

**Butrans<sup>®</sup> (buprenorphine) transdermal system (BTDS) improves health-related quality of life in patients with moderate-to-severe chronic low back pain**

Aaron Yarlas<sup>1</sup>, Warren Wen<sup>2</sup>, Maribeth Kowalski<sup>2</sup>, Shau Yu Lynch<sup>2</sup>, Bradley Dain<sup>2</sup>, Steven Ripa<sup>2</sup>

<sup>1</sup>QualityMetric, Inc., Lincoln, RI, USA, <sup>2</sup>Purdue Pharma LP, Stamford, CT, USA

**Purpose**

To evaluate the burden of moderate-to-severe chronic low back pain (LBP) on the health-related quality of life (HRQL) and to compare the impact of 12 weeks treatment with BTDS, relative to a placebo, for improving HRQL.

**Method**

Opioid-naïve patients with moderate-to-severe chronic LBP were enrolled in a multicenter, randomized, double-blind (DB), placebo-controlled trial which evaluated BTDS 10 (10 mcg/hour) and BTDS 20 (20 mcg/hour) for treatment of chronic pain. This enriched trial used a run-in period to establish tolerability and responsiveness to BTDS dosages, followed by a 12-week DB phase. Before and after the run-in period, and at 4, 8, and 12 weeks during the DB phase, patients completed the SF-36v2, a 36-item survey measuring 8 domains of HRQL (physical functioning, role-physical, pain, general health, vitality, social functioning, role-emotional, and mental health), with physical (PCS) and mental (MCS) health summaries. Posthoc analyses of treatment impact at week 12 and of change over weeks 4, 8, and 12 between BTDS 10/20 and placebo were conducted using ANCOVA and repeated measures analysis of SF-36v2 scores, respectively. Burden was examined by comparing trial patients with U.S. general-population norms.

**Results**

SF-36v2 scores were collected from a total of 541 patients at the pre-run-in visit, and from 498 patients at the week 12 DB visit (BTDS: n=237; placebo: n=261). ANOVA analyses indicated that all SF-36v2 scales and summary scores were statistically equivalent across treatment groups at both pre-run-in and post-run-in visits (all  $P > .05$ ). Results of ANCOVA analyses on week 12 SF-36v2 scores (with both pre- and post-run-in scores treated as covariates) showed significantly higher scores for the combined BTDS doses than for the placebo group on all 8 domains and both physical and mental summaries (all  $P < .05$ ). Repeated measures analysis of PCS and MCS scores using mixed linear models indicated that the relative improvements associated with BTDS treatment over placebo for both measures were apparent by week 4 of treatment, and that these improvements were maintained through the remainder of the 12-week DB phase. Results of the burden analysis indicated that all domain and summary SF-36v2 baseline scores for the trial sample were significantly below those of an age- and gender- matched US representative sample (all  $P < .05$ ), with the largest deficits seen in the domains of pain, physical functioning, and role-physical. By week 12, deficits relative to the matched norms were fully eliminated in the BTDS arm for the MCS as well as 3 domains (general health, vitality and mental health), with the deficits greatly reduced for the PCS and the remaining 5 health domains.

**Conclusions**

These results show that patients with moderate-to-severe chronic LBP who received BTDS had significantly greater improvements in all measured aspects of HRQL than did patients receiving placebo. Evaluation of changes in HRQL over the course of the trial indicate that improvements associated with BTDS treatment emerged within 4 weeks of treatment, and were maintained throughout the remaining 8 weeks of the DB phase. The burden of LBP, which was observed on all aspects of HRQL, was either eliminated or significantly reduced for each domain as a function of 12 weeks of BTDS treatment compared to placebo.