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ID: AFX01_202 Safety and Efficacy of Peginesatide Injection for the Maintenance of Anemia in Chronic Renal Failure Participants Who Are on Hemodialysis or Do Not Require Dialysis and Previously Treated With Darbepoetin Alfa. NCT00752609

Results Preview

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Participant Flow

Recruitment Details	Participants enrolled at 18 investigative sites in the United Kingdom, Italy, Australia, and the United States from 22 September 2008 to 24 December 2009.
Pre-Assignment Details	Participants with a diagnosis of chronic renal failure (on hemodialysis or not on dialysis) and receiving stable Darbepoetin alfa maintenance therapy were enrolled into one treatment group (peginesatide injection).

Arm/Group Title	**Peginesatide - On Dialysis**	**Peginesatide - Not on Dialysis**	Total (Not public)
Arm/Group Description	Participants on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.	Participants not on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.	
Period Title: Overall Study			
Started	53	49	102
Full Analysis Set	52 [1]	49	101
Completed	44	47	91
Not Completed	9	2	11
Reason Not Completed			
Adverse Event	2	2	4
Withdrawal by Subject	3	0	3
Physician Decision	1	0	1
Death	1	0	1
Met exclusion criteria	1	0	1
Received Aranesp in error	1	0	1
(Not Public)	Not Completed = 9	Not Completed = 2	

	Total from all reasons = 9	Total from all reasons = 2

[1] One patient withdrew consent before receiving any study medication.

Baseline Characteristics

Arm/Group Title	**Peginesatide - On Dialysis**	**Peginesatide - Not on Dialysis**	**Total**
Arm/Group Description	Participants on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.	Participants not on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.	
Overall Number of Baseline Participants	52	49	**101**
Baseline Analysis Population Description	[Not specified]		
Age, Continuous [1] Mean (Standard Deviation) Units: years	66.4 (12.60)	68.6 (12.07)	67.5 (12.33)
	[1] Baseline characteristics are reported for the Full Analysis Set.		
Age, Customized Measure Type: Number Units: participants			
< 65 years	22	18	40
≥65 - <75 years	13	13	26
≥ 75	17	18	35
Gender, Male/Female Measure Type: Number Units: participants			
Female	17	33	50
Male	35	16	51

Outcome Measures

1. Primary Outcome

Title: Mean Change in Hemoglobin Between Baseline and the Evaluation Period

Description: Mean change in Hemoglobin between Baseline (the mean of the 4 most recent hemoglobin values prior to enrollment and the hemoglobin on the day of enrollment) and the Evaluation Period (mean hemoglobin from Weeks 19 to 24).

Time Frame: Baseline and Week 19 to Week 24.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

The Full Analysis Set including all patients who received at least 1 dose of study drug where data was available (indicated by N).

Arm/Group Title	**Peginesatide - On Dialysis**	**Peginesatide - Not on Dialysis**
Arm/Group Description:	Participants on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.	Participants not on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.
Number of Participants Analyzed	52	49
Mean (Standard Deviation) Units: g/dL		
Baseline [N=52, 49]	11.22 (0.514)	11.11 (0.447)
Evaluation Period [N=45, 47]	10.78 (0.845)	11.64 (0.673)
Change from Baseline [N=45, 47]	-0.42 (0.761)	0.49 (0.769)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Peginesatide - On Dialysis
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Other[Mean change from baseline]
	Estimated Value	-0.42

	Confidence Interval	(2-Sided) 95% -0.65 to -0.19
	Estimation Comments	A two-sided 95% CI of the estimated mean change from Baseline in hemoglobin was derived from the t-distribution.

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Peginesatide - Not on Dialysis
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Other[Mean change from baseline]
	Estimated Value	0.49
	Confidence Interval	(2-Sided) 95% 0.26 to 0.71
	Estimation Comments	A two-sided 95% CI of the estimated mean change from Baseline in hemoglobin was derived from the t-distribution.

2. Secondary Outcome

Title: Percentage of Participants With Hemoglobin Within the Target Range of 10.0 to 12.0 g/dL During the Evaluation Period

Description: Mean hemoglobin was calculated from measurements taken during the Evaluation Period from Week 19 to Week 24. The target hemoglobin range was between 10.0 to 12.0 g/dL.
The 95% confidence interval was calculated from the normal approximation with continuity correction.

Time Frame: Week 19 to Week 24

Safety Issue? No

Outcome Measure Data

Analysis Population Description
Full Analysis Set where data was available.

