

# DER DEUTSCHE SCHMERZ- und PALLIATIVTAG 2008

## Anmeldung eines wissenschaftlichen Beitrages

**Titel:** PATIENT RELEVANT OUTCOMES OF A TREATMENT WITH OROS® HYDROMORPHONE (JURNISTA®) DURING A 3 MONTH PERIOD IN PATIENTS WITH CHRONIC SEVERE PAIN DUE TO OSTEOPOROSIS IN A DAILY ROUTINE SETTING

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**Objective:** Chronic pain in osteoporosis mainly back pain is caused by fracture related mechanical displacement of the spine with resulting hyperkyphosis, muscle spasm, and osteoarthritic changes in the vertebral joints. Severe chronic pain leads to impairment of activities of daily living and thus results in reduced quality of life. Reduced mobility due to pain accelerates the progression of bone loss. Physical therapy, which is important to avoid disease progression, is often not feasible because of the patients pain. Accordingly adequate pain control is crucial in the treatment of osteoporosis. A novel, once-daily, extended-release hydromorphone formulation was developed that uses the oral osmotic (OROS®) push-pull system to provide pain relief during a 24 hours dosing interval.

**Method:**

Planned interim analysis of a multicenter, prospective, non-interventional, open study (OROS-ANA-4001) to obtain data on pain control and treatment satisfaction under a therapy with OROS® hydromorphone of the first 100 patients (300 planned in total) with chronic severe pain due to osteoporosis during a 3 month treatment under daily routine conditions. With the exception of short-acting opioids for break-through pain, patients should not be treated with other opioids of WHO-stage III. A total of 6 visits should have been performed, on day 0 (V1), 6 and 15 as well as at the end of first, second and third month (V6). The dosing regimen was at the discretion of the treating physician. Primary endpoints inter alia: treatment satisfaction, patients physical therapy capability. Secondary endpoint inter alia: Brief Pain Inventory (BPI). Impact of pain on activities of daily living was assessed using the Brief Pain Inventory (BPI), assessed on a numeric rating scale (NRS 0-10). Patients/Investigators rated treatment satisfaction in regard to both: pain control and tolerability on a verbal rating scale: very satisfied, satisfied, sufficiently satisfied, not satisfied. Physical therapy capability was assessed as: very good, good, sufficient or poor. Sleep quality during the past four weeks was assessed via 6 questions on a verbal rating scale (1 = all of the time to 6 = none of the time). Additionally questions on individually defined quality of life were intraindividually assessed over the time using 4 point verbal rating scale (no, slight, high and extreme interference). Previous/concomitant medication and adverse events were documented. Pre-post-changes between V1 and V6 were tested with the Wilcoxon test for dependent samples. Missing values were replaced using the last observation carried forward (LOCF) method.

**Results:**

100 patients were available for the safety analysis (80.0 % of the patients were female. Mean age was 69.1 years), 94 for the ITT analysis. On average patients suffered from chronic pain for 6.1 years. Mean dose of OROS® hydromorphone was 15.1 mg/d (median: 8.1). In BPI assessments for worst pain during previous week, least pain, average pain and pain right now improved all significantly from baseline to endpoint ( $p < 0.0001$ ). The BPI interference of pain with general activities, the impact on mood, the effect on walking abilities, the normal work, the relations with others, the pain at sleep, by pain affected quality of life and the resulting mean pain interference total score improved all significantly from baseline to endpoint ( $p < 0.0001$ ). Compared to baseline treatment satisfaction improved in 63.9 %, the physical therapy capability in 69.6 % of patients ( $p < 0.0001$ ). Sleep quality improved significantly in all 6 variables ( $p < 0.0017$ ). Both quality of life assessments regarding daily activities and social activities limited by pain improved significantly ( $p < 0.0001$ ). Compared to baseline, 42.4 % of patients ( $n = 28/66$ ) reported a better ease of use, 44.8 % ( $n = 30/67$ ) a better independence to planning of daily routine, 61.8 % ( $n = 42/68$ ) a better protection from recurrent pain and 50.7 % ( $n = 34/67$ ) a higher confidence in pain medication ( $p < 0.0001$  for all). At last visit 32.4 % ( $n = 22/68$ ) of patients took only a single tablet per day in total. 238 adverse events were observed in 76 patients, in 4 patients serious adverse events (all not related to study drug). Adverse event profile was consistent with the one known for OROS® hydromorphone.

**Conclusion:**

A treatment with OROS® hydromorphone once daily in patients with chronic severe pain due to osteoporosis provides significant improvements in patient relevant outcome parameters, like the reduced impact of pain on activities of daily living, physical therapy capability, sleep or individual quality of life.