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Fixed-Dose Epoetin Alfa Shows Efficacy and Safety for Cancer-Associated Anaemia: Presented at EHA

STOCKHOLM, SWEDEN -- June 9, 2005 -- Epoetin alfa administered at a fixed dose of 40,000 IU once weekly may offer efficacy and safety comparable with that of weight-based dosing for patients with cancer-associated anaemia, according to a retrospective analysis presented here at the 10th Congress of the European Hematology Association (EHA).

The added advantage of the fixed dose regimen is greater convenience for physicians and patients, said Nicolas Denys, MD, clinical research & development, haematology/oncology, Johnson & Johnson, Beerse, Belgium, who presented the study on here June 3rd for the investigators.

The research team conducted the retrospective analysis because of a growing interest in and use of fixed-dose regimens of epoetin alfa, Dr. Denys said. The fixed-dose regimen of epoetin alfa 40,000 IU once weekly is approved in the United States for treatment of nonmyeloid malignancies in patients with chemotherapy-associated anaemia.

The retrospective analysis aimed to evaluate the effect of body weight on the efficacy of epoetin alfa administered as a fixed dose and to evaluate whether a fixed-dose regimen produces adequate efficacy across all weight ranges compared with a weight-based dose.

The researchers compared data from 1 fixed dose trial involving 2964 patients who were administered 40,000 IU epoetin alfa once weekly, increased to 60,000 IU once weekly for insufficient response, against data from 8 weight-based dose studies with a total of 944 patients who took epoetin alfa 150 IU/kg 3 times weekly, increased to 300 IU/kg 3 times weekly for insufficient response.

The adult patients had a variety of solid and haematological malignancies.

Body weights were defined by quartiles using the European Cancer Anemia Survey (ECAS): Q1 </=60.3 kg, Q2 >60.3 to </=70.0 kg, Q3 >70.0 to 79.5 kg, Q4 >79.5 kg.

Fixed-dose body weights analysed corresponded to the ECAS-based body-weight quartiles Q2 (600 IU/kg dose) and Q4 (450 IU/kg dose). Efficacy endpoints were erythropoietic response and changes in haemoglobin levels from baseline.

Results show that erythropoietic response was somewhat greater in patients with lower body weights in the Q2 arm of the fixed-dose group than in heavier patients in the Q4 arm (65% vs 61%). In the weight-based dose group, erythropoietic response rates were 72% and 63%, respectively. These differences in the dosing regimens were not significant (*P* =.3005).

Focusing on the Q2 and Q4 groups, investigators said the probability of transfusion or haemoglobin levels of 8 g/dL or lower after 4 weeks of treatment was somewhat greater for heavier than lighter patients in the fixed-dose (16% vs 13%) and the weight-based dose population (20% vs 17%).

Heavier patients had slightly smaller haemoglobin increases from baseline with both fixed dosing (2.0 g/dL, Q2 vs 1.8 g/dL, Q4) and weight-based dosing (2.2 g/dL, Q2 vs 1.9 g/dL, Q4).

Effect size was similar with the 2 regimens.

Fixed-dose epoetin alfa was well tolerated with no sign of increased safety risk in lower-weight patients, who may receive a higher dose relative to body weight, the investigators said.

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[Presentation title: Effect of Body Weight on the Efficacy and Safety of Fixed Dose Epoetin Alfa for Cancer-Associated Anaemia. Abstract 0076]