 100, 160 mg BID AGN 203818 or placebo over 12 week treatment duration.
Detailed Description:	

Conditions

Conditions:	Fibromyalgia
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	4
Masking:	Double Blind (Subject, Investigator)

Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	211 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Placebo Comparator: Placebo Part A: Placebo every 12 hours for 4 weeks	Drug: placebo Part A: Placebo every 12 hours for 4 weeks
Experimental: AGN 203818 3 mg Part A: 3 mg AGN 203818 every 12 hours for 4 weeks	Drug: AGN 203818 Part A: AGN 203818 3 mg every 12 hours for 4 weeks
Experimental: AGN 203818 20 mg Part A: 20 mg AGN 203818 every 12 hours for 4 weeks	Drug: AGN 203818 Part A: AGN 203818 20 mg every 12 hours for 4 weeks
Experimental: AGN 203818 60 mg Part A: 60 mg AGN 203818 every 12 hours for 4 weeks	Drug: AGN 203818 Part A: AGN 203818 60 mg every 12 hours for 4 weeks

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	75 Years
Gender:	Female
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Diagnosis of fibromyalgia syndrome
- Moderate or severe pain associated with fibromyalgia

Exclusion Criteria:

- Any other uncontrolled disease
- Pregnant or nursing females

Contacts/Locations

Study Officials:	Medical Director

Study Director
Allergan, Inc.

Locations: United States, Ohio
Canton, Ohio, United States

United Kingdom
Stanmore, United Kingdom

Switzerland
Geneva, Switzerland

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Placebo	Part A: Placebo every 12 hours for 4 weeks
AGN 203818 3 mg	Part A: 3 mg AGN 203818 every 12 hours for 4 weeks
AGN 203818 20 mg	Part A: 20 mg AGN 203818 every 12 hours for 4 weeks
AGN 203818 60 mg	Part A: 60 mg AGN 203818 every 12 hours for 4 weeks

Overall Study

	Placebo	AGN 203818 3 mg	AGN 203818 20 mg	AGN 203818 60 mg
Started	53	53	52	53
Completed	44	42	41	39
Not Completed	9	11	11	14

Baseline Characteristics

Reporting Groups

	Description
Placebo	Part A: Placebo every 12 hours for 4 weeks
AGN 203818 3 mg	Part A: 3 mg AGN 203818 every 12 hours for 4 weeks
AGN 203818 20 mg	Part A: 20 mg AGN 203818 every 12 hours for 4 weeks
AGN 203818 60 mg	Part A: 60 mg AGN 203818 every 12 hours for 4 weeks

Baseline Measures

	Placebo	AGN 203818 3 mg	AGN 203818 20 mg	AGN 203818 60 mg	Total
Number of Participants	53	53	52	53	211
Age, Continuous [units: years] Median (Full Range)	50.5 (23 to 68)	50.0 (25 to 69)	49.5 (18 to 67)	51.0 (24 to 71)	50.0 (18 to 71)
Gender, Male/Female [units: participants]					
Female	53	53	52	53	211
Male	0	0	0	0	0

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline in Mean Daily-Average-Pain Score at Week 4
Measure Description	Change from Baseline in mean daily-average-pain score at week 4. Patients recorded their daily average pain on a 11-point scale (where 0 equals no pain and 10 equals worst pain imaginable) using a diary during the 4-week treatment period. A negative number change from baseline represents a decrease in average pain (improvement).
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Modified Intent-To-Treat (m-ITT). The m-ITT population included all patients who started the study (randomized) and received study medication with at least one post-treatment mean daily-average-pain score.

Reporting Groups

	Description
Placebo	Part A: Placebo every 12 hours for 4 weeks
AGN 203818 3 mg	Part A: 3 mg AGN 203818 every 12 hours for 4 weeks
AGN 203818 20 mg	Part A: 20 mg AGN 203818 every 12 hours for 4 weeks
AGN 203818 60 mg	Part A: 60 mg AGN 203818 every 12 hours for 4 weeks

Measured Values

	Placebo	AGN 203818 3 mg	AGN 203818 20 mg	AGN 203818 60 mg
Number of Participants Analyzed	50	51	50	50
Change From Baseline in Mean Daily-Average-Pain Score at Week 4 [units: Scores on a Scale] Mean (Standard Deviation)				
Baseline	6.7 (1.04)	6.7 (1.10)	6.6 (0.96)	6.7 (1.14)
Change from Baseline at Week 4	-1.3 (1.66)	-1.2 (1.82)	-1.5 (1.79)	-1.5 (1.85)

2. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Short Form Brief Pain Inventory (SF-BPI) Average Pain Score at Week 4
Measure Description	Change from baseline in the SF-BPI average pain question score at week 4. The SF-BPI is a patient-rated questionnaire that assesses certain aspects of pain including location, intensity, and interference with certain daily activities. The “average pain” question was rated on an 11-point scale (where 0=no pain and 10=worst pain imaginable). A negative number change from baseline indicates a reduction in average pain.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Modified Intent-To-Treat (m-ITT). The m-ITT population included all patients who started the study (randomized) and received study medication with at least one post-treatment mean daily-average-pain score.

