

European Commission nod for Novartis' Exjade

26 December 2012 | Regulatory | By BioSpectrum Bureau



Singapore: European Commission has approved Exjade (deferasirox) for the treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients aged 10 years and older with non-transfusion-dependent thalassemia (NTDT) syndromes.

Developed by Novartis, Exjade is the first oral treatment approved in the European Union (EU) specifically indicated for the treatment of chronic iron overload in patients with these types of thalassemia.

Thalassemia refers to a diverse group of genetic disorders that affect red blood cell production, causing anemia. Unlike patients with other types of thalassemia, those with NTDT syndromes don't receive regular transfusions, a significant cause of chronic iron overload.

However, even without transfusions, NTDT patients still accumulate excess iron through intestinal absorption, leading to debilitating health complications like liver fibrosis and cirrhosis, blood clots, bone disease, pulmonary hypertension, and vascular and endocrine diseases.

"This approval is a critical milestone for patients with NTDT syndromes," said Mr Hervé Hoppenot, president, Novartis Oncology. "For the first time, Exjade will be available to thalassemia patients who are not regularly transfused but still suffer from the life-altering effects of excess iron."