Clinical Trial Results Summary
Study EN3261-001

Study Number: EN3261-001	
Title of Study: A Randomized, Double-Blind Study Comparing the Efficacy and Safety of Lidocaine 5% Patch With Placebo in Patients With Chronic Axial Low Back Pain	
Investigators: 19 investigators	
Study Centers: 19 study centers in the United States	
Publication (reference): None.	
Study Period (years): August 5, 2004 to October 25, 2005	**Phase of Development:** II
Objectives: The primary objective of the study was to assess the efficacy of lidocaine 5% patch compared with placebo in treating chronic axial low back pain (LBP). A secondary objective was to assess the safety of lidocaine 5% patch compared with placebo.	
Methodology: This multicenter study was conducted using a randomized, double-blind, placebo-controlled, parallel-group design consisting of up to 14 days of placebo run-in followed by a 12-week double-blind treatment period. Patients with moderate-to-severe chronic axial LBP were enrolled at up to 20 investigational sites in the US. After the screening visit (Day –14), patients who provided written informed consent and met eligibility criteria entered the placebo run-in period for up to 14 days during which time they discontinued use of all analgesic medications. (Patients were permitted to use a stable dose of aspirin daily for cardiac prophylaxis.) During the placebo run-in period, patients applied placebo patches daily according to instructions provided by the investigator. For the duration of the placebo run-in period, patients used a diary to record (at bedtime) average daily pain intensity associated with LBP. Site personnel contacted patients at least every other day (via telephone) during this period to monitor average daily pain intensity scores, adverse events (AEs), and to ensure that analgesic medications were not being used. When patients' pain intensity reached a score of 6 or greater (on a scale of 0 to 10 using Question 5 of the Brief Pain Inventory [BPI]) for 3 days out of the 5 consecutive days immediately prior to the baseline visit, all baseline procedures were conducted. After all baseline assessments were completed, eligible patients were randomly allocated to receive one of two treatments for 12 weeks: lidocaine 5% patch or matching placebo patch. Patients returned to the study site at Weeks 2, 4, 6, and 8 (i.e., Visits 3, 4, 5, and 6) for study assessments and again at Week 12 (Visit 7) for end of study (EOS) assessments. Because the results of this study did not meet the primary objective, an abbreviated clinical study report (CSR) was prepared, which includes only the safety and primary efficacy objectives.	
Number of Patients Planned and Analyzed: Planned enrollment was approximately 200 patients (100 per treatment arm). A total of 363 patients entered Placebo Run-In. Of those, 215 were randomized (106 active, 109 placebo) and analyzed for safety. Of those randomized, 201 patients (101 active, 100 placebo) were included in the Modified Intent-to-Treat (MITT) population and analyzed for efficacy.	
Diagnosis and Main Criteria for Inclusion: Patients 18 years of age or older who were in generally good health and had axial LBP with or without radiating pain present for at least 3 months and daily moderate to severe LBP as the primary source of pain.	
Test Product, Dose and Mode of Administration, Batch Number(s): Lidocaine 5% patch (Lidoderm®, Endo Pharmaceuticals Inc.), 2 patches applied directly to the most painful area of the low back once daily (q24h), lot number 3112.	

Reference Therapy, Dose and Mode of Administration, Batch Number(s): Matching placebo patch, 2 patches applied directly to the most painful area of the low back once daily (q24h), lot number 3111.

Duration of Treatment: 12 weeks

Criteria for Safety and Primary Efficacy Evaluation:

Safety

- AEs
- Dermal assessments
- Clinical laboratory test results, including urinalysis
- Vital sign measurements
- Physical and neurological examinations
- Plasma lidocaine concentration

Efficacy

- Pain intensity (Question 5 of the BPI)

Statistical Methods: The safety population was defined as all randomized patients who received at least one dose of study medication. Assessments of safety were based on treatment-emergent AEs, treatment related AEs, serious AEs (SAEs), discontinuations as a result of AEs, application site reactions, physical examinations, vital signs, body weight and clinical laboratory data, including urinalysis. Tabular and textual summaries of the safety outcomes were presented by treatment group.

Results were determined to be statistically significant when the accompanying statistical test (two-tailed) yielded a probability of less than 0.05. P-values were shown to three decimal places to assess statistical significance against the criterion ($p<0.050$).

Demographic and baseline summaries were performed on safety and MITT populations. Descriptive statistics were used to summarize treatment group characteristics.

SUMMARY: The lidocaine 5% patch was well-tolerated compared to placebo. The incidence of treatment related AEs was similar in both groups, and low overall. Mean pain scores for patients who completed the study (i.e., participated through Week 12, not including those who discontinued early) decreased by >30% in both treatment groups using BPI Question 5. Although this is generally considered to be a clinically meaningful difference in pain scores, there was no statistically significant difference between the two treatment groups.