ID: AFX01_201 Efficacy and Safety of Peginesatide Injection for the Maintenance Treatment of Anemia in Peritoneal Dialysis Participants Previously Treated With Epoetin. NCT00752791

Results Preview

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Participant Flow

Recruitment Details: Participants enrolled at 26 sites in Australia, Italy, New Zealand, the United Kingdom and the United States from 31 October 2008 to 19 May 2010.

Pre-Assignment Details: Participants with chronic renal failure on peritoneal dialysis and receiving stable Epoetin (alfa or beta) maintenance therapy were enrolled into 1 treatment group (peginesatide injection).

Arm/Group Title	**Peginesatide**	Total (Not public)
Arm/Group Description	Peginesatide 0.04 to 0.16 mg/kg, subcutaneous injection, once every 4 weeks for up to 25 weeks. Initial dose based on patient's previous total weekly Epoetin 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	59		59
Completed	43		43
Not Completed	16		16
Reason Not Completed			
Adverse Event	7		7
Withdrawal by Subject	1		1
Physician Decision	1		1
Death	1		1
Renal transplant	3		3
Switched to hemodialysis	2		2
Protocol deviation	1		1
(Not Public)	Not Completed = 16 Total from all reasons = 16		

Baseline Characteristics

Arm/Group Title	**Peginesatide**
Arm/Group Description	Peginesatide 0.04 to 0.16 mg/kg, subcutaneous injection, once every 4 weeks for up to 25

		weeks. Initial dose based on patient's previous total weekly Epoetin 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		59
Baseline Analysis Population Description		[Not specified]
Age, Continuous		
Mean (Standard Deviation)		
Units: years		54.0 (15.99)
Age, Customized		
Measure Type: Number		
Units: participants		
	<65 years	42
	≥65 to <75 years	10
	≥75 years	7
Gender, Male/Female		
Measure Type: Number		
Units: participants		
	Female	32
	Male	27

Outcome Measures

1. Primary Outcome

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

Description: The primary efficacy endpoint was the 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 20 to 25).

Time Frame: Baseline and Week 20 to Week 25.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

The Full Analysis Set included all patients who received at least 1 dose of peginesatide injection and where data was available at both time points (indicated by N).

Arm/Group Title	**Peginesatide**
Arm/Group Description:	Peginesatide 0.04 to 0.16 mg/kg, subcutaneous injection, once every 4 weeks for up to 25 weeks. Initial dose based on patient's previous total weekly Epoetin 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	59
Mean (Standard Deviation)	
Units: g/dL	

Baseline [N=59]	11.22 (0.495)
Evaluation Period [N=46]	11.33 (1.066)
Change from Baseline [N=46]	0.10 (1.154)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Peginesatide
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Other[Mean change from Baseline]
	Estimated Value	0.10
	Confidence Interval	(2-Sided) 95% -0.24 to 0.44
	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 (Week 20 to Week 25). The target hemoglobin range was 10.0 to 12.0 g/dL.
The 95% confidence interval was calculated from the normal approximation with continuity correction.

Time Frame: Week 20 to Week 25.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set where data was available.

Arm/Group Title	**Peginesatide**
Arm/Group Description:	Peginesatide 0.04 to 0.16 mg/kg, subcutaneous injection, once every 4 weeks for up to 25 weeks. Initial dose based on patient's previous total weekly Epoetin 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	46
Number (95% Confidence Interval) Units: percentage of participants	63.0 (48.0 to 78.1)

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 from measured at Weeks 20 to 25) 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 20 to Week 25.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set where data was available.

Arm/Group Title	**Peginesatide**
Arm/Group Description:	Peginesatide 0.04 to 0.16 mg/kg, subcutaneous injection, once every 4 weeks for up to 25 weeks. Initial dose based on patient's previous total weekly Epoetin 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	46
Number (95% Confidence Interval) Units: percentage of participants	60.9 (45.7 to 76.1)

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 1 - 19) and Evaluation Period (Weeks 20 -25). 95% Confidence Intervals were calculated from the normal approximation with continuity correction. One patient had the last study visit during the titration period and the transfusion after the titration period. This patient is excluded from the summary of evaluation period.