Reporting Groups

	Description
Placebo	Part A: Placebo every 12 hours for 4 weeks

	Description
AGN 203818 3 mg	Part A: 3 mg AGN 203818 every 12 hours for 4 weeks
AGN 203818 20 mg	Part A: 20 mg AGN 203818 every 12 hours for 4 weeks
AGN 203818 60 mg	Part A: 60 mg AGN 203818 every 12 hours for 4 weeks

Measured Values

	Placebo	AGN 203818 3 mg	AGN 203818 20 mg	AGN 203818 60 mg
Number of Participants Analyzed	50	51	50	50
Change From Baseline in the Short Form Brief Pain Inventory (SF-BPI) Average Pain Score at Week 4 [units: Scores on a Scale] Mean (Standard Deviation)				
Baseline	6.4 (1.19)	6.6 (1.21)	6.5 (1.23)	6.5 (1.28)
Change from Baseline at Week 4	-1.3 (1.88)	-1.2 (1.79)	-1.7 (2.24)	-1.3 (1.68)

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Fibromyalgia Impact Questionnaire (FIQ) Total Score of Physical Impairment at Week 4
Measure Description	Change from baseline in FIQ total score of physical impairment at week 4. The FIQ is a disease-specific questionnaire consisting of 10 questions and visual analog scales regarding functional disability, pain intensity, sleep function, stiffness, anxiety, depression, and overall sense of wellbeing. Each question is scored from 0 to 10 with 0 = no impairment (best) and 10 indicates maximum impairment (worst), for a minimum possible score (best) of 0 and a maximum possible (worst) total score of 100. A negative number change from baseline indicates improvement.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Modified Intent-To-Treat (m-ITT). The m-ITT population included all patients who started the study (randomized) and received study medication with at least one post-treatment mean daily-average-pain score.

Reporting Groups

	Description
Placebo	Part A: Placebo every 12 hours for 4 weeks
AGN 203818 3 mg	Part A: 3 mg AGN 203818 every 12 hours for 4 weeks

	Description
AGN 203818 20 mg	Part A: 20 mg AGN 203818 every 12 hours for 4 weeks
AGN 203818 60 mg	Part A: 60 mg AGN 203818 every 12 hours for 4 weeks

Measured Values

	Placebo	AGN 203818 3 mg	AGN 203818 20 mg	AGN 203818 60 mg
Number of Participants Analyzed	50	51	50	50
Change From Baseline in the Fibromyalgia Impact Questionnaire (FIQ) Total Score of Physical Impairment at Week 4 [units: Scores on a Scale] Mean (Standard Deviation)				
Baseline	59.9 (15.35)	65.5 (15.55)	65.7 (13.63)	63.0 (13.44)
Change from Baseline at Week 4	-13.3 (16.67)	-15.1 (18.17)	-18.7 (20.51)	-12.8 (20.41)

4. Secondary Outcome Measure:

Measure Title	Patient Global Impression of Change (PGIC) for Fibromyalgia Syndrome Status at Week 4
Measure Description	PGIC status for fibromyalgia syndrome at week 4. The PGIC consists of a self-evaluation by the patient of the overall change of their fibromyalgia syndrome since the beginning of the study, rated on a 7-point scale (score of 1-3 = very much improved to minimally improved; 4= no change; 5-7 = minimally worse to very much worse). Results are presented for the percentage of patients reporting each status: “improved”= score of 1-3; “no change”=score of 4; and “worse”=score of 5-7.
Time Frame	Week 4
Safety Issue?	No

Analysis Population Description

Modified Intent-To-Treat (m-ITT). The m-ITT population included all randomized patients who started study (randomized) and who received the study medication with at least one post-treatment mean daily-average-pain score.

