



Zurich, 7 December 2007

## Press Release

### **Nycomed files marketing authorisation application for an intranasal fentanyl spray in Europe**

- Marketing authorisation application filed for Europe through the Centralised Procedure
- Treatment aimed at opioid tolerant patients with cancer experiencing breakthrough pain
- Strengthening the Nycomed pain control portfolio

**Nycomed filed a marketing authorisation application with the European Medicines Agency (EMA) for an intranasal fentanyl spray in Europe on December 7, 2007. It is seeking approval for the indication of managing breakthrough pain (BTP) in adults already receiving maintenance opioid therapy for cancer pain. If approved, the centralised filing could allow Nycomed to be the first to enter the market in 29 European countries with an intranasally administered formulation of fentanyl.**

Intranasal fentanyl is aimed at managing breakthrough pain in adult cancer patients already receiving maintenance opioid therapy for chronic pain. Breakthrough pain is a transitory exacerbation of pain experienced by the patient who has relatively stable and adequately controlled baseline pain. The onset of breakthrough pain is sudden. It peaks in less than three minutes and usually lasts for no longer than 30 minutes in total.

“We are aiming for a product profile of the intranasal fentanyl spray that provides patients with a rapid onset of action and adequate short duration, closely matching the typical breakthrough pain episode. We want to offer a clear medical utility through tight control of the breakthrough pain”, explained Anders Ullman, Executive Vice President Research and Development. “It is a significant medical milestone marking progress in the treatment of breakthrough pain”, added Dick Söderberg, Executive Vice President International Marketing.

Nycomed has an established presence in pain control and several pain products in its Research and Development Pipeline. With the introduction of the intranasal fentanyl spray, Nycomed would provide products to manage both background and breakthrough pain for patients with cancer, confirming their strong commitment to the pain control arena.

Nycomed’s intranasal fentanyl application is not approved by any regulatory authority for any indication and is currently being evaluated.

## About Breakthrough Pain

The prevalence of patients with cancer in Europe is approximately 2.9 million.<sup>1</sup> Over 80% of patients with cancer experience pain, in later stage disease, and approximately two-thirds of these experience breakthrough pain.<sup>2-4</sup> Breakthrough pain is a transitory exacerbation of pain experienced by the patient who has relatively stable and adequately controlled baseline pain.<sup>5</sup> The typical breakthrough pain episode is characterised by a fast onset, is often very severe, usually reaching a peak of intensity within three minutes, with an average duration of approximately 30 minutes. About 90% of the episodes have a duration of less than one hour.<sup>2-4</sup> People can experience breakthrough pain several times per day.<sup>2-4,6</sup> Breakthrough pain may significantly impact the patient's life.

Healthcare professionals can find more information about breakthrough pain at [www.breakthroughpain.eu](http://www.breakthroughpain.eu)

Nycomed does not provide information directly to patients. Patients should always consult their physician.

## About Nycomed

Nycomed is a pharmaceutical company that provides medicines for hospitals, specialists and general practitioners, as well as over-the-counter medicines in selected markets.

The company is active within a range of therapeutic areas, including cardiology, gastroenterology, osteoporosis, respiratory, pain and tissue management. New products are sourced both from own research and from external partners. Operating throughout Europe and in fast-growing markets such as Latin America, Russia/CIS and the Asia-Pacific region Nycomed has a presence in about 50 markets worldwide.

Privately owned, the combined group had annual sales of approximately €3.4 billion and an EBITDA of €933.4 million (2006 results).

For more information visit [www.nycomed.com](http://www.nycomed.com)

## For further information

### **Media:**

Tobias Cottmann, Director External Communications  
Phone +41 44 55-515 10

### **Medical professionals and scientific media:**

Ulf Jonson, International Product Manager  
Phone +45 4677 10 78

## Notes for editors

A background document focusing on breakthrough cancer pain is available on request. Please contact Ulf Jonson (contact above).

Healthcare professionals can find more information about breakthrough pain at [www.breakthroughpain.eu](http://www.breakthroughpain.eu)

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