I.C.3.3.

Tabular Listings of all Clinical Studies

I.C.3.3. Tabular Listing of All Clinical Studies

Cymbalta™
(Duloxetine Hydrochloride)
Major Depressive Disorder

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

NOTE: Section IV.B.1.5 has not been submitted, as requested by TGA – see overall table of contents for more detail

Sections IV.B.1.6 – IV.B.1.7 have been removed and are included in SUI Part IV submitted to Stream 3 – see overall table of contents for more detail

These studies have not been submitted, however, for your information they have not been removed from the Tabular Listing.

Table I.C.3.3. Listing of Clinical Studies

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-HMAQa Section IV.B.1.1.1.1; Complete; Full	Safety and Efficacy	February 1999 Complete May 2000	Multicenter, parallel group, double-blind, randomized placebo-controlled, blinded placebo lead-in and lead-out	Duloxetine capsules: 10 mg, 20 mg Fluoxetine capsules: 20 mg Placebo capsules Duloxetine: 20-60 mg PO BID Fluoxetine: 20 mg PO QD Placebo	N=173 (M=62; F=111) 41.4 years (18.7-65)	DSM-IV-defined MDD (current episode duration ≥2 weeks); CGI-Severity score ≥4; clinician-rated $HAMD_{17}$ total score ≥15 at Visits 1 and 2	8 weeks	$HAMD_{17}$ Total Score

(continued)

Table I.C.3.3. Listing of Clinical Studies

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-HMAQb Section IV.B.1.1.1.2; Complete; Full	Safety and Efficacy	March 1999 Complete January 2001	Multicenter, parallel group, double-blind, randomized placebo-controlled, blinded placebo lead-in and lead-out	Duloxetine capsules: 10 mg, 20 mg Fluoxetine capsules: 20 mg Placebo capsules Duloxetine: 20-60 mg PO BID Fluoxetine: 20 mg PO QD Placebo	N=194 (M=65; F=129) 40.4 years (18.9-64.4)	DSM-IV–defined MDD (current episode duration ≥2 weeks); CGI-Severity score ≥4; clinician-rated $HAMD_{17}$ total score ≥15 at Visits 1 and 2	8 weeks	$HAMD_{17}$ Total Score

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-HMATb Section IV.B.1.1.1.3; Complete; Full	Safety and Efficacy	March 2000 Complete February 2001	Multicenter, parallel, double-blind, randomized, placebo- and active comparator-controlled study with blinded placebo lead-in and placebo lead-out	Duloxetine capsules: 20 mg Paroxetine capsules: 20 mg Placebo capsules Duloxetine: 20 mg or 40 mg PO BID Paroxetine: 20 mg PO QD Placebo	N=353 (M=136; F=217) 40.5 years (18.2-78.2)	DSM-IV–defined MDD; CGI-Severity score ≥4 at Visits 1 and 2; clinician-rated $HAMD_{17}$ total score ≥15 at Visits 1 and 2	8 weeks	$HAMD_{17}$ Total Score
F1J-MC-HMATa Section IV.B.1.1.1.4; Complete; Full	Safety and Efficacy	March 2000 Complete April 2001	Multicenter, parallel, double-blind, randomized, placebo- and active comparator-controlled study with blinded placebo lead-in and placebo lead-out	Duloxetine capsules: 20 mg Paroxetine capsules: 20 mg Placebo capsules Duloxetine: 20 mg or 40 mg PO BID Paroxetine: 20 mg PO QD Placebo	N=354 (M=136; F=218) 43.7 years (18.0-82.2)	DSM-IV–defined MDD; CGI-Severity score ≥4 at Visits 1 and 2; clinician-rated $HAMD_{17}$ total score ≥15 at Visits 1 and 2	8 weeks	$HAMD_{17}$ Total Score