Time Frame: Up to 25 weeks.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full Analysis Set.

Arm/Group Title	**Peginesatide**

Arm/Group Description:	Peginesatide 0.04 to 0.16 mg/kg, subcutaneous injection, once every 4 weeks for up to 25 weeks. Initial dose based on patient's previous total weekly Epoetin 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	59
Number (95% Confidence Interval) Units: percentage of participants	
Entire study (n=59)	10.2 (1.6 to 18.7)
Titration Period (n=59)	5.1 (0.0 to 11.5)
Evaluation period (n=47)	4.3 (0.0 to 11.1)

5. Secondary Outcome

Title:	Mean Hemoglobin During 4-week Intervals
Description:	Hemoglobin was measured every 2 weeks during the Titration Period (Weeks 1-19) and weekly during the Evaluation Period (Weeks 20-25). One patient did not have central lab hemoglobin value during a regularly scheduled visit during weeks 2-5.
Time Frame:	Up to 25 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**
Arm/Group Description:	Peginesatide 0.04 to 0.16 mg/kg, subcutaneous injection, once every 4 weeks for up to 25 weeks. Initial dose based on patient's previous total weekly Epoetin 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	59
Mean (Standard Deviation) Units: g/dL	
Week 2-5 [N=58]	11.57 (0.741)
Week 6-9 [N=56]	11.65 (1.044)
Week 10-13 [N=54]	11.53 (1.119)
Week 14-17 [N=52]	11.33 (1.037)
Week 18-21 [N=45]	11.46 (1.004)
Week 22-25 [N=46]	11.25 (1.122)

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 1-19) and weekly during the Evaluation Period (Weeks 20-25). 95% Confidence Intervals were calculated from the normal approximation with continuity correction.

Time Frame: Up to 25 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**
Arm/Group Description:	Peginesatide 0.04 to 0.16 mg/kg, subcutaneous injection, once every 4 weeks for up to 25 weeks. Initial dose based on patient's previous total weekly Epoetin 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	59
Number (95% Confidence Interval) Units: percentage of participants	
Week 2-5 [N=58]	67.2 (54.3 to 80.2)
Week 6-9 [N=56]	53.6 (39.6 to 67.5)
Week 10-13 [N=54]	59.3 (45.2 to 73.3)
Week 14-17 [N=52]	61.5 (47.4 to 75.7)
Week 18-21 [N=45]	64.4 (49.3 to 79.5)
Week 22-25 [N=46]	63.0 (48.0 to 78.1)

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 1-19) and Evaluation Period (Weeks 20-25). 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 25

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Safety Analysis Set. 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	**Peginesatide**
Arm/Group Description:	Peginesatide 0.04 to 0.16 mg/kg, subcutaneous injection, once every 4 weeks for up to 25 weeks. Initial dose based on patient's previous total weekly Epoetin 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	59
Measure Type: Number Units: percentage of participants	
Any adjustment in Titration Period [N=57]	80.7
Any adjustment in Evaluation Period [N=42]	52.4
Dose increased in Titration Period [N=57]	28.1
Dose increased in Evaluation Period [N=42]	16.7
Dose decreased in Titration Period [N=57]	66.7
Dose decreased in Evaluation Period [N=42]	35.7

Adverse Events

Treatment-emergent adverse events are adverse

Time Frame	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. 13.0
Assessment Type	Systematic Assessment

