



European Agency for the Evaluation of Medicinal Products Recommends Suspension of Marketing Authorisation for IONSYS®

Company Conducts Root-Cause Analysis of September Recall

Beerse, Belgium (November 20, 2008) - Janssen-Cilag International NV announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended suspension of the marketing authorisation for IONSYS® (fentanyl iontophoretic transdermal system), indicated for the management of acute moderate to severe post-operative pain for use in a hospital setting only.

Janssen-Cilag recalled IONSYS in the European Union (EU) in September 2008, as a precautionary measure following identification of corrosion in a component of the system in one lot of the product. This corrosion could lead to self-activation of the system resulting in the delivery of doses of fentanyl to the patient that had not been requested. As a result, IONSYS is not currently available for use anywhere in the EU. There have been no reports of serious adverse events associated with the malfunction of the device.

The company continues to analyse the root cause of the defect found in one lot of IONSYS. Part of the company's ongoing analysis is to determine what initiated corrosion observed in the systems that were recalled.

The CHMP has concluded that until the current defect is understood, corrected and the company demonstrates the quality of the product, the benefits of IONSYS no longer outweigh its risks, and has recommended that the marketing authorization should be suspended across the European Union (EU). Lifting of the suspension will be conditional on the company resolving the issues identified by the EMA.

The European Commission granted marketing authorization for IONSYS throughout the EU in January 2006. In November 2007, the Commission approved a Type II variation, in reference to a change in product packaging and a change in the package leaflet. IONSYS was made available commercially in the EU in January 2008 and had been marketed in Austria, Belgium, Denmark, Finland, France, Germany, Luxembourg, Netherlands, Slovenia, Sweden, United Kingdom and Ireland.

Notes to the Editor

The Janssen-Cilag companies have a track record in developing and marketing treatments for a wide variety of conditions such as infectious disease, HIV, pain management, fungal infections, multiple myeloma, gastroenterological disorders, epilepsy, Alzheimer's disease, schizophrenia, acute bipolar mania, behavioural psychological symptoms of dementia, disruptive behaviour disorders, and autism. More information can be found at <http://www.janssen-cilag.com>. The Janssen-Cilag companies are part of the Johnson & Johnson family of companies.

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from Janssen-Cilag's expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2007. Copies of this Form 10-K, as well as subsequent filings, are available online at <http://www.sec.gov>, www.jnj.com or on request from Johnson & Johnson. Janssen-Cilag does not undertake to update any forward-looking statements as a result of new information or future events or developments.