# SAFETY AND TOLERABILITY OF DULOXETINE IN THE TREATMENT OF MAJOR DEPRESSIVE DISORDER: ANALYSIS OF POOLED DATA FROM EIGHT PLACEBO-CONTROLLED CLINICAL TRIALS

Barraco Alessandra, Mancini Michele, Rossi Andrea

Eli Lilly Italia S.p.A.

Objective: To examine the safety and tolerability of the antidepressant duloxetine across multiple studies for major depressive
disorder (MDD).
Method: Safety data were integrated from the acute phases of eight double-blind, placebo-controlled trials in which patients were randomized to duloxetine (40–120 mg/d; n¼1139) or placebo (n¼777) for up to 9 weeks. Safety assessments included serious adverse
event reports, rates of discontinuation, spontaneously reported treatment-emergent adverse events, changes in vital signs and laboratory values, and electrocardiograms.
Results: The rates of serious adverse events for duloxetine- and placebo-treated patients were 0.3% and 0.6%, respectively (p¼0.282). Adverse events led to discontinuation in 9.7% of duloxetine-treated patients, compared with 4.2% of patients receiving placebo (p<0.001). Treatment-emergent adverse events with an incidence for duloxetine 5.0% and significantly greater than placebo were nausea, dry mouth, constipation, insomnia, dizziness, fatigue, somnolence, increased sweating and decreased appetite. Mean changes in blood pressure and heart rate were small, and the incidence of increases above normal ranges was low. Duloxetine-treated patients had a mean decrease in weight of 0.5 kg compared with an increase of 0.2 kg for patients receiving placebo (p<0.001). No significant differences were found between duloxetine and placebo in the incidence of potentially clinically significant laboratory values at anytime while on treatment.
Conclusion: These results are consistent with those obtained previously from smaller pooled data sets, and suggest that duloxetine is safe and well tolerated in patients with MDD.