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The Efficacy and Safety of Butrans (buprenorphine) Transdermal System in Opioid-Naïve Patients with Moderate to Severe Low Back Pain: A Double-Blind Study

March 25, 2011, National Harbor, MD—Physicians from Purdue Pharma LP, Stamford, CT, showcased study results that demonstrate the analgesic efficacy and safety of Butrans for the relief of moderate to severe chronic low back pain in opioid-naïve patients.

Butrans is a transdermal delivery system that provides systemic delivery of buprenorphine, a Schedule III medication, continuously over a 7-day period.

“Butrans is a new treatment for chronic pain that was approved [by the Food and Drug Administration] on June 30, 2010, and is available in the market today,” said Deborah Steiner, MD, MS, medical director at Purdue Pharma. “We were able to demonstrate that Butrans was superior to placebo in treating opioid-naïve patients with moderate to severe chronic low back pain and that the safety profile of Butrans is consistent with that associated with opioid analgesics and transdermal patches.”

The randomized, double-blind, 12-week study employed an enriched design. A total of 1,024 patients were treated with Butrans during the open-label run-in period and were randomized to Butrans 10 and Butrans 20, or matching placebos. Age, gender, and weight were equally distributed across the two treatment groups.

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“In the open-label run-in period, if Butrans 10 was tolerated but adequate analgesia was not reached, the dose was increased to Butrans 20 for an additional 10 to 12 days,” Dr. Steiner said. “Patients who achieved adequate analgesia and tolerated Butrans were then randomized to remain on the titrated dose of Butrans (10 or 20) or a matching placebo. To demonstrate adequate analgesia in the open-label run-in period, patients had to have pain scores of less than or equal to 4 on an 11-point scale for 3 consecutive days and at least a 2-point reduction from their screening pain scores.”

The primary efficacy outcome, the “average pain over the last 24 hours” at Week 12, resulted in a statistically significant treatment difference of -0.58 in favor of Butrans over placebo (P=.0104). The proportions of patients with at least 30% and at least 50% pain score improvements were larger for Butrans-treated patients.

The treatment adverse events occurring in at least 5% of Butrans-treated patients included nausea, application-site rash, and headache. In the double-blind phase of the study, serious adverse events occurred in 1.2% of Butrans-treated patients and .7% of placebo-treated patients.

“Healthcare professionals require a range of therapeutic options to manage chronic pain conditions that affect many Americans,” Dr Steiner said. “Appropriate adult patients suffering from moderate to severe chronic pain now have a new option when an around-the-clock opioid may be needed to manage their pain.”

The full prescribing information for Butrans is available at www.purduepharma.com/PI/prescription/ButransPI.pdf. Additional information, including a medication guide, is available at www.Butrans.com. Working with the FDA,

Purdue has also developed a Risk Evaluation and Mitigation Strategy (REMS) for Butrans. The Butrans REMS includes a medication guide; elements to assure safe use, such as healthcare providers training; and a timetable for submitting assessments of the REMS. This information is available at www.butransrems.com

For more information: www.painmed.org/press

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