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-HMAYa Section IV.B.1.1.1.5; Complete; Full	Safety and Efficacy	November 2000 Complete July 2002	Multicenter, parallel, double-blind, randomized, placebo- and active comparator-controlled study with blinded placebo lead-in and placebo lead out	Duloxetine capsules: 20 mg Paroxetine capsules: 20 mg Placebo capsules Duloxetine: 40 or 60 mg PO BID Paroxetine: 20 mg PO QD Placebo	N=367 (M=100; F=267) 43.4 years (19.3-74.4)	DSM-IV–defined MDD; CGI-Severity score ≥4 at Visits 1 and 2; clinician-rated $HAMD_{17}$ total score ≥15 at Visits 1 and 2	34 weeks	$HAMD_{17}$ Total Score
F1J-MC-HMAYb Section IV.B.1.1.1.6; Complete; Full	Safety and Efficacy	October 2000 Complete July 2002	Multicenter, parallel, double-blind, randomized, placebo- and active comparator-controlled study with blinded placebo lead-in and placebo lead out	Duloxetine capsules: 20 mg Paroxetine capsules: 20 mg Placebo capsules Duloxetine: 40 or 60 mg PO BID Paroxetine: 20 mg PO QD Placebo	N=392 (M=119; F=273) 45.2 years (20.1-76.7)	DSM-IV–defined MDD; CGI-Severity score ≥4 at Visits 1 and 2; clinician-rated $HAMD_{17}$ total score ≥15 at Visits 1 and 2	34 weeks	$HAMD_{17}$ Total Score

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-HMBHa Section IV.B.1.1.2.1; Complete; Full	Safety and Efficacy	November 2000 Complete May 2001	Multicenter, double-blind, placebo-controlled, parallel-group study	Duloxetine capsules: 20 mg Placebo capsules Duloxetine: 60 mg PO QD Placebo	N=245 (M=82; F=163) 42.4 years (18.6-77.7)	DSM-IV–defined MDD; CGI-Severity score ≥4 at Visits 1 and 2; clinician-rated $HAMD_{17}$ total score ≥15 at Visits 1 and 2	9 weeks	$HAMD_{17}$ Total Score
F1J-MC-HMBHb Section IV.B.1.1.2.2; Complete; Full	Safety and Efficacy	November 2000 Complete May 2001	Multicenter, double-blind, placebo-controlled, parallel-group study	Duloxetine capsules: 20 mg Placebo capsules Duloxetine: 60 mg PO QD Placebo	N=267 (M=83; F=184) 40.9 years (19.2-82.9)	DSM-IV–defined MDD; CGI-Severity score ≥4 at Visits 1 and 2; clinician-rated $HAMD_{17}$ total score ≥15 at Visits 1 and 2	9 weeks	$HAMD_{17}$ Total Score

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-HMBC Section IV.B.1.1.2.3; Ongoing	Safety and Efficacy	March 2002 Ongoing	Randomized, double-blind, placebo-controlled, parallel group study	Duloxetine capsules: 20 mg Placebo capsules Duloxetine: 60 mg PO QD Duloxetine 60 mg PO BID (rescue phase) Placebo	N=163 as of 01 November 2002) ≥18 years	DSM-IV–defined MDD; CGI-Severity score ≥4 at Visits 1 and 2 and $HAMD_{17}$ total score ≥18 at Visits 1 and 2. Must have had one depressive episode.	38 weeks	Time to relapse during continuation phase using the log rank test
F1J-MC-HMAU Section IV.B.1.2.1; Complete; Abbreviated	Safety and Efficacy	February 2000 Complete Oct 2001	Multicenter, long-term, open-label	Duloxetine capsules: 20 mg Duloxetine: 40 – 60 mg PO BID	N=1279 (M=351; F=928) 44.4 years (18.1-87.4)	DSM-IV–defined MDD; CGI-Severity score ≥3 at Visits 1 and 2	52 weeks	Safety

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-HMAG Section IV.B.1.3.1; Complete; Abbreviated	Safety and Efficacy	February 1993 Complete November 1994	Double-blind, stratified, randomized, parallel design with an "enriched" population	Duloxetine tablets: 10 mg Placebo tablets Duloxetine: 20 mg PO QD Placebo	N=105 (M=48; F=57) 40.4 years (19.7-64.7)	DSM-III-R-defined unipolar MDD; for at least 1 month. $HAMD_{17}$ total score of ≥17 at Visit 1.	10 weeks	$HAMD_{17}$, MADRS Total Scores
F1J-MC-HMAHb Section IV.B.1.3.2; Complete; Abbreviated	Safety and Efficacy	November 1993 Complete September 1995	Double-blind, placebo-controlled, randomized, parallel design	Duloxetine tablets: 10 mg Duloxetine tablets: 20 mg Placebo tablets Duloxetine: 20 or 30 mg PO QD Placebo	N=177 (M=75; F=102) 36.5 years (19.1-68.3)	DSM-III-R-defined MDD. $HAMD_{17}$ total score of ≥17 at Visit 1.	54 weeks	$HAMD_{17}$, MADRS, CGI-Severity, CGI-Improvement Scores

