Press release 28 August 2008

Anticipated approval of Onsolis™ during first half 2009 following receipt of Complete Response letter from FDA

The U.S. Food and Drug Administration (FDA) has issued a Complete Response letter to BioDelivery Sciences International (BDSI) for Onsolis - formerly known as BEMA Fentanyl, in the U.S. The implication is that the FDA in principal accepts the registration application but requests certain modifications to the submitted risk management program. FDA has stated that all other aspects of the registration application were complete and no other deficiencies were noted. The FDA will be provided with a resubmission allowing for an anticipated approval during first half of 2009.

FDA's request for a Risk Evaluation and Mitigation Strategy (REMS) was expected. However, REMS was not requested by the FDA prior to the NDA submission in late 2007, but is believed to be a result of recent experiences with other high-potency opioid products. REMS is relatively new term for a comprehensive strategy and plan aimed at ensuring that the benefits of a drug outweigh any potential risks. The inclusion of these added components will help assure that Onsolis is used appropriately, and that patients and healthcare practitioners will benefit from the enhancements made.

Meda has worked with BDSI over the last several months to prepare for a potential REMS requirement. The FDA has not brought forward any other point of views and has also outlined a clear pathway to the approval of Onsolis. FDA will be provided with the requested information and depending on FDA review time, final approval could occur as early as the first quarter of 2009 or as late as the second quarter.

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About Onsolis

Onsolis has been evaluated for the management of breakthrough pain (BTP) in cancer patients who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

Onsolis is a patented product with a unique delivery system designed to give rapid and reliable delivery of the opioid narcotic substance fentanyl. The product consists of a small, dissolvable, polymer film, formulated with fentanyl, for application to the buccal (inner lining of cheek) membranes.

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