Press release, 17 July 2009

Onsolis receives FDA approval

The U.S. Food and Drug Administration (FDA) has approved Onsolis *(fentanyl buccal soluble film)*. This new and patented product is indicated for the management of breakthrough pain in cancer patients who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Onsolis uses a unique delivery system designed to give rapid and reliable delivery of fentanyl. The product consists of a small dissolvable disc for application of fentanyl to the buccal (inner lining of cheek) membranes. The product is unique and offers an important step to a better pain treatment of cancer patients.

"I'm very pleased that Onsolis has been approved for marketing in the U.S. For Meda in the U.S., we get yet another important product addition. The interest among specialists for this new technology is significant, and we are making preparations for product launch during the fourth quarter of 2009. The registration procedures for Onsolis in other key markets are progressing according to plan", said Anders Lönner, CEO Meda.

Meda has, in close collaboration with the FDA and Meda's development partner BioDelivery Sciences Inc, developed the REMS (Risk Evaluation and Mitigation Strategy) program for Onsolis. This REMS program has also been approved by the FDA.

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