SANDOZ A Novartis Division

Clinical Trial Results Website

Sponsor

Hexal AG

Generic Drug Name

HX575 recombinant human erythropoietin alfa

Trial Indication(s)

Anemia associated with chronic kidney disease

Protocol Number

HX575-304

Protocol Title

An open label, single-arm, baseline-controlled, multicenter study to evaluate the efficacy, safety and immunogenicity of subcutaneous HX575 administered once a week (qw) and once every two weeks (q2w) in the treatment of anemia associated with chronic kidney disease in pre-dialysis and dialysis subjects

Clinical Trial Phases

Phase III

Study Start/End Dates

28 Apr 2009 to 04 Aug 2009

Reason for Termination (If applicable)

The study was terminated after 8 patients were enrolled and none treated yet, due to Hexal's decision not to pursue the subcutaneous development of HX575 in the treatment of anemia associated with chronic kidney disease until results of investigations of recent events in another Hexal study applying HX575 by the subcutaneous route to patients with chronic kidney disease (study 2007-22-INJ-17).

Study Design/Methodology

This study was an open label, single-arm, baseline-controlled, multicenter study, aiming to enroll 500 patients stable under s.c. ESA treatment for their anemia associated with CKD.

Centers

19 centers in 5 countries: Bulgaria (4), France (2), Germany (6), Romania (5), Spain (2)

Objectives:

Primary Objective:

- To demonstrate that HX575 administered s.c. qw and q2w maintains the correction of anemia associated with CKD.

Test Product (s), Dose(s), and Mode(s) of Administration

Not Applicable as no patient received treatment with study medication.

Statistical Methods

The primary endpoint was planned to be the mean absolute intra-individual change in the Hb levels from the start of the respective study period (screening/baseline or evaluation period of study part I, respectively) to the end of the study period (evaluation period of study part I or study part II, respectively). A two-sided 95% confidence interval for the mean absolute intra-individual change was to be computed. The Hb levels were to considered equivalent for the start and the end of the respective study period if the 95% confidence interval of the mean absolute intra-individual change lies entirely within the interval [-0.5 g/dL; 0.5 g/dL]. Descriptive statistical methods were planned to be applied for secondary efficacy and safety parameters.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion criteria

- Male and female CKD patients with or without dialysis treatment.
- Age > 18 years.
- Patients under documented stable maintenance therapy with ESA, s.c. at least once per week and in accordance with the relevant SmPC, for at least 3 months with a total weekly dose of ≤ 300 IU/kg/week.
- Patients with controlled symptomatic anemia, defined as mean Hb level between 10.0 g/dL and 12.0 g/dL, based on four Hb measurements during the four-week baseline period.
- Adequate iron status, serum ferritin ≥ 100 µg/L or transferrin saturation ≥ 20%.
- Confirmed negative anti-EPO antibody assay.

Exclusion criteria

- History of PRCA or aplastic anemia.
- History of anti-EPO antibodies.
- Uncontrolled hypertension.
- Previous or concomitant use of systemic cyclosporine.

Participant Flow Table

Subject disposition

Description	Number of patients
Enrolled	8
Treated	0
Withdrawn (due to termination of study)	8

Baseline Characteristics

Demographic data

Parameter	Number of patients
Sex	
Male	4
Female	4

Summary of Efficacy

Primary Outcome Result:

Not applicable, no patient received treatment with study medication.

Summary of Safety

Safety Results

Not applicable, no patient received treatment with study medication.

Serious Adverse Events and Deaths

Not applicable, no patient received treatment with study medication.

Other Relevant Findings

Not Applicable

Date of Clinical Trial Report

19 Oct 2009