Arm/Group Title	**Peginesatide - On Dialysis**	**Peginesatide - Not on Dialysis**
Arm/Group Description:	Participants on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based	Participants not on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's

	on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.	previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.
Number of Participants Analyzed	45	47
Number (95% Confidence Interval) Units: percentage of participants	73.3 (59.3 to 87.4)	68.1 (53.7 to 82.5)

3. Secondary Outcome

Title:	Percentage of Participants With a Change in Hemoglobin From Baseline to the Evaluation Period Within 1 g/dL
Description:	Percentage of participants with a mean change in hemoglobin between Baseline (the mean of the 4 most recent hemoglobin values prior to enrollment and the hemoglobin on the day of enrollment) and the Evaluation Period (mean hemoglobin measured at Weeks 19 to 24) of less than or equal ± 1 g/dL. The 95% confidence interval was calculated from the normal approximation with continuity correction.
Time Frame:	Baseline and Week 19 to Week 24.
Safety Issue?	No

Outcome Measure Data

Analysis Population Description
Full analysis set where data was available.

Arm/Group Title	**Peginesatide - On Dialysis**	**Peginesatide - Not on Dialysis**
Arm/Group Description:	Participants on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.	Participants not on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.
Number of Participants Analyzed	45	47
Number (95% Confidence Interval) Units: percentage of participants	80.0 (67.2 to 92.8)	68.1 (53.7 to 82.5)

4. Secondary Outcome

Title: Percentage of Participants With Red Blood Cell Transfusions

Description: The percentage of participants who received one or more red blood cell transfusions, including packed red blood cells and whole blood transfusions, during the Titration Period (Weeks 0 - 18) and Evaluation Period (Weeks 19 -24). 95% Confidence Intervals were calculated from the normal approximation with continuity correction.

Time Frame: Up to 24 weeks.

Safety Issue? No

Outcome Measure Data

Analysis Population Description
Full Analysis Set.

Arm/Group Title	**Peginesatide - On Dialysis**	**Peginesatide - Not on Dialysis**
Arm/Group Description:	Participants on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.	Participants not on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.
Number of Participants Analyzed	52	49
Number (95% Confidence Interval) Units: percentage of participants		
Entire study	5.8 (0.0 to 13.1)	2.0 (0.0 to 7.0)
Titration Period	5.8 (0.0 to 13.1)	2.0 (0.0 to 7.0)
Evaluation Period	0 (0.0 to 1.1)	0 (0.0 to 1.1)

5. Secondary Outcome

Title: Mean Hemoglobin During 4-week Intervals
Description: Hemoglobin was measured every 2 weeks during the Titration Period (Weeks 0-18) and weekly during the Evaluation Period (Weeks 19-24).
Time Frame: Up to 24 weeks.
Safety Issue? No

Outcome Measure Data

Analysis Population Description
Full Analysis Set where data was available for each time interval (indicated by N).

Arm/Group Title	**Peginesatide - On Dialysis**	**Peginesatide - Not on Dialysis**
Arm/Group Description:	Participants on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.	Participants not on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.
Number of Participants Analyzed	52	49
Mean (Standard Deviation) Units: g/dL		
Week 1-4 [N=52, 49]	11.54 (0.728)	11.74 (0.863)
Week 5-8 [N=49, 49]	11.16 (0.876)	11.94 (0.917)
Week 9-12 [N=49, 47]	10.99 (0.919)	11.95 (0.837)
Week 13-16 [N=47, 46]	10.64 (0.975)	11.95 (0.815)
Week 17-20 [N=46, 47]	10.78 (0.989)	11.84 (0.747)
Week 21-24 [N=44, 47]	10.81 (0.827)	11.58 (0.687)

6. Secondary Outcome

Title:	Percentage of Participants With Target Hemoglobin of 10.0 to 12.0 g/dL by 4-week Intervals.
Description:	Percentage of participants with mean hemoglobin levels falling between the target level of 10.0 to 12.0 g/dL during 4-week study intervals. Hemoglobin was measured every 2 weeks during the Titration Period (Weeks 0-18) and weekly during the Evaluation Period (Weeks 19-24). 95% Confidence Intervals were calculated from the normal approximation with continuity correction.
Time Frame:	Up to 24 weeks.
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

Full analysis set where data was available for each time interval (indicated by N).

Arm/Group Title	**Peginesatide - On Dialysis**	**Peginesatide - Not on Dialysis**
Arm/Group Description:	Participants on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.	Participants not on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.
Number of Participants Analyzed	52	49
Number (95% Confidence Interval) Units: percentage of participants		
Week 1-4 [N=52, 49]	71.2 (57.9 to 84.4)	69.4 (55.5 to 83.3)
Week 5-8 [N= 49, 49]	81.6 (69.8 to 93.5)	51.0 (36.0 to 66.0)
Week 9-12 [N= 49, 47]	77.6 (64.8 to 90.3)	44.7 (29.4 to 60.0)
Week 13-16 [N= 47, 46]	74.5 (60.9 to 88.0)	52.2 (36.7 to 67.7)
Week 17-20 [N=46, 47]	69.6 (55.2 to 83.9)	59.6 (44.5 to 74.7)
Week 21-24 [N=44, 47]	79.5 (66.5 to 92.6)	63.8 (49.0 to 78.6)

7. Secondary Outcome

Title: Percentage of Participants With Dose Adjustments During the Study

Description: The peginesatide dose was adjusted to maintain Hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline during the Titration Period (Weeks 0-18) and Evaluation Period (Weeks 19-24). A dose was classified as adjusted if it was not within 20% of the previous dose. A dose was classified as increased or decreased if it was >20% higher or >20% lower respectively, than

the previous dose.