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-HMAI Section IV.B.1.3.3; Complete; Abbreviated	Safety and Efficacy	December 1993 Complete January 1996	Randomized, parallel, double-blind, placebo- and active comparator-controlled study	Duloxetine tablets: 5 mg Duloxetine tablets: 10 mg Duloxetine tablets: 20 mg Clomipramine capsules: 25 mg Clomipramine capsules: 50 mg Placebo capsules Duloxetine: 5, 10, or 20 mg PO QD Clomipramine: 150 mg PO BID Placebo	N=648 (M=212; F=436) 42.4 years (17.8-84.1)	DSM-III-R-defined unipolar MDD. $HAMD_{17}$ total score of $\geq$18.	8-week acute phase plus a double-blind extension phase for a total of 55 weeks	$HAMD_{17}$ Total Scores
F1J-EW-E001 Section IV.B.1.3.4; Complete; Abbreviated	Safety and Efficacy	March 1993 Complete October 1993	Single arm, noncontrolled	Duloxetine tablets: 20 mg Duloxetine: 20 mg PO QD	N=93 (M=31; F=62) 38.0 years (18.4-63.8)	DSM-III-R-defined unipolar MDD	6 weeks	$HAMD_{17}$ Total Scores

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-US-HMBY Section IV.B.1.4.1; Ongoing	Safety	June 2002 Ongoing	Double-blind, dose escalation	Duloxetine capsules: 30 mg Placebo capsules Duloxetine: 60-120 mg PO QD Placebo	N=128 as of 01 November 2002 ≥18 years	DSM-IV-defined MDD; $HAMD_{17}$ total score ≥15 at Visits 1 and 2	7 weeks	Safety
F1J-US-HMBZ Section IV.B.1.4.2; Ongoing	Safety and Efficacy	November 2002 Ongoing	Multicenter, open-label, flexible dose	Duloxetine capsules: 30 mg Duloxetine: 60-120 mg PO QD	No patients enrolled as of 01 November 2002. ≥18 years	DSM-IV-defined MDD; $HAMD_{17}$ total score ≥15 and CGI-Severity total score ≥4 at Visits 1 and 2	12 weeks	Compare the stabilized duloxetine dose in treatment-naïve patients and SSRI switch patients

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-HMBO Section IV.B.1.5.1; Complete, Full	Safety and Efficacy	July 2001 Complete March 2002	Parallel, double-blind, placebo-controlled	Duloxetine capsules: 20 mg Placebo capsules Duloxetine: 60 mg PO BID Placebo	N=207 (M=23; F=184) 49.1 years (18.8-79.7)	Met criteria for fibromyalgia as defined by the American College of Rheumatology Score of ≥4 on the Fibromyalgia Impact Questionnaire at Visits 1 and 2	12 weeks	FIQ

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-HMAW Section IV.B.1.5.2; Ongoing	Safety and Efficacy	Acute Phase: June 2001 Completed March 2002 Extension phase: Ongoing	Acute phase: Double-blind, randomized, parallel, placebo-controlled	Duloxetine capsules: 20 mg Placebo capsules Duloxetine: 60 mg PO BID Duloxetine: 60 mg PO QD Duloxetine: 20 mg PO QD Placebo	Acute phase: N=457 (M=281; F=176) 60.1 years (22.4- 88.8) Extension phase: N=338 (as of 01 November 2002) ≥18	Pain due to bilateral peripheral neuropathy caused by Type I or II diabetes mellitus. Score of at least 3 on MNSI. Daily pain present for ≥6 month.	Acute phase: 12 weeks Extension phase: 52 weeks	Weekly mean of the 24-hour average pain severity scores recorded daily on an 11-point Likert scale

