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An open-label, long-term, phase III extension trial of duloxetine in Japanese patients with fibromyalgia.

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Abstract

OBJECTIVES:

We aimed to evaluate the long-term safety and efficacy of duloxetine 60 mg in Japanese patients with fibromyalgiaenrolled from a preceding randomized, placebo-controlled, phase III duloxetine trial.

METHODS:

This was a long-term, open-label extension study. Patients received oral duloxetine once daily at a dose of 20 mg for 1 week, followed by 40 mg for 1 week, and then 60 mg for 48 weeks. The primary outcome was the frequency of adverse events (AEs) and adverse drug reactions (ADRs) of duloxetine. Efficacy and health outcomes were assessed.

RESULTS:

In total, 149 patients were enrolled from the preceding study. The median length of treatment was 364.0 days. The incidence of AEs and ADRs was 92.6 and 63.8%, respectively. ADRs occurring at an incidence of ≥5% were somnolence, constipation, nausea, weight increase, thirst, and malaise. The proportion of patients with mild, moderate, and severe AEs was 80.5, 10.1, and 2.0%. There were no serious treatment-related AEs in this study. The Brief Pain Inventory average pain score improved at all time-points compared with baseline (mean change ± standard deviation at Week 50 was -1.31 ± 1.70).

CONCLUSIONS:

Duloxetine was safe and effective in the long-term treatment of Japanese patients with fibromyalgia.