

## Evaluation of Lacosamide in Diabetic Neuropathic Pain Trials

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To evaluate the efficacy and safety of the investigational antinociceptive and anticonvulsant drug lacosamide dosed at 400mg/day in the treatment of diabetic neuropathic pain, data were collected from Phase II and III double-blind, randomized, placebo-controlled trials. Three fixed-dose trials (SP742, SP743, SP768) contained a 12-week maintenance period; the Phase II flexible-dose trial (SP614) consisted of a 4-week maintenance period. Primary outcome was within-subject change in average daily pain score (11-point pain scale) from baseline to the last 4 weeks of maintenance for the fixed-dose trials and from baseline to the end of maintenance for the flexible-dose trial.

Subjects receiving lacosamide 400 mg/day (n=426) showed numerically reduced pain scores over placebo (n=291) in all trials. Results were statistically significant in two trials (SP614;  $P=.04$  SP742;  $P=.01$ ) and at the level of significance in SP768 ( $P=.0507$ ) for the primary variable. Significance was not reached in SP743, due to a strong placebo effect at the final visit. When using the secondary variable of change from baseline to the entire maintenance phase, lacosamide 400mg/day significantly reduced pain over placebo in the fixed-dose trials ( $P=.02$ ,  $P=.01$  and  $P=.007$  for SP742, SP743 and SP768, respectively). Treatment with 400 mg/day lacosamide resulted in the occurrence of four adverse events with an incidence  $>5\%$  and greater than placebo: dizziness (13.8%), fatigue (7.7%), nausea (6.8%), and tremor (5.6%).

Lacosamide 400mg/day significantly reduced pain and showed good tolerability in clinical trials of diabetic neuropathic pain.