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-HMBT Section IV.B.1.5.3; Ongoing	Safety and Efficacy	July 2002 Ongoing	Open-label safety study	Duloxetine capsules: 30 mg Duloxetine: 60 mg PO BID Duloxetine: 120 mg PO QD	N=453 (as of 01 November 2002) ≥18	Pain due to bilateral peripheral neuropathy caused by Type I or II diabetes mellitus. Score of at least 3 on MNSI. Daily pain present for ≥6 months.	28 weeks	MNSI
F1J-MC-HMCA Section IV.B.1.5.4; Ongoing	Safety and Efficacy	November 2002 Ongoing	Parallel, double-blind, placebo-controlled study	Duloxetine capsules: 30 mg Placebo capsules Duloxetine: 60 mg BID PO Duloxetine 60 mg QD PO Placebo	0 patients randomized as of 01 November 2002. ≥18	Fibromyalgia as defined by the American College of Rheumatology. A score of ≥4 on the average pain item on the BPI at Visit 2.	13 weeks	Brief Pain Inventory-average pain item

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-HMAV(a) Section IV.B.1.5.5; Ongoing	Safety and Efficacy	October 2002 Ongoing	Multicenter, parallel, double-blind, randomized, placebo-controlled	Duloxetine capsules: 30 mg Placebo capsules Duloxetine: 60 mg PO QD Duloxetine: 60 mg PO BID Placebo Routine care	N=330 (planned, 0 patients randomized as of 01 November 2002) ≥18 years	Pain due to bilateral diabetic neuropathy caused by Type I or II diabetes mellitus	12 weeks 52-week continuation	Reduction in average pain severity as measured by an 11-point Likert scale
F1J-MC-HMAV(b) Section IV.B.1.5.6; Ongoing	Safety and Efficacy	October 2002 Ongoing	Multicenter, parallel, double-blind, randomized, placebo-controlled	Duloxetine capsules: 30 mg Placebo capsules Duloxetine: 60 mg PO QD Duloxetine: 60 mg PO BID Placebo Routine care	N=330 (planned, 0 patients randomized as of 01 November 2002) ≥18 years	Pain due to bilateral diabetic neuropathy caused by Type I or II diabetes mellitus	12 weeks 52-week continuation	Reduction in average pain severity as measured by an 11-point Likert scale

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-US-HMCB Section IV.B.1.5.7; Complete	Safety and Efficacy	March 2002 Ongoing	Double-blind, placebo controlled	Duloxetine capsules: 30 mg Placebo capsules Duloxetine: 60 mg QD PO Placebo	N=282 ≥18 years	DSM-IV-defined MDD, $HAMD_{17}$ total score ≥15, CGI-Severity total score ≥4 at both Visits 1 and 2, and BPI average pain score (question 3) of ≥2 at Visit 2	9 weeks	BPI-question 3

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J- MC-SBAT IV.B.1.6.1; Complete; Full	Safety and Efficacy	December 2000 Complete April 2002	Double-blind, stratified, randomized, parallel, placebo-controlled, multicenter study Blinded placebo lead-in	Duloxetine capsules: 20 mg Placebo capsules Duloxetine: 40 mg PO BID Placebo	N=494 (F=494) 52.9 years (24.2-82.6)	SUI Average of at least 7 incontinent episodes per week before enrollment. Positive Cough Stress Test, positive Stress Pad Test result (>2.0 g); first sensation of bladder fill (urge to void) ≥100 mL, bladder capacity >400 mL; normal day and night urinary frequency	12 weeks (subjects completing trial are eligible to continue in Study SBAU)	IEF – percent change from baseline; percent change for I-QOL total score

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J- MC-SBAV IV.B.1.6.2; Complete; Full	Safety and Efficacy	November 2000 Complete February 2002	Double-blind, stratified, randomized, parallel, placebo-controlled, multicenter study Blinded placebo lead-in	Duloxetine capsules: 20 mg Placebo capsules Duloxetine: 40 mg PO BID Placebo	N=683 (F=683) 52.8 years (22.5-83.8)	SUI Average of at least 7 incontinent episodes per week before enrollment. Positive Cough Stress Test, positive Stress Pad Test result (>2.0 g); first sensation of bladder fill (urge to void) ≥100 mL, bladder capacity >400 mL; normal day and night urinary frequency	12 weeks (subjects completing trial are eligible to continue in Study SBAW)	IEF percent change from baseline; percent change for I-QOL total score

