

## The CHMP/EMA has confirmed that the benefit/risk profile of Nimesulide is positive

London, 21st September 2007

Helsinn's Top Management today announced the positive outcome of the EMA procedure, according to Article 107, initiated due to concerns over serious liver problems. The Committee for Medicinal Products for Human Use (CHMP) today confirmed Nimesulide's positive benefit/risk profile. The benefits of these medicines outweigh their risks, but there is a need to limit the duration of use and to restrict their use to ensure that the risk of patients developing liver problems is kept to a minimum.

Medicines containing nimesulide in systemic formulations are authorised in a number of European Union (EU) Member States to treat acute pain, and the symptoms of painful osteoarthritis and primary dysmenorrhoea (period pains). Nimesulide is therefore confirmed to be an anti-inflammatory drug with a scientific value proved for over 22 years of commercialisation, that is, since it was launched on the Italian market in October 1985.

The marketing authorisations for nimesulide-containing medicines were suspended by the Irish competent authority in Ireland on 15 May 2007, because of reports of serious side effects affecting the liver. After the Irish authority had notified the EMA about the suspension, the Committee for Medicinal Products for Human Use (CHMP) started an assessment of the hepatic safety of these medicines in June 2007 to reach a conclusion on whether the regulatory actions taken by Ireland should be implemented throughout the EU.

Having considered all of the available evidence, the CHMP concluded that the data did not support a suspension of all marketing authorisations in Europe. It is also concluded that there was a need for the marketing authorisations to be changed, with the information provided to doctors and patients to be amended to limit the risk of liver injury.

The CHMP therefore recommended that treatment with nimesulide should be limited to a maximum of 15 days and that consequently all packs containing more than 30 doses (tablets or sachets) should be removed from the market. Doctors are advised to base their decision to prescribe nimesulide on an assessment of the individual patient's overall risks.

*“Helsinn is proud of the result obtained, both for the importance this drug represents within the Helsinn Group and for the wide use and the benefit it provides to patients worldwide. Nimesulide-containing medicinal products should be used in an appropriate way as recommended by the CHMP”* said Riccardo Braglia, Chief Executive Officer.

#### About NIMESULIDE

NIMESULIDE is one of the most used non-steroidal anti-inflammatory drugs in the EU. Present on the market since 1985, nimesulide-containing products are currently available in approximately 50 countries. To date, 500 million courses of treatment have been made in 22 years of marketing.

#### About HELSINN HEALTHCARE

HELSINN HEALTHCARE SA, a privately owned pharmaceutical group with headquarters in Switzerland, is the worldwide licensor of nimesulide. HELSINN's core business is the licensing of pharmaceuticals in various therapeutic niche areas (anti-inflammatory, gastroenterology, oncology and supportive care). The company's business strategy is to in-license early stage new chemical entities and complete their development from the performance of pre-clinical/clinical studies and CMC development to the attainment of market approvals in strategic markets (U.S. and Europe). HELSINN's products are eventually out-licensed to its marketing partners for distribution. The active pharmaceutical ingredients and the finished dosage forms are manufactured at HELSINN's cGMP facilities and supplied worldwide to its customers.

For more information about HELSINN, please visit the company's Web site at [www.helsinn.com](http://www.helsinn.com).

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