The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the authorisation of Glybera (alipogenetiparvovec) for marketing, the first gene-therapy medicine to be recommended for authorisation in the European Union.
Glyberais intended to treat lipoprotein lipase (LPL) deficiency in patients with severe or multiple pancreatitis attacks, despite dietary fat restrictions.LPL deficiency is an ultra-rare inherited disorder estimated to affect no more than one or two people per million. Due to a defective gene, patients with this disorder cannot produce enough LPL, an enzyme responsible for breaking down fats.

The CHMP recommended the granting of the marketing authorisation under 'exceptional circumstances'. The company that markets Glybera will be required to provide data from a registry set up to monitor outcomes in patients treated with Glybera, which the Agency will review as they become available.

More information **here** [1].

27 July 2012

Links
[1] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/07/news_detail_001574.jsp&am