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Janssen's EPREX® (epoetin alfa) Demonstrates Effectiveness as a Treatment for Anaemia in Patients with Low or Intermediate-1 Risk Myelodysplastic Syndromes

Final results from Phase 3 EPOANE 3021 study also showed significantly fewer patients needing transfusion and significant improvements in quality of life

COPENHAGEN, DENMARK AND BEERSE, BELGIUM, June 11, 2016 – Janssen-Cilag International NV today announced results from the international Phase 3, randomised, double-blind, placebo-controlled, multicentre study, EPOANE 3021. The study demonstrated the efficacy and safety of EPREX® (epoetin alfa) as a treatment for anaemia, in adult patients with low or intermediate-1 risk myelodysplastic syndromes (MDS), as classified by an International Prognostic Scoring System (IPSS).[1] EPOANE 3021 data were presented at the 21st Annual Congress of the European Hematology Association (EHA) (Abstract P248).

These data, along with three registry studies from across Europe, have been submitted to the French health authority Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), as the reference health authority for EPREX (epoetin alfa) within the mutual recognition procedure, to extend the existing marketing authorisation in Europe. A decision is expected in the coming months.

EPOANE 3021 was designed to evaluate whether epoetin alfa improves anaemia in patients with MDS, versus placebo over 24-weeks of treatment. It consisted of 130 randomised patients, with 85 patients receiving epoetin alfa. Results showed that

compared to placebo, patients in the epoetin alfa arm demonstrated a statistically significantly higher erythroid response rate (according to IWG2006 criteria) in the first 24 weeks, the primary endpoint of the study (31.8 percent vs. 4.4 percent, p<0.001). Significantly fewer patients required transfusion on epoetin alfa (24.7 percent vs. 54.1 percent).[1] Additional analysis, accounting for dose adjustments within the protocol, also confirmed a statistically significant erythroid response for epoetin alfa (45.9 percent) compared to placebo (4.4 percent) (p<0.001).[1] Quality of life for responding patients in the epoetin alfa arm improved significantly compared to non-responders (FACT-An p=0.025, EQ-5D index score p=0.007, EQ-5D VAS p=0.037). There were no new safety signals for epoetin alfa from the study and safety findings were consistent with the known safety profile of epoetin alfa.[1]

”Anaemia affects the vast majority of patients with MDS and contributes substantially to their symptoms. However, there are currently no approved erythropoiesis stimulating agents approved for treating anaemia in lower-risk MDS patients,” said Pierre Fenaux, M.D., PhD., principal investigator of EPOANE 3021, and Professor of Hematology, Hôpital St Louis/Université, Paris, France. “These data provide important evidence that epoetin alfa can effectively manage lower risk MDS-related anaemia, beyond transfusion, and without any impact on progression to acute myeloid leukaemia (AML).”

“EPREX (epoetin alfa) has shown great potential across a range of indications throughout its clinical development programme. We are excited to be building on this evidence base once again, with the findings of this new study demonstrating the meaningful difference this medicine can make to patients with MDS-related anaemia. We’re also extremely pleased to see the improvements in quality of life offered by EPREX, where alternative treatment options have so far been limited,” said Jane Griffiths, Company Group Chairman, Janssen Europe, Middle East and Africa.

For more information on the EPOANE 3021 data presented at EHA 2016, please view the abstract online.

#ENDS#

About the EPOANE 3021 Study[1]
EPOANE 3021 was a randomised, double-blind, placebo-controlled, multicentre clinical trial investigating the efficacy and safety of EPREX® (epoetin alfa) as a treatment for

anaemia, in adult patients with low or Intermediate-1 risk myelodysplastic syndromes (MDS), as classified by an International Prognostic Scoring System (IPSS). Results demonstrated that 31.8 percent of patients treated with epoetin alfa achieved the primary endpoint of erythroid response versus 4.4 percent of placebo patients ($p<0.001$). An ad hoc analysis, accounting for the dose adjustments as per the protocol, confirmed a statistically significant erythroid response for epoetin alfa, with 45.9 percent of epoetin alfa patients, versus 4.4 percent of placebo patients achieving an erythroid response ($p<0.001$). Median erythroid response duration for epoetin alfa patients was 197 days. The number of patients needing transfusion in the epoetin alfa arm steadily decreased from 51.8 percent in the 8 weeks prior to baseline, to 24.7 percent by week-24. Transfusion need remained unchanged in the placebo patients (48.9 percent - 54.1 percent) over the same interval. Time to first transfusion was longer in the epoetin alfa group ($p=0.046$). Epoetin alfa demonstrated a statistically significant improvement of quality of life in responding patients.