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-SBAX Section IV.B.1.6.3; Complete; Full	Safety and efficacy	May 2001 Complete May 2002	Double-blind, stratified, randomized, parallel, placebo-controlled, multicenter study	Duloxetine capsules: 20 mg Placebo capsules Duloxetine: 40 mg PO BID Placebo	N=458 (F=458) 53.2 years (27-79)	SUI Average of at least 7 incontinent episodes per week before enrollment. Positive Cough Stress Test, positive Stress Pad Test result (>2.0 g); first sensation of bladder fill (urge to void) ≥100 mL, bladder capacity >400 mL; normal day and night urinary frequency.	Duloxetine: 12 weeks Placebo: 12 weeks	IEF percent change from baseline; percent change for I-QOL total score

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-SAAW Section IV.B.1.6.4; Completed; Full	Safety and efficacy	June 1998 Complete September 1999	Double-blind, randomized, placebo-controlled study	Duloxetine capsules: 10 mg Duloxetine capsules: 20 mg Placebo capsules Duloxetine: 20, 40, or 80 mg/day PO Placebo	N=553 (F=553) 49.6 years (27.1-65.7)	Subjects with SUI reporting ≥4 incontinent episodes per week	12 weeks	IEF
F1J-MC-SBBL Section IV.B.1.6.5; Ongoing	Safety and efficacy	June 2001 Ongoing	Double-blind, stratified, randomized, parallel, placebo-controlled, multicenter, pilot study	Duloxetine capsules: 20 mg Placebo capsules Duloxetine: 40-60 mg BID PO Placebo	N=195 (as of 01 November 2002). (F=195) (as of 01 November 2002). 18-78 years	Subjects with bladder overactivity defined as bothersome urinary urgency or UUI for a minimum of three consecutive months	12 weeks	24-hour diary

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-SBAF Section IV.B.1.6.6; Ongoing	Safety and efficacy	January 2002 Ongoing	Double-blind, randomized, parallel, placebo-controlled multicenter study	Duloxetine capsules: 20 mg Placebo capsules Duloxetine: 40 mg BID PO plus PFMT Placebo plus PFMT	N=153 (as of 01 November 2002) (F=153) (as of 01 November 2002) 18-75 years	Subjects with symptoms of SUI, including ≥2 accidential urine leaks per day	Active therapy: 12 weeks Open-label period: until duloxetine is commercially available or the sponsor stops the study	IEF I-QOL
F1J-MC-SBBA Section IV.B.1.6.7; Ongoing	Safety and efficacy	November 2001 Ongoing	Double-blind, randomized, parallel, placebo-controlled., multicenter study	Duloxetine capsules: 20 mg Placebo capsules Duloxetine: 40 mg PO BID Placebo	N=424 (as of 01 November 2002) F=424 (as of 01 November 2002) ≥18 years	Subjects with SUI or mixed incontinence for ≥3 months including ≥1 accidental urine leaks per week	36 weeks	I-QOL improvement

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-SBAU Section IV.B.1.6.8; Ongoing	Safety and efficacy	April 2001 Ongoing	Multicenter, open-label, single-treatment-group extension study to Study F1J-MC-SBAT	Duloxetine capsules: 20 mg Duloxetine: 40 mg PO BID	N=363 (as of 01 November 2002) (F=363) (as of 01 November 2002) ≥18 years	Subjects with SUI (who successfully completed SBAT)	Until duloxetine is commercially available for the treatment of UI or sponsor stops the study	Long-term safety data
F1J-MC-SBAW Section IV.B.1.6.9; Ongoing	Safety and efficacy	February 2001 Ongoing	Multicenter, open-label, single-treatment-group extension study to Study F1J-MC-SBAV	Duloxetine capsules: 20 mg Duloxetine: 40 mg PO BID	N=494 (as of 01 November 2002) (F=494) (as of 01 November 2002) ≥18 years	Subjects with SUI (who successfully completed SBAV)	Until duloxetine is commercially available for the treatment of UI or the sponsor stops the study	Long-term safety data
F1J-MC-SBAY Section IV.B.1.6.10; Ongoing	Safety and efficacy	March 2001 Ongoing	Multicenter, open-label, single-treatment-group	Duloxetine capsules: 20 mg Duloxetine: 40 mg PO BID	N=662 (as of 01 November 2002) (F=662) (as of 01 November 2002) (planned) ≥18 years	Subjects with SUI for ≥3 months prior to study entry	Until duloxetine is commercially available for the treatment of UI or the sponsor stops the study	Long-term safety data