Reporting Groups

	Description
Placebo	Part A: Placebo every 12 hours for 4 weeks
AGN 203818 3 mg	Part A: 3 mg AGN 203818 every 12 hours for 4 weeks

	Description
AGN 203818 20 mg	Part A: 20 mg AGN 203818 every 12 hours for 4 weeks
AGN 203818 60 mg	Part A: 60 mg AGN 203818 every 12 hours for 4 weeks

Measured Values

	Placebo	AGN 203818 3 mg	AGN 203818 20 mg	AGN 203818 60 mg
Number of Participants Analyzed	50	51	50	50
Patient Global Impression of Change (PGIC) for Fibromyalgia Syndrome Status at Week 4 [units: Percentage of Patients]				
Improved	69.8	67.4	69.1	69.1
No Change	18.6	21.7	23.8	19.0
Worse	11.6	10.9	7.1	11.9

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	The safety population was used to calculate the number of participants at risk for SAEs and AEs and is the total number of patients that were randomized AND treated.

Reporting Groups

	Description
Placebo	Part A: Placebo every 12 hours for 4 weeks
AGN 203818 3 mg	Part A: 3 mg AGN 203818 every 12 hours for 4 weeks
AGN 203818 20 mg	Part A: 20 mg AGN 203818 every 12 hours for 4 weeks
AGN 203818 60 mg	Part A: 60 mg AGN 203818 every 12 hours for 4 weeks

Serious Adverse Events

	Placebo	AGN 203818 3 mg	AGN 203818 20 mg	AGN 203818 60 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/52 (0%)	0/53 (0%)	1/52 (1.92%)	2/52 (3.85%)
Gastrointestinal disorders				
Gastric ulcer [A] †	0/52 (0%)	0/53 (0%)	0/52 (0%)	1/52 (1.92%)
Gastrointestinal haemorrhage [A] †	0/52 (0%)	0/53 (0%)	1/52 (1.92%)	0/52 (0%)
Pancreatitis [A] †	0/52 (0%)	0/53 (0%)	0/52 (0%)	1/52 (1.92%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (10.0)

Other Adverse Events

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

	Placebo	AGN 203818 3 mg	AGN 203818 20 mg	AGN 203818 60 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	36/52 (69.23%)	37/53 (69.81%)	34/52 (65.38%)	38/52 (73.08%)
Gastrointestinal disorders				
Diarrhoea [A] *	5/52 (9.62%)	4/53 (7.55%)	0/52 (0%)	5/52 (9.62%)
Dry Mouth [A] *	0/52 (0%)	1/53 (1.89%)	1/52 (1.92%)	8/52 (15.38%)
Dyspepsia [A] *	1/52 (1.92%)	3/53 (5.66%)	1/52 (1.92%)	0/52 (0%)
Nausea [A] *	5/52 (9.62%)	8/53 (15.09%)	7/52 (13.46%)	5/52 (9.62%)
General disorders				
Fatigue [A] *	3/52 (5.77%)	4/53 (7.55%)	5/52 (9.62%)	4/52 (7.69%)
Oedema peripheral [A] *	1/52 (1.92%)	2/53 (3.77%)	0/52 (0%)	3/52 (5.77%)
Infections and infestations				
Nasopharyngitis [A] †	3/52 (5.77%)	5/53 (9.43%)	2/52 (3.85%)	1/52 (1.92%)
Upper respiratory tract infection [A] †	5/52 (9.62%)	5/53 (9.43%)	1/52 (1.92%)	4/52 (7.69%)
Urinary tract infection [A] †	3/52 (5.77%)	1/53 (1.89%)	0/52 (0%)	1/52 (1.92%)

	Placebo	AGN 203818 3 mg	AGN 203818 20 mg	AGN 203818 60 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Musculoskeletal and connective tissue disorders				
Muscle spasms [A] *	1/52 (1.92%)	0/53 (0%)	0/52 (0%)	3/52 (5.77%)
Musculoskeletal stiffness [A] *	1/52 (1.92%)	0/53 (0%)	3/52 (5.77%)	0/52 (0%)
Nervous system disorders				
Dizziness [A] *	3/52 (5.77%)	5/53 (9.43%)	7/52 (13.46%)	9/52 (17.31%)
Headache [A] *	7/52 (13.46%)	13/53 (24.53%)	9/52 (17.31%)	13/52 (25%)
Migraine [A] †	3/52 (5.77%)	3/53 (5.66%)	0/52 (0%)	0/52 (0%)
Somnolence [A] *	1/52 (1.92%)	4/53 (7.55%)	4/52 (7.69%)	6/52 (11.54%)

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (10.0)

Limitations and Caveats

This study was terminated early due to company decision. Only Part A results are presented; Part B was never conducted.

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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