Nimesulide: European Medicines Agency concludes positive review under Article 31 of Directive 2001/83/EC

Lugano, Switzerland, June 27, 2011 – The European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) has concluded the review of systemic nimesulide containing medicines conducted in the context of a formal review under Article 31 of Directive 2001/83/EC, initiated in January 2010 at the request of the European Commission.

EMA’s CHMP concluded that the benefits of systemic nimesulide-containing medicines continue to outweigh their risks in the treatment of patients with acute pain and primary dysmenorrhea, but is recommending that systemic nimesulide should no longer be used for the symptomatic treatment of painful osteoarthritis. In fact - according to the CHMP - the use of systemic nimesulide for the symptomatic treatment of this chronic condition would increase the risk of the medicines being used long-term with a consequent increase in the risk of liver injury.

Nimesulide has been developed and licensed worldwide by the Swiss pharmaceutical Helsinn Group and was first approved for use in 1985. “To date about 9 billion nimesulide Defined Daily Doses (100 mg twice a day), corresponding to about 600 million nimesulide treatments have been administered worldwide since our product was first launched in Italy, more than 25 years ago. Nimesulide is a very effective anti-inflammatory drug providing with an excellent pain relief and we are pleased that EMA has confirmed its positive benefits/risk balance. We are glad it will remain as a treatment option for patients who need a rapid anti-inflammatory and analgesic action”, Riccardo Braglia, CEO of the Helsinn Group, said.

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