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-SBBM Section IV.B.1.6.11; Ongoing	Safety and efficacy	September 2001 Ongoing	Multicenter, open-label, single-treatment-group extension study to Study F1J-MC-SBAX	Duloxetine capsules: 20 mg Duloxetine: 40 mg BID PO	N=334 (as of 01 November 2002) (F=334) (as of 01 November 2002) ≥18 years	Subjects with SUI (who successfully completed SBAX)	Until duloxetine is commercially available for the treatment of SUI or the sponsor stops the study	Long-term safety data
F1J-MC-SBAB Section IV.B.1.6.12; Ongoing	Safety and efficacy	October 2001 Ongoing	Double-blind, randomized, parallel, placebo-controlled, multicenter study	Duloxetine capsules: 20 mg Placebo capsules Duloxetine: 80 mg/day, given as 40 mg PO BID Placebo	N=42 (as of 01 November 2002) (F=42) (as of 01 November 2002) 18-75 years	Subjects with genuine stress incontinence confirmed on urodynamic studies	Active therapy: 4 weeks Open-label extension: duloxetine 40 mg BID until duloxetine is commercially available or the sponsor stops the study	IEF

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-SBAM Section IV.B.1.6.13; Ongoing	Safety and efficacy	May 2001 Ongoing	Double-blind, stratified, randomized, parallel, placebo-controlled, multicenter study	Duloxetine capsules: 20 mg Placebo capsules Duloxetine: 40-60 mg PO BID Placebo	N=109 (as of 01 November 2002) (F=109) 18-75 years	Subjects electing surgery for severe pure genuine stress incontinence	Active period: up to 12 weeks Open-label period: until duloxetine is commercially available for the treatment of UI or until the sponsor stops the study	Percent change in IEF from baseline to endpoint, and the change in I-QOL

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-SAAA Section IV.B.1.7.1; Completed; Full	Safety and efficacy	December 1993 Complete March 1995	Double-blind, randomized, placebo-controlled study	Duloxetine capsules: 20 mg Duloxetine: 20 mg PO QD	N=92 (F=92)	Outpatients diagnosed with either stress, urge, or mixed incontinence .	3 weeks	CMG, voiding diary, 24-hour pad test, stress pad test, and social activity questionnaire.
F1J-MC-SAAB Section IV.B.1.7.2; Complete; Abbreviated	Safety and efficacy	August 1995 Complete November 1996	Multicenter, double-blind, placebo-controlled, stratified, randomized, parallel study	Duloxetine capsules: 10 mg, 20 mg Placebo capsules Duloxetine 20, 30, and 40 mg/day PO QD Placebo	N=288 (F=288) 54.8 years (22.2-78.7)	Diagnosis of stress or mixed (with a significant stress component) urinary incontinence .	6 weeks	one-hour stress pad test (SPT) weight

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-SAAH Section IV.B.1.7.3; Complete; Abbreviated	Safety and efficacy	August 1996 Complete June 1997	Double-blind, placebo-controlled, randomized, parallel study	Duloxetine capsules: 10 mg, 20 mg Placebo capsules Duloxetine: 30, 40 mg/day QD PO Placebo	N=32 (M=5; F=27) 50.5 years (21-75.5)	One of the following diagnoses: urge urinary incontinence, urinary urgency (absent infection) without incontinence, or reflex neurogenic bladder	Double-Blind: Duloxetine: 1 week or Placebo: 1 week Open-Label: Duloxetine: 12 weeks	DAI
F1J-MC-SAAI Section IV.B.1.7.4; Complete; Abbreviated	Safety and efficacy	April 1996 Complete August 1996	Double-blind, placebo-controlled, randomized, parallel study	Duloxetine capsules: 10 mg, 20 mg Placebo capsules Duloxetine: 30, 40 mg/day QD PO Placebo	N=91 (M=91) 62.5 years (40.5-85.7)	Diagnosis of mild to moderate BPH	Duloxetine: 8 weeks Placebo: 9 weeks	AUA Symptom Index score

