

## **Comparable Analgesic Efficacy of Buprenorphine Transdermal System (BTDS) in Patients Over and Under 65 Years of Age**

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### **Purpose**

BTDS is a transdermal delivery system that provides continuous delivery of buprenorphine, a mu opioid partial agonist, over a 7-day period. This analysis investigated the analgesic efficacy of BTDS in patients <65 years old and ≥65 years old with moderate to severe chronic low back pain.

### **Method**

The efficacy of BTDS with respect to the primary efficacy endpoint from two 12-week studies, defined as the score for "average pain over the last 24 hours" at week 12 of double-blind treatment, was analyzed separately for each study by age subgroups (<65 year-old and ≥65 year-old). The first study evaluated the superiority of BTDS 20 and immediate release oxycodone (40 mg/day) to BTDS 5 in opioid experienced patients; the second study compared the efficacy of BTDS 10/20 to placebo in opioid naïve patients.

### **Results**

In both studies, patients in the <65 and ≥65 age subgroups were similar in race and weight across treatment groups. In the 1<sup>st</sup> study, gender distribution and discontinuation rate were different among patients ≥65. In the 2<sup>nd</sup> study, the gender distribution was similar between the age subgroups and discontinuation rates were lower in patients <65 across treatments.

Improvement in the week-12 "average pain over the last 24 hours" scores was greater for patients treated with BTDS 20 (compared to BTDS 5 in the 1<sup>st</sup> study) or BTDS 10/20 (compared to placebo in the 2<sup>nd</sup> study) in both <65 and ≥65 age subgroups. Similar results were seen with immediate release oxycodone (compared with BTDS 5). In the 1<sup>st</sup> study, the LS means at week 12 for the above age subgroups were 3.67 and 3.61 for BTDS 20 (decreased from baseline mean of 6.46 and 6.50), respectively, compared to 4.24 and 4.09 for BTDS 5 after treatment. In the 2<sup>nd</sup> study, the LS means at week-12 for the above age subgroups were 3.75 and 3.67 for BTDS 10/20 (decreased from baseline mean of 7.25 and 7.17), respectively, compared to 4.36 and 3.82 for placebo after treatment.

### **Conclusions**

The treatment effect of BTDS is similar across age groups with respect to the score for "average pain over the last 24 hours" at week 12.