

Fibromyalgia is a chronic, multisymptomatic disorder generally causing widespread pain, affecting up to 5% of the population and disproportionately affecting middle-aged women. While many patients report inadequate relief from current treatments, serotonin-norepinephrine reuptake inhibitors (SNRIs) have demonstrated promising results in pain reduction. Drug-X is a novel SNRI previously shown to treat neurogenic orthostatic hypertension and may have therapeutic potential for fibromyalgia. Here, we report on the results of a Phase II, randomized, double-blind, placebo-controlled clinical trial assessing the efficacy of 5 mg and 20 mg of Drug-X administered daily over 6 weeks to adults meeting the 1990 American College of Rheumatology (ACR) fibromyalgia criteria. The primary endpoint for this study investigated change from baseline in daily pain, reported on an 11-point numeric scale (Pain-NRS). Secondary endpoints included the Patient's Global Impression of Change (PGI-C) and Fibromyalgia Impact Questionnaire (FIQ), and exploratory endpoints assessed fatigue with the Daily Fatigue Score – Fibromyalgia (DFS-Fibro) and Multidimensional Assessment of Fatigue (MAF). Treatment with 20 mg of Drug-X demonstrated a trend towards improvement in reported Pain-NRS scores, consistent with previously established SNRI therapeutic effects. Moreover, these trends extend across the key secondary endpoints, with significant improvements in PGI-C scores ($p=0.0070$), FIQ scores ($p=0.0097$), DFS-Fibro physical ($p=0.0384$), DFS-Fibro overall ($p=0.0453$), and MAF scores ($p=0.0052$). Adverse events (AEs) for Drug-X were considered mild and within expected norms for other SNRIs. Altogether, these data demonstrate consistent improvements across all reported measures of pain, fatigue, and patient perception of treatment with a daily, 20 mg dose of Drug-X and supporting its use as a novel modality for fibromyalgia treatment. Although the primary endpoint narrowly missed statistical significance, there is clear evidence supporting further investigation in a more robust Phase III clinical trial to confirm the therapeutic potential of Drug-X.