There were no new safety signals for epoetin alfa from the study and safety findings are consistent with the known safety profile of epoetin alfa. The proportion of patients with at least one treatment emergent adverse event (TEAE) was numerically higher in the placebo group compared with the epoetin alfa group (88.9 percent vs. 77.6 percent). Drug discontinuation due to adverse events was 10.6 percent in the epoetin alfa group versus 13.3 percent in placebo. Four patients in the epoetin alfa arm (4.7 percent) and none in placebo reported a thrombovascular event (TVE). There were four fatal outcomes in the epoetin alfa arm versus one in the placebo arm; none were reported to be related to the study drug. During the study, progression to acute myeloid leukaemia (AML) was similar between groups (3.5 percent in epoetin alfa; 4.4 percent in placebo).

About Myelodysplastic Syndromes (MDS)

Myelodysplastic syndromes (MDS) are a group of diverse bone marrow disorders in which the bone marrow does not produce enough healthy blood cells.[2] The low numbers of normal blood cells (cytopenias) eventually cause symptoms, including infection, anaemia, spontaneous bleeding, or easy bruising.[2,3] The natural course of MDS is highly variable, with overall survival ranging from a few weeks to several years.[4] MDS is primarily a disease of the elderly with a median age at diagnosis of 70 years, but it can affect younger patients as well.[4] The incidence in Europe is about four cases per 100,000 per year, reaching 40-50 per 100,000 in patients aged 70 years and over.[4]

Approximately 60-80 percent of patients with MDS experience symptomatic anaemia,[5] which can significantly reduce quality of life and often requires repeated blood transfusions.[2] Controlling anaemia and improving quality of life are the principal aims of treatment in lower risk MDS patients.[4] At present, blood transfusions are currently the only approved treatment option; however these lead to iron overload, which is associated with significant morbidity and mortality.[4,5]

About EPREX® (epoetin alfa)

EPREX (epoetin alfa) is an erythreopoiesis-stimulating agent (ESA) that works by stimulating the production of red blood cells (RBCs).[6] ESAs are an important treatment option for patients with certain types of anaemia, including chemotherapy-induced anaemia and anaemia due to chronic kidney disease. Without ESAs, patients with certain types of anaemia may require regular blood transfusions to maintain RBCs at concentrations necessary to sustain normal oxygen levels throughout the body.[4]

EPREX is currently indicated for the treatment of:[6]

- Symptomatic anaemia associated with chronic renal failure (CRF):

  - In adult and paediatric patients aged 1 to 18 years on haemodialysis and adult patients on peritoneal dialysis.
  - In adults with renal insufficiency not yet undergoing dialysis for the treatment of severe anaemia of renal origin accompanied by clinical symptoms in patients.
- Adults receiving chemotherapy for solid tumours, malignant lymphoma or multiple myeloma, and at risk of transfusion as assessed by the patient's general status (e.g. cardiovascular status, pre-existing anaemia at the start of chemotherapy) for the treatment of anaemia and reduction of transfusion requirements.
- Adults in a predonation programme to increase the yield of autologous blood. Treatment should only be given to patients with moderate anaemia (haemoglobin concentration range between 10 to 13 g/dl [6.2 to 8.1 mmol/l], no iron deficiency) if blood saving procedures are not available or insufficient when the scheduled major elective surgery requires a large volume of blood (4 or more units of blood for females or 5 or more units for males).
- Non-iron deficient adults prior to major elective orthopaedic surgery having a high perceived risk for transfusion complications to reduce exposure to allogeneic blood transfusions. Use should be restricted to patients with moderate anaemia (e.g. haemoglobin concentration range between 10 to 13 g/dl) who do not have an autologous predonation programme available and with expected moderate blood loss (900 to 1,800 ml).

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at http://www.janssen.com/emea. Follow us at www.twitter.com/janssenEMEA.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development including a potential new indication. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialise, actual results could vary materially from the expectations and projections of Janssen-Cilag International NV and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; competition, including technological advances, new products and patents attained by competitors; challenges to patents; manufacturing difficulties and delays; changes in behaviour and spending patterns or financial distress of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2016, including in Exhibit 99 thereto, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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