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# Instanyl(R) (intranasal fentanyl spray) Sets New Standard in Management of Breakthrough Cancer Pain

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LISBON, Portugal, September 11 /PRNewswire/ -- New data presented today further demonstrate the efficacy of Instanyl in management of breakthrough cancer pain. The data which were presented at the 6th congress of the European Federation of Chapters of the International Association for the Study of Pain (EFIC) are from a multinational, crossover trial comparing Instanyl with oral transmucosal fentanyl citrate (OTFC) for the treatment of breakthrough pain in patients with cancer. The study concludes that pain relief was significantly greater for Instanyl compared to OTFC at all time points:

- 25% of episodes showed meaningful pain relief already at 5 minutes after treatment with Instanyl, as compared to 7% with OTFC. (p<0.001)[1]
- 51% of the Instanyl treated patients had a meaningful pain relief at 10 minutes, as compared to 24% with OTFC. (p<0.001)[1]

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"These data confirm the superiority of the intranasal drug administration over OTFC. Rapid pain relief is essential for the management of breakthrough cancer pain and with evidence of onset of pain relief as early as 5 minutes, Instanyl offers patients a much more effective pain control than OTFC," said Professor Sebastiano Mercadante, principal investigator of the comparative study and Director of the Anesthesia and Intensive Care and Pain Relief and Palliative Care Units at La Maddalena Cancer Center, Palermo, Italy.

The study also showed that patients found Instanyl significantly easier to administer than OTFC, with 90% of patients finding Instanyl 'easy' or 'very easy' to use, compared to 40% of OTFC patients.[2] Instanyl is the First intranasal treatment for breakthrough cancer pain to be licensed and The study showed that 77% of patients preferred Instanyl to OTFC.[2]

"With a preference for Instanyl more than three-fold higher compared to OTFC, the study confirms that with Instanyl patients now have a treatment that they feel better matches their need," said Professor Mercadante and concluded: "Instanyl represents a major step forward in the management of breakthrough cancer pain."

Up to 95% of patients with cancer pain experience breakthrough pain,[3] Of which two-thirds experience inadequate pain control.[4] Interim results From the first European survey of breakthrough cancer pain[5] also presented for the first time in Lisbon show that on average a patient will have 3 episodes of BTCP per day, each one lasting on average 60 minutes and 96% of episodes being rated as moderate or severe. 87% of patients reported that their BTCP interfered with their daily living including their ability to sleep, walk and get on with other people.

"Breakthrough cancer pain afflicts a large proportion of cancer patients, yet there is a significant under-treatment and sub-optimal treatment of these patients. Time has come for a change in management of breakthrough cancer pain and with Instanyl now approved we have an intranasal product with fast onset of pain relief, short duration which is easy to use. This will enable us to improve the care of cancer patients," commented President of EFIC, Professor Giustino Varrassi, Dept. of Anesthesiology and Pain Medicine L&apos;Aquila University, Italy.

Instanyl is approved for the management of breakthrough cancer pain in adults already receiving maintenance opioid therapy for chronic cancer pain. This first-in class drug was granted marketing authorisation on the 20th July 2009, and will be launched across Europe from September 2009.

### About Nycomed

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Nycomed employs 12,000 associates worldwide, and its products are available in more than 100 countries. It has strong platforms in Europe and in fast-growing markets such as Russia/CIS and Latin America. While the US and Japan are commercialised through best-in-class partners, Nycomed plans to further strengthen its own position in key Asian markets.

Headquartered in Zurich, Switzerland, the company generated total sales of EUR3.4 billion in 2008 and an adjusted EBITDA of EUR1.2 billion.

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#### About the study

- A multinational, open-label, crossover trial comparing Instanyl(R) and Actiq(R) for breakthrough cancer pain in patients receiving chronic opioid treatment.
- The trial investigated the efficacy of Instanyl compared to Actiq as well as ease of administration and patient preference.
- Primary efficacy measurement was time to onset of meaningful pain relief.
- Of 196 patients enrolled and 139 randomised, 86 patients completed the trial.

Results showed that:

- 25.3% of episodes showed meaningful pain relief (greater than or equal

to 33% reduction in PI score) at 5 minutes after treatment with Instanyl versus 6.8% with Actiq.

- 51% of the Instanyl treated patients had a meaningful pain relief (greater than or equal to 33% reduction in PI score) at 10 minutes versus 23.6% with Actiq.
- 90% of patients found Instanyl was 'easy' or 'very easy' to use versus 40% for Actiq.
- 77% of patients preferred Instanyl to Actiq.
- Both treatments were well tolerated with adverse events experienced being those typical for this group of opioid drugs.

## References

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3. Zeppetella G, Ribeiro MD. Pharmacotherapy of cancer-related episodic pain. Expert Opin. Pharmacother. 2003;4:493-502
4. Davis MP, Walsh D, Lagman R, LeGrand SB. Controversies in pharmacotherapy of pain management. Lancet Oncol. 2005;6:696-704.
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