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Pegmolesatide for the Treatment of Anemia in Non-dialysis-dependent Chronic Kidney Disease Patients: Post-hoc Analysis of a Phase 3 Trial

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Introduction

Pegmolesatide, a novel long-acting pegylated erythropoietin mimetic peptide (EMP), is approved in China for treating anemia in both dialysis-dependent (DD) and non-dialysis-dependent (NDD) chronic kidney disease (CKD) patients. A randomized, multicenter, open-label, active-controlled, non-inferiority phase 3 study (Figure 1) demonstrated comparable efficacy and safety of pegmolesatide to epoetin alfa in managing renal anemia in NDD-CKD patients.

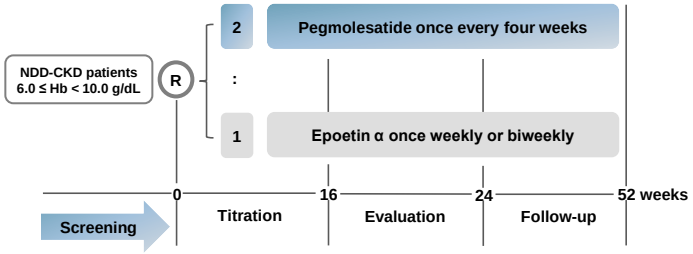
Objective

To explore further benefits of pegmolesatide in NDD-CKD patients with anemia.

Methods

- A total of 175 NDD-CKD patients without erythropoiesis-stimulating treatment were randomized (2:1) to receive pegmolesatide or epoetin alfa for 52 weeks.
- This post-hoc analysis included subgroup-assessments of hemoglobin (Hb) level change from baseline to evaluation period, as well as evaluation of iron therapy, serum ferritin (SF) and transferrin saturation (TSAT).

Figure 1. Study Design



R = random assignment

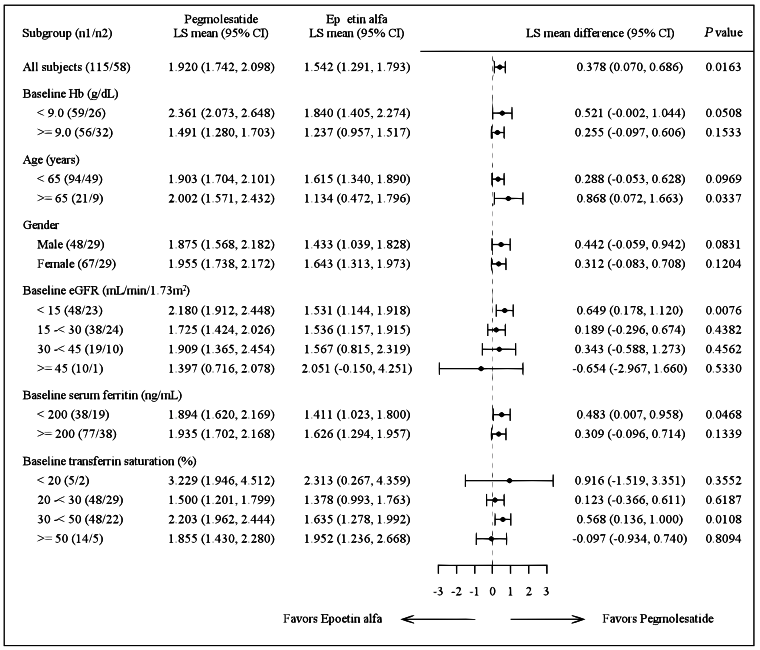
Results

- Pegmolesatide resulted in a greater increase in Hb from baseline to evaluation period compared to epoetin alfa (*P*=0.0163, Figure 2).
- Better efficacy was observed in patients ≥65 years old, with baseline eGFR <15 mL/min/1.73 m^2 or SF <200 ng/mL.
- Numerically less patients in pegmolesatide group required iron therapy (41.7% vs. 56.9%), or folic acid and vitamin B12 (24.3% vs. 29.3%) compared to epoetin alfa group.
- Those who received pegmolesatide were more likely to have a smaller reduction in SF and TSAT over 52 weeks (Figure 3).

Conclusion

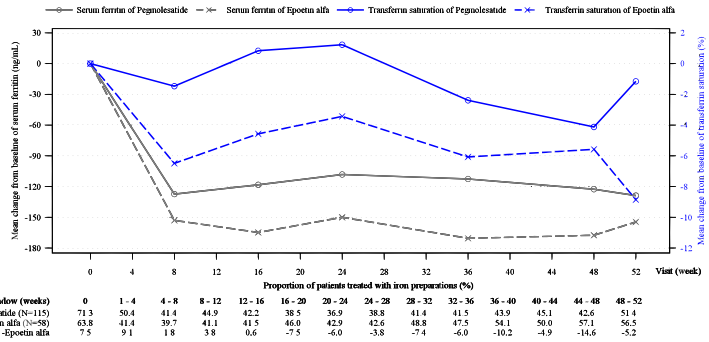
Pegmolesatide is non-inferior in increasing Hb level compared to epoetin alfa, and may optimize iron supplements and utilizations in NDD-CKD patients.

Figure 2. Forest Plot in Subgroup Analysis of the Change in Hemoglobin Level from Baseline to the Evaluation Period (FAS)



The *P* values for the difference between the two groups were estimated based on Analysis of Covariance model (ANCOVA), with the mean change in Hb level from baseline to the efficacy evaluation period as the dependent variable, treatment group as the explanatory variable and baseline Hb values as the covariate.

Figure 3. Changes in Iron Usage, Serum Ferritin, and Transferrin Saturation (TSAT) Levels (FAS)



Financial Disclosures

None

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