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-MC-SAAL Section IV.B.1.7.5; Complete, Abbreviated	Safety and efficacy	May 1996 Complete November 1996	Multicenter, placebo-controlled, double-blind, randomized, crossover study	Duloxetine capsules: 10 mg, 20 mg Oxybutynin capsules: 2.5 mg Placebo capsules Duloxetine: 30/40 mg/day, PO QD Oxybutynin: 7.5/10 mg/day, PO QD Placebo PO QD	N=68 (F=68) 56.88 years (21.87-83.84)	Urinary frequency, urinary urgency, and nocturia	Duloxetine: 4 weeks Oxybutynin: 4 weeks	BUS
F1J-JE-301G Section IV.B.1.8.2.1; Complete; Full	Safety and efficacy	September 1994 Complete January 1996	Open-label study	Duloxetine: 10 mg/day, 5 mg/day, or 20 mg/day administered once per day orally after breakfast	N=43 (F=43) 20-79 years	Stress urinary incontinence	4 weeks	Pad tests as recommended by the ICS, urethral pressure measurement, and cystometrography, final global improvement

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-JE-401G Section IV.B.1.8.2.2; Complete; Full	Safety and efficacy	September 1994 Complete January 1996	Multicenter, open-label study	Duloxetine: 10 mg/day (x 4 weeks) 5 or 20 mg/day (x 4 weeks) administered once a day after breakfast	N=42 Efficacy evaluation: N=31 (Efficacy evaluation M=21; W=10) 20-80 years	Patients diagnosed as having symptoms of urinary frequency, urinary urgency, or urinary incontinence caused by neurogenic bladder with uninhibited detrusor contraction or unstable bladder	4 weeks	Final global improvement rating

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-JE-102G Section IV.B.1.8.2.3; Complete; Full	Safety and efficacy	November 1994 Complete December 1995	Open-label study	Duloxetine capsules: 10 mg Duloxetine: 10 mg PO QD	N=55 51.1 years (22-81)	DSM-III-R classifications of: Major depressive disorder, single episode; Major depressive disorder, recurrent; Depressive disorder, not otherwise specified; Bipolar disorder, depressive	6 weeks	$HAMD_{17}$, global severity (weekly), global improvement (weekly), HAMD score (weekly), and final global improvement

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-JE-221G Section IV.B.1.8.2.4; Complete, Full	Safety and efficacy	April 1994 Complete April 1995	Open-label clinical study (fixed-flexible dose method)	Duloxetine: 5-mg capsules and 10-mg capsules administered orally QD after breakfast	N=78 (M=44; F=34) 44.3 years (20-68)	DSM-III-R classification: Major depression, single episode; Major depression, recurrent; Dysthymia; Depressive disorder not otherwise specified; Adjustment disorder with depressive mood. Subjects with a baseline $HAMD_{17}$ total score of ≥17.	4 weeks	$HAMD_{21}$

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-JE-311G Section IV.B.1.8.2.5; Complete; Full	Safety and efficacy	January 1998 Completed April 2001	Non-blinded study using a single-group, fixed-flexible administration method	Duloxetine: 5 mg capsules, 10 mg capsules, 20 mg capsules taken orally once a day after breakfast	N=73 (M=25; F=23) (30-<65)	Diagnostic classification (DSM-IV): Major depression, single episode; major depression, recurrent; dysthymic disorder; depressive disorder not otherwise specified; or adjustment disorder with depressed mood	26-52 weeks	Final global improvement rating

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-JE-312G Section IV.B.1.8.2.6; Complete; Full	Safety and efficacy	September 1998 Complete March 2000	Non-blind, multicenter collaborative clinical study (single group, fixed flexible dose method)	Duloxetine: 5 mg capsule, 10 mg capsule, 20 mg capsule taken orally once daily after breakfast at a starting dose of 5 mg/day, with flexible dosage of 5 mg to 20 mg/day during Week 2 and later	N=20 ≥65 years	DSM-IV classifications of major depression, single episode; major depression, recurrent; dysthymic disorder; depressive disorder, not otherwise specified; and adjustment disorder with depressed mood. Baseline $HAMD_{17}$ total score of 17 points or higher.	4 weeks	Final global improvement rating

