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Trial record **5 of 13** for: peginesatide | affymax [Lead]
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Extension Study to Evaluate Safety and Tolerability of Peginesatide for Long-Term Treatment of Anemia in Participants With CKD (EU)

This study has been terminated.

(Due to more robust long-term data generated in other active-controlled studies)

Sponsor:
Affymax

Information provided by (Responsible Party):
Affymax

ClinicalTrials.gov Identifier:
NCT00453973

First received: March 27, 2007
Last updated: June 22, 2012
Last verified: June 2012
History of Changes

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Results First Received: April 26, 2012

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Chronic Renal Failure Chronic Kidney Disease Anemia
Intervention:	Drug: **peginesatide**

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
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description

Maintenance Switch in Dialysis Participants	Participants were from a prior Affymax peginesatide treatment study conducted in participants who were on dialysis and had been on Epoetin at study entry, and who were switched to peginesatide (NCT00434330). The median first dose at study start was 0.044 milligram per kilogram (mg/kg) with an interquartile range of 0.028 to 0.076 mg/kg. This group is categorized as "Maintenance Switch in Dialysis Participants" regardless of dialysis status at the start of or during this study.
Treatment Initiation in Non-Dialysis Participants	Participants were from a prior Affymax peginesatide treatment study conducted in participants who were not on dialysis and not on erythropoiesis stimulating agents (ESAs), and who received peginesatide (NCT00228436). The median first dose at study start was 0.024 mg/kg with an interquartile range of 0.017 to 0.035 mg/kg. This group is categorized as "Initiation of Treatment in Non-Dialysis Participants" regardless of dialysis status at the start of or during this study.

Participant Flow: Overall Study

	Maintenance Switch in Dialysis Participants	Treatment Initiation in Non-Dialysis Participants
STARTED	**51**	**63**
COMPLETED	**0**	**15**
NOT COMPLETED	**51**	**48**
Adverse Event	**4**	**9**
Withdrawal by Subject	**7**	**6**
PI Decision	**0**	**2**
Relocation	**1**	**0**
Renal transplant	**1**	**1**
Site closed by sponsor	**3**	**0**
Sponsor Decision to Terminate Study	**35**	**30**

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
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	as "Initiation of Treatment in Non-Dialysis Participants" regardless of dialysis status at the start of or during this study.
Pooled AF37702 Inj.	No text entered.

Baseline Measures

	Maintenance Switch in Dialysis Participants	Treatment Initiation in Non-Dialysis Participants	Pooled AF37702 Inj.
Number of Participants [units: participants]	**51**	**63**	**114**
Age [units: participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**42**	**22**	**64**
>=65 years	**9**	**41**	**50**
Age [units: years] Mean (Standard Deviation)	**53.2 (11.92)**	**66.4 (13.48)**	**60.5 (14.36)**
Gender [units: participants]			
Female	**19**	**34**	**53**
Male	**32**	**29**	**61**

Outcome Measures

1. Primary: Proportion of Participants With Mean Hemoglobin in the Target Range of 10.0-12.0 Grams Per Deciliter (g/dL) After Final Dosing Guideline Change [Time Frame: Up to 54 months]

Show Outcome Measure 1

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

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
Early termination of study due to generation of controlled long-term data in Phase 3 studies. Amended dosing guidelines during the trial to reflect label changes for ESAs; the primary outcome was assessed after the dosing guideline change.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** 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.
The agreement is: ☐ The only 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 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only 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 **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. **Restriction Description:** Publications may not contain Sponsor confidential information, and will be subject to Sponsor review prior to submission for publication.

Results Point of Contact:

Name/Title: Vice President, Clinical Development
Organization: Affymax
phone: 650-812-8700
e-mail: info@affymax.com

Responsible Party:	Affymax
ClinicalTrials.gov Identifier:	NCT00453973 History of Changes
Other Study ID Numbers:	AFX01-10 2006-003846-41 (EudraCT Number)
Study First Received:	March 27, 2007
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Last Updated:	June 22, 2012
Health Authority:	United Kingdom: Medicines and Healthcare Products Regulatory Agency United Kingdom: Research Ethics Committee Bulgaria: Bulgarian Drug Agency Bulgaria: Ethics committee Romania: National Medicines Agency Romania: Ethics Committee Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Poland: The Central Register of Clinical Trials Poland: Ethics Committee

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