5.2. Tabular Listing of All Clinical Studies

Cymbalta
(Duloxetine Hydrochloride)
Fibromyalgia

Date approved by Lilly: 16 July 2007

Lilly Research Laboratories
Eli Lilly and Company
Indianapolis, Indiana, USA

Table Abbreviations:

ACR = American College of Rheumatology

BID = twice daily

FIQ = Fibromyalgia Impact Questionnaire

FMS = fibromyalgia syndrome

MDD = Major Depressive Disorder

No = Number

PGI-I = Patient's Global Impressions of Improvement

PO = by mouth

QD = once daily

Table 5.2.1. Tabular Listing of Clinical Studies
Cymbalta (duloxetine hydrochloride)
Fibromayalgia

Study Identifier; Location; Status; Report Type	Objectives	Enrollment Start Status End (Total/Goal)	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	No. Patients Completed No. Patients Entered	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint(s)
F1J-MC-HMEF Modual 5; Completed; Clinical Study Report	Safety and Efficacy	Sep 2005 Complete Dec 2006 (330/320)	Multicenter, randomized, parallel, double-blind, fixed-dose, placebo-controlled, Phase 3 study	Duloxetine 60 mg QD PO Duloxetine 120 mg QD PO Placebo QD PO	204 completed 330 randomized	Male or female patients ≥18 years old diagnosed with FMS, as defined by ACR, with or without MDD.	Up to 58 weeks (27 weeks of double-blind therapy)	Change in pain severity as measured by the average pain item of the Brief Pain Inventory score (BPI-modified short score) and change in patient-reported improvement on the PGI-I scale

Table 5.2.1. Tabular Listing of Clinical Studies
Cymbalta (duloxetine hydrochloride)
Fibromayalgia (Continued)

Study Identifier; Location; Status; Report Type	Objectives	Enrollment Start Status End (Total/Goal)	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	No. Patients Completed No. Patients Entered	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint(s)
F1J-MC-HMEH Module 5; Completed; Clinical Study Report	Safety and Tolerability	July 2005 Complete March 2007 (307/320)	Multicenter, parallel, Phase 3, one year safety study consisting of an 8-week open-label period followed by a 52-week double-blind, randomized period.	Duloxetine 30 mg QD Duloxetine 60 mg QD Duloxetine 120 mg QD	195 completed (double-blind study phase) 350 entered	Female and male outpatients ≥18 years of age with diagnosis of FM, as defined by the ACR, and score at least 4 on the average pain item of the BPI – Modified Short Form at Visit 1 and Visit 2	8 weeks open-label, followed by 52 weeks double-blind, and a 2-week taper period (up to 62 weeks treatment duration)	Long-term safety and tolerability measures

Table 5.2.1. Tabular Listing of Clinical Studies
Cymbalta (duloxetine hydrochloride)
Fibromayalgia (Continued)

Study Identifier; Location; Status; Report Type	Objectives	Enrollment Start Status End (Total/Goal)	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	No. Patients Completed No. Patients Entered	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint(s)
F1J-MC-HMCJ Module 5; Completed; Clinical Study Report	Safety and Efficacy; dose response study	June 2005 Complete Nov 2006 (520/490)	Multicenter, randomized, parallel, double-blind, placebo-controlled, Phase 3 study	Duloxetine 20 mg QD PO Duloxetine 60 mg QD PO Duloxetine 120 mg QD PO Placebo QD PO	325 completed (3-Month Acute Therapy Phase) 277 completed (6-Month Therapy Phase) 520 randomized	Male or female patients ≥18 years old diagnosed with FM, as defined by ACR, with or without MDD.	15 weeks acute double-blind therapy; 13 weeks continuation therapy, 28 weeks open-label, and a 2-week taper period	Reduction of pain, as measured by the average pain item on the BPI and the PGI-I
F1J-MC-HMBO Module 5; Completed; Clinical Study Report	Safety and Efficacy	July 2001 Complete March 2002 (207/200)	Double-blind, randomized, parallel, multicenter, Phase 2 study	Duloxetine 60 mg BID PO Placebo BID PO	124 completed 555 entered	Female and male outpatients ≥18 years of age with primary fibromyalgia (FM), as defined by the American College of Rheumatology (ACR), with or without MDD	12 weeks	Reduction of pain as measured by the Fibromyalgia Impact Questionnaire (FIQ) Pain Item and the FIQ Total Score

Table 5.2.1. Tabular Listing of Clinical Studies
Cymbalta (duloxetine hydrochloride)
Fibromayalgia (Concluded)

Study Identifier; Location; Status; Report Type	Objectives	Enrollment Start Status End (Total/Goal)	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	No. Patients Completed No. Patients Entered	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint(s)
F1J-MC-HMCA Module 5; Completed; Clinical Study Report	Safety and Efficacy	Nov 2002 Complete Oct 2003 (354/345)	Double-blind, randomized, parallel, multicenter, Phase 3 study	Duloxetine 60 mg BID PO Duloxetine 60 mg QD PO Placebo BID PO.	216 completed 746 entered	Female outpatients ≥18 years of age with primary FM, as defined by the ACR, with or without MDD	12 weeks	Reduction of pain as measured by the average pain item of the Brief Pain Inventory (BPI)