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-JE-313G Section IV.B.1.8.2.7; Complete; Full	Safety and efficacy	August 1998 Complete December 2000	Parallel, intergroup, double-blind study	Duloxetine: 5-mg capsules, 10-mg capsules taken orally after breakfast. Placebo: 5-mg and 10-mg capsules taken orally after breakfast. Trazodone: 25-mg tablets and 25-mg placebo tablets taken orally 3 times daily, after breakfast, lunch, and dinner	N=210 43.2 years (20-69)	DSM-IV classifications: Major depression, single episode; Major depression, recurrent; Dysthymia; Depressive disorder, not otherwise specified; Adjustment disorder with depressed mood. Severity: Baseline total score of 17 points or more on items 1-17 on the HAMD.	4 weeks	$HAMD_{21}$

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-JE-321G Section IV.B.1.8.2.8; Complete; Full	Safety and Efficacy	March 1998 Complete April 2001	Non-blinded single group, fixed-flexible dose study	Duloxetine: 10-mg capsules, 20-mg capsules administered orally once daily after breakfast	N=429 PPS=315 (PPS: M=182; F=133) 20-69 years	DSM-IV: Major depressive disorder, single episode; major depressive disorder, recurrent; dysthymic disorder; bipolar I disorder, most recent episode depressed; bipolar II disorder, recurrent major depressive episodes with hypomaniac episodes	26-52 weeks	Final global improvement ratings

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-JE-321G (compassionate use) Section IV.B.1.8.1.1; Ongoing	Safety and Efficacy	June 2002 Ongoing	Compassionate use, open label, single group fixed-flexible dosing in long-term administration of duloxetine	Duloxetine: 10-mg capsules, 20-mg capsules administered orally once daily after breakfast	N=2 (as of 1 November 2002) 20-69 years	DSM-IV criteria for major depression, dysthymic disorder or depressive bipoloar disorder	Long-term until duloxetine is approved in Japan	Final global improvement ratings

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-JE-322G Section IV.B.1.8.2.9; Complete; Full	Safety and efficacy	March 1998 Complete April 2000	Single-group non-blinded multicenter collaborative study using the fixed–flexible dose method	Duloxetine: 10 mg capsules; 20 mg capsules administered orally once daily after breakfast	N=45 ≥65 years	DSM-IV classifications of major depression, single episode; major depression, recurrent; dysthymic disorder; bipolar depressive disorder type I, most recent episode of depression; bipolar depressive disorder type II. Baseline total score of ≥17 on $HAMD_{17}$.	6 weeks	HAMD, final global improvement rating

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-JE-323G Section IV.B.1.8.2.10; Complete, Full	Safety and efficacy	August 1998 Complete July 2000	Controlled, double-blind, parallel-groups, study	Duloxetine: 5 mg capsule, 10 mg capsule, 20 mg capsule and a placebo capsule for each formulation taken orally once daily after breakfast Mianserin: 10 mg tablet and placebo tablet taken orally 3 times daily after each meal	N=234 41.7 years (20-69)	Patients with depression or depressive conditions Major depressive disorder, single-episode; Major depressive disorder, recurrent; Dysthymia; Bipolar I, most recent episode depressed; Bipolar II, recurrent episodes of major depression with mild manic episodes	4 weeks	HAMD

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-JE-324G Section IV.B.1.8.2.11; Complete; Final	Safety and efficacy	January 2000 Complete October 2000	Single-group, non-blinded multicenter collaborative study using fixed-flexible dose method	Duloxetine: 10 mg capsules administered orally once daily after breakfast, initial dose of 10 mg/day, flexible dose of 10-30 mg/day from Week 2	N=24 ≥65 years	DSM-IV classifications of major depression, single episode; major depression, recurrent; dysthymic disorder; bipolar depressive disorder type type I, most recent episode of depression; bipolar depressive disorder type II. Baseline total score of ≥17 on $HAMD_{17}$.	6 weeks	HAMD, final global improvement rating

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-JE-1008 Section IV.B.1.8.2.12; Complete; Full	Safety and efficacy	July