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Rienso gets marketing authorization in Europe

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Singapore: Takeda Pharmaceutical and AMAG Pharmaceuticals have been granted marketing authorization by the European Commission for ferumoxytol, a new intravenous (IV) iron therapy to treat iron deficiency anemia in adult patients with chronic kidney disease.

The marketing authorization follows a positive opinion issued on April 19, 2012, by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). With receipt of the EC decision, Takeda intends to launch ferumoxytol across Europe in the near future.

"The granting of European marketing authorization for ferumoxytol marks an important milestone for Takeda in our ongoing commitment to the field of renal medicine. We look forward to providing ferumoxytol, a valuable new therapeutic option, to clinicians in the near future," said Mr Trevor Smith, head of Commercial Operations, Europe & Canada, Takeda Pharmaceuticals.

The marketing authorization, which will be held by Takeda Global Research & Development Centre, is valid in the current EU member states as well as in Iceland and Norway, and is based on data obtained from an extensive clinical development program. Across the three pivotal phase III safety and efficacy studies, 1,726 subjects were exposed to ferumoxytol, including 1,562 patients with all stages of chronic kidney disease; in which ferumoxytol was administered as a rapid injection. From these studies, ferumoxytol significantly increased haemoglobin levels as compared to oral iron across the spectrum of chronic kidney disease.

Moreover, ferumoxytol was well tolerated by chronic kidney disease patients with iron deficiency anemia and had a similar overall treatment-related adverse event rate to oral iron. 1 These outcomes were further supported by additional retrospective observational data from three large haemodialysis clinics in the United States involving more than 8,600 patients and more than 33,300 administered doses of ferumoxytol.

Iron deficiency is a common cause of anaemia often seen in the later stages of chronic kidney disease, as renal function

deteriorates and erythropoiesis (red blood cell production) declines. IDA can have a profound impact on patients' lives, causing fatigue, shortness of breath and an increase in the risk of cardiovascular complications including congestive heart failure.