Time Frame: From Week 4 to Week 20

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Safety Analysis set, which included all patients who received at least 1 dose of study drug. N indicates the number of patients with study drug administered during the period after excluding the initial dose of study drug and excluding the first dose after a restart of study drug and is the denominator for percentage calculations.

Arm/Group Title	**IV Peginesatide - On Dialysis**	**SC Peginesatide - On Dialysis**	**Peginesatide - Not on Dialysis**
Arm/Group Description:	Participants on dialysis received 0.04 to 0.16 mg/kg Peginesatide intravenous (IV) injection once every 4 weeks for 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.	Participants on dialysis received 0.04 to 0.16 mg/kg Peginesatide subcutaneous (SC) injection, once every 4 weeks for 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.	Participants not on dialysis received 0.04 to 0.16 mg/kg Peginesatide subcutaneous injection, once every 4 weeks for 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.
Number of Participants Analyzed	47	5	49
Measure Type: Number Units: percentage of participants			
Any adjustment in Titration Period [N=44, 5, 49]	81.8	80.0	81.6
Any adjustment in Evaluation Period [N=38, 5, 44]	31.6	60.0	43.2
Any adjustment during entire study [N=44, 5, 49]	90.9	80.0	87.8
Dose increased in Titration Period [N=44, 5, 49]	56.8	40.0	10.2
Dose increased in Evaluation Period [N=38, 5, 44]	21.1	40.0	2.3
Dose increased during entire study [N=44, 5,	65.9	60.0	12.2

49]			
Dose decreased in Titration Period [N=44, 5, 49]	50.0	60.0	73.5
Dose decreased in Evaluation Period [N=38, 5, 44]	13.2	20.0	40.9
Dose decreased during entire study [N=44, 5, 49]	59.1	60.0	79.6

Adverse Events

Time Frame	Treatment-emergent adverse events are adverse events that occurred on or after the day of the first dose of peginesatide injection through the Follow-up phone call, which occurred within 28 days after the last dose.
Additional Description	At each visit the investigator had to document any occurrence of adverse events and abnormal laboratory findings. Any event spontaneously reported by the participant or observed by the investigator was recorded, irrespective of the relation to study treatment.
Source Vocabulary Name	MedDRA v. 12.1
Assessment Type	Systematic Assessment

Arm/Group Title	Peginesatide - On Dialysis	Peginesatide - Not on Dialysis
Arm/Group Description	Participants on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.	Participants not on dialysis received peginesatide 0.04 to 0.16 mg/kg, subcutaneous or intravenous injection, once every 4 weeks for up to 24 weeks. Initial dose based on patient's previous total weekly darbepoetin alfa dose, and thereafter could be adjusted to maintain hemoglobin values in the target range of 10 to 12 g/dL and ±1.5 g/dL from Baseline.

Serious Adverse Events

	Peginesatide - On Dialysis Affected / at Risk (%)	**Peginesatide - Not on Dialysis** Affected / at Risk (%)
Total	16/52 (30.77%)	6/49 (12.24%)
Cardiac disorders		
Atrial fibrillation † A	1/52 (1.92%)	0/49 (0%)
Cardiac failure congestive † A	1/52 (1.92%)	2/49 (4.08%)
Ischaemic cardiomyopathy † A	1/52 (1.92%)	0/49 (0%)
Mitral valve incompetence † A	1/52 (1.92%)	0/49 (0%)
Gastrointestinal disorders		

Diarrhoea † A	1/52 (1.92%)	0/49 (0%)
Gastritis † A	1/52 (1.92%)	0/49 (0%)
General disorders		
Chest pain † A	2/52 (3.85%)	0/49 (0%)
Hepatobiliary disorders		
Cholecystitis acute † A	1/52 (1.92%)	0/49 (0%)
Cholelithiasis † A	1/52 (1.92%)	0/49 (0%)
Infections and infestations		
Dermo-hypodermitis † A	1/52 (1.92%)	0/49 (0%)
Infective exacerbation of chronic obstructive airways disease † A	1/52 (1.92%)	0/49 (0%)
Pneumonia † A	1/52 (1.92%)	0/49 (0%)
Injury, poisoning and procedural complications		
Ankle fracture † A	1/52 (1.92%)	0/49 (0%)
Arteriovenous fistula site complication † A	1/52 (1.92%)	0/49 (0%)
Arteriovenous fistula thrombosis † A	2/52 (3.85%)	0/49 (0%)
Arteriovenous graft thrombosis † A	1/52 (1.92%)	0/49 (0%)
Fall † A	1/52 (1.92%)	0/49 (0%)
Humerus fracture † A	1/52 (1.92%)	0/49 (0%)
Joint dislocation † A	1/52 (1.92%)	0/49 (0%)
Metabolism and nutrition disorders		
Fluid overload † A	1/52 (1.92%)	0/49 (0%)
Hyperkalaemia † A	2/52 (3.85%)	0/49 (0%)
Metabolic acidosis † A	1/52 (1.92%)	0/49 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Lung cancer metastatic [1] † A	1/52 (1.92%)	0/49 (0%)
Nervous system disorders		
Cerebrovascular accident † A	0/52 (0%)	1/49 (2.04%)
Convulsion † A	1/52 (1.92%)	0/49 (0%)
Diabetic neuropathy † A	0/52 (0%)	1/49 (2.04%)
Encephalopathy † A	0/52 (0%)	1/49 (2.04%)
Ischaemic cerebral infarction [1] † A	1/52 (1.92%)	0/49 (0%)
Renal and urinary disorders		
Renal failure acute † A	0/52 (0%)	1/49 (2.04%)
Respiratory, thoracic and mediastinal disorders		
Dyspnoea † A	0/52 (0%)	1/49 (2.04%)
Pleural effusion † A	1/52 (1.92%)	0/49 (0%)
Surgical and medical procedures		
Aortic valve replacement † A	1/52 (1.92%)	0/49 (0%)
Vascular disorders		
Peripheral vascular disorder † A	1/52 (1.92%)	0/49 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA v. 12.1

[1] This treatment-emergent death occured during titration period and is not related.

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events: 5%

	Peginesatide - On Dialysis Affected / at Risk (%)	Peginesatide - Not on Dialysis Affected / at Risk (%)
Total	31/52 (59.62%)	28/49 (57.14%)
Blood and lymphatic system disorders		
Anaemia † A	3/52 (5.77%)	0/49 (0%)
Gastrointestinal disorders		
Consitpation † A	4/52 (7.69%)	2/49 (4.08%)
Diarrhoea † A	8/52 (15.38%)	6/49 (12.24%)
Nausea † A	6/52 (11.54%)	3/49 (6.12%)
Vomiting † A	6/52 (11.54%)	0/49 (0%)
General disorders		
Astenia † A	1/52 (1.92%)	3/49 (6.12%)
Chest Discomfort † A	3/52 (5.77%)	0/49 (0%)
Injection Site Extravasation † A	3/52 (5.77%)	0/49 (0%)
Oedema Peripheral † A	2/52 (3.85%)	6/49 (12.24%)
Infections and infestations		
Sinusitis † A	0/52 (0%)	3/49 (6.12%)
Upper Respiratory Tract Infection † A	3/52 (5.77%)	6/49 (12.24%)
Injury, poisoning and procedural complications		
Thrombosis in Device † A	4/52 (7.69%)	0/49 (0%)
Vascular Graft Complication † A	3/52 (5.77%)	0/49 (0%)
Metabolism and nutrition disorders		
Decreased Appetite † A	7/52 (13.46%)	2/49 (4.08%)
Musculoskeletal and connective tissue disorders		
Arthralgia † A	3/52 (5.77%)	1/49 (2.04%)
Pain in Extremity † A	1/52 (1.92%)	4/49 (8.16%)
Nervous system disorders		
Dizziness † A	2/52 (3.85%)	5/49 (10.2%)
Headache † A	4/52 (7.69%)	2/49 (4.08%)
Psychiatric disorders		
Insomnia † A	2/52 (3.85%)	3/49 (6.12%)
Respiratory, thoracic and mediastinal disorders		
Cough † A	4/52 (7.69%)	4/49 (8.16%)
Dyspnoea † A	3/52 (5.77%)	1/49 (2.04%)
Vascular disorders		
Hypertension † A	4/52 (7.69%)	3/49 (6.12%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA v. 12.1

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.

The first study related publication will be a multi-center publication submitted within 24 months after conclusion or termination of a study at all sites. After such multi site publication, all proposed site publications and presentations will be submitted to sponsor for review 60 days in advance of publication. Site will remove Sponsor confidential information unrelated to study results. Sponsor can delay a proposed publication for another 60 days to preserve intellectual property.

Results Point of Contact

Name/Official Title:	Sr. VP, Clinical Science
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