PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

An Open-Label Study to Investigate the Efficacy and Safety of Peginesatide in the Treatment of Anemia Caused by Antibody-Mediated Pure Red Cell Aplasia in Patients With Chronic Kidney Disease

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The purpose of this study is to evaluate the ability of peginesatide to increase and maintain increased hemoglobin levels in participants with chronic kidney disease (CKD) (either not on dialysis, receiving regular hemodialysis or peritoneal dialysis, or following renal transplant) with confirmed antibody-mediated pure red cell aplasia (PRCA).

Brief Summary in Scientific Language

This is an open-label treatment study; all participants enrolled into the study will receive peginesatide. Participants with CKD with documented antibody-mediated PRCA, a hemoglobin level < 10 grams per deciliter (g/dL) (without an erythropoiesis stimulating agent [ESA]), and who meet the eligibility criteria will be enrolled. It is anticipated that up to 40 patients will be enrolled in the trial.

The first group of 5 participants will receive a starting dose of 0.05 milligram per kilogram (mg/kg), administered every 4 weeks (for this study, 1 month is defined as 4 weeks). Based on the assessment of the dose response in this initial group of 5 participants, the starting dose in subsequent participants may be increased. The dose and frequency of peginesatide will be modified based on hemoglobin response in order to achieve

and maintain hemoglobin in the target range of 10.0-12.0 g/dL.

Organizational Data

- DRKS-ID: **DRKS00006505**
- Date of Registration in DRKS: **2015/01/09**
- Date of Registration in Partner Registry or other Primary Registry: **2006/04/13**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2005-004944-30**
- Primary Registry-ID: **NCT00314795 (ClinicalTrials.gov)**
- Sponsor-ID: **AFX01-06 (Takeda)**
- Other Secondary-ID: **2005-004944-30**

Health condition or Problem studied

- Free text: **Anemia**
- Free text: **Chronic Kidney Disease**
- Free text: **Chronic Renal Failure**
- Free text: **Pure Red Cell Aplasia**
- ICD10: **D60 - Acquired pure red cell aplasia [erythroblastopenia]**

Interventions/Observational Groups

- Arm 1: **Drug: peginesatide**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Single arm study**

Blinding: **[---]***

- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Proportion of participants who increase and maintain hemoglobin levels (two consecutive values) greater than or equal to the lower limit of the target range in the absence of red blood cell transfusion in the previous 28 days by Week 24.; time frame: 24 weeks

Secondary Outcome

- Number of red blood cell transfusions during the 26 week pre-treatment period (prior to enrollment) and during 13- and 26 week intervals during the study.; time frame: 26 weeks prior to enrollment to end of study
- Time to initial achievement of hemoglobin greater than or equal to the lower limit of the target range in the absence of red blood cell transfusions in the previous 28 days.; time frame: While On Study
- Proportion of participants with red blood cell transfusions during the 26 week pre-treatment period (prior to enrollment) and during 13- and 26 week intervals during the study.; time frame: 26 weeks prior to enrollment to end of study

Countries of recruitment

- FR **France**
- DE **Germany**
- UK **United Kingdom**

Locations of Recruitment

- **Research Facility, Erlangen**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2006/04/30**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Participants who have confirmed antibody-mediated PRCA are potentially eligible for enrollment into this study.

- Participants must be ≥ 18 years old at the time of consent.

- ESAs must be discontinued for a minimum of 1 month prior to screening.

- Participant requires periodic transfusions to maintain hemoglobin.

- Hemoglobin < 10 g/dL for at least 2 measurements or participant has received a transfusion within the past 4 weeks to achieve a hemoglobin > 10 g/dL.

- Confirmation that an anti-erythropoietin antibody sample was obtained for analysis by the central reference laboratory within 1 month prior to baseline.

- Participants can either be participants with chronic kidney disease not yet requiring renal replacement therapy (participants not on dialysis), those on regular hemodialysis or peritoneal dialysis, or following a renal transplant.

- Participants may or may not have previously been treated with immunosuppressive therapy.

- Pre-menopausal females (with the exception of those who are surgically sterile) must have a negative pregnancy test at screening;

- Written informed consent must be obtained.

Exclusion criteria

- Participants already successfully on another erythropoietic agent.

- Abnormal bone marrow findings consistent with the diagnosis of myelodysplasia, a myeloproliferative disorder, hematologic malignancy or evidence of metastatic infiltration.

- Poorly controlled hypertension.

- Previous exposure to any investigational agent within 4 weeks prior to administration of study drug or planned receipt during the study period.

- High likelihood of early withdrawal or interruption of the study.

- Participants who refuse to give informed consent.

- Women who are pregnant, lactating or not using a medically approved birth control.

- Life expectancy < 12 months.

Addresses

■ **Primary Sponsor**

Takeda

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

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Medical Director

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■ **Contact for Public Queries**

Takeda
Medical Director

Contact for Public Queries

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Medical Director

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URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Trial results **Macdougall IC, Rossert J, Casadevall N, Stead RB, Duliege AM, Froissart M, Eckardt KU. A peptide-based erythropoietin-receptor agonist for pure red-cell aplasia. N Engl J Med. 2009 Nov 5;361(19):1848-55.; 19890127**

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 1
- Last processed date by ClinicalTrials.gov: 2014/07/16

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*