Arm/Group Title	Peginesatide
Arm/Group Description	Peginesatide 0.04 to 0.16 mg/kg, subcutaneous injection, once every 4 weeks for up to 25 weeks. Initial dose based on patient's previous total weekly Epoetin 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 Affected / at Risk (%)
Total	27/59 (45.76%)
Blood and lymphatic system disorders	
Leukocytosis † A	1/59 (1.69%)
Cardiac disorders	
Angina pectoris † A	1/59 (1.69%)
Atrial fibrillation † A	1/59 (1.69%)
Cardiac failure congestive † A	1/59 (1.69%)
Myocardial ischaemia [1] † A	1/59 (1.69%)
Ventricular fibrillation † A	1/59 (1.69%)
Gastrointestinal disorders	
Colonic polyp † A	1/59 (1.69%)
Diverticular perforation † A	1/59 (1.69%)
Gastrointestinal haemorrhage † A	1/59 (1.69%)
Peritoneal haemorrhage † A	1/59 (1.69%)
Peritonitis [2] † A	9/59 (15.25%)
General disorders	
Medical device complication † A	1/59 (1.69%)
Hepatobiliary disorders	
Cholecystitis † A	1/59 (1.69%)
Infections and infestations	
Abdominal abscess † A	1/59 (1.69%)
Catheter site infection † A	1/59 (1.69%)
Diabetic foot infection † A	1/59 (1.69%)
Fungal peritonitis † A	1/59 (1.69%)
Sepsis [3] † A	1/59 (1.69%)
† A	

Septic shock	1/59 (1.69%)
Injury, poisoning and procedural complications	
Avulsion fracture † A	1/59 (1.69%)
Fall † A	1/59 (1.69%)
Joint dislocation † A	1/59 (1.69%)
Tibia fracture † A	1/59 (1.69%)
Metabolism and nutrition disorders	
Cachexia † A	1/59 (1.69%)
Fluid overload † A	1/59 (1.69%)
Hypokalaemia † A	1/59 (1.69%)
Nervous system disorders	
Cerebrovascular accident † A	1/59 (1.69%)
Myasthenia gravis [4] † A	1/59 (1.69%)
Respiratory, thoracic and mediastinal disorders	
Dyspnoea † A	2/59 (3.39%)
Nasal polyps † A	1/59 (1.69%)
Pulmonary Oedema † A	1/59 (1.69%)
Respiratory failure † A	2/59 (3.39%)
Sleep apnoea syndrome † A	1/59 (1.69%)
Skin and subcutaneous tissue disorders	
Pseudoporphyria † A	1/59 (1.69%)
Vascular disorders	
Hypertensive crisis † A	1/59 (1.69%)
Peripheral vascular disorder † A	1/59 (1.69%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA v. 13.0

[1] This treatment emergent death occurred during titration period and is considered related.
[2] This treatment-emergent death occured during titration period and is not related.
[3] This treatment-emergent death occured during evaluation period period and is not related.
[4] This treatment-emergent death was reported 74 days after last dose of study drug and is considered related to study drug.

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%

	Peginesatide Affected / at Risk (%)
Total	41/59 (69.49%)
Gastrointestinal disorders	
Constipation † A	5/59 (8.47%)
Diarrhoea † A	9/59 (15.25%)
Nausea † A	5/59 (8.47%)
Peritonitis † A	6/59 (10.17%)
Vomiting † A	5/59 (8.47%)
General disorders	
Oedema Peripheral † A	5/59 (8.47%)
Infections and infestations	
† A	4/59 (6.78%)

Catheter Site Infection	
Cellulitis † A	3/59 (5.08%)
Nasopharygitis † A	4/59 (6.78%)
Sinusitis † A	4/59 (6.78%)
Urinary Tract Infection † A	5/59 (8.47%)
Injury, poisoning and procedural complications	
Excoriation † A	3/59 (5.08%)
Metabolism and nutrition disorders	
Hypercalcaemia † A	3/59 (5.08%)
Hypokalaemia † A	4/59 (6.78%)
Musculoskeletal and connective tissue disorders	
Arthralgia † A	3/59 (5.08%)
Nervous system disorders	
Dizziness † A	3/59 (5.08%)
Respiratory, thoracic and mediastinal disorders	
Cough † A	6/59 (10.17%)
Dyspnoea † A	6/59 (10.17%)
Skin and subcutaneous tissue disorders	
Rash † A	4/59 (6.78%)
Vascular disorders	
Hypertension † A	8/59 (13.56%)
Hypotension † A	6/59 (10.17%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA v. 13.0

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.

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

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