

RAPID AND EFFECTIVE CONTROL OF BREAKTHROUGH PAIN (BTP) AND FAVORABLE TOLERABILITY IN CANCER PATIENTS TREATED WITH BEMA™ (BIOERODIBLE MUCOADHESIVE) FENTANYL. WD Charlie Hill, RN, Invisions Consultants, LLC, San Antonio, TX, USA; David Blum, MD, BioDelivery Sciences International, Raleigh, NC, USA; and Eldred Giefer, MS, Statisticians Without Borders, Bahama, NC, USA.

Transmucosal delivery of fentanyl can provide prompt control of breakthrough pain (BTP) in cancer patients taking stable doses of opioids for chronic pain.

The BEMA™ drug delivery system was designed for rapid oral transmucosal drug delivery with dose to dose reliability of plasma concentrations and ease of patient use. BEMA™ Fentanyl consists of a small, dissolvable, polymer disc formulated with the opioid narcotic fentanyl for application to the buccal membranes. The mucoadhesive polymers adhere to the membrane and rapidly deliver fentanyl into the bloodstream.

Eighty adult cancer patients on stable opioid doses who achieved adequate control of BTP with BEMA™ Fentanyl (200 to 1200µg) in an open label titration phase were treated for up to 9 BTP episodes with the previously determined BEMA™ Fentanyl dose (6 episodes) and placebo (3 episodes) in a double-blind random sequence. Subjects recorded pain intensity (PI; 11 point scale) at the time of treatment, and at 5, 10, 15, 30, 45, and 60 minutes after treatment; the primary outcome measure was the sum of PI differences (SPID) at 30 minutes. Subjects also recorded their overall satisfaction with study medication (5 point categorical scale) at 60 minutes after dosing or at the time of rescue medication use.

A total of 394 BTP episodes were treated with BEMA™ Fentanyl and 197 with placebo. SPID values for BEMA™ Fentanyl-treated episodes were statistically significantly greater than placebo-treated episodes beginning at 15 minutes through 60 minutes. At 60 minutes after dosing or at the time of rescue medication use, subjects rated their overall satisfaction with study medication as 'Good' or better for 67.1% of their BEMA™ Fentanyl-treated BTP episodes compared with 47.2% of placebo-treated BTP episodes. The mean score for overall satisfaction with study medication was statistically significantly greater for BEMA™ Fentanyl compared with placebo. The most commonly reported treatment related adverse events were somnolence (6.0%), nausea (5.3%), dizziness (4.6%), and vomiting (4.0%), which are commonly associated with opioid use. There were no reports of treatment related mucositis or respiratory depression.

BEMA™ Fentanyl provides patients with a rapid, effective, and convenient means to control cancer BTP with a favorable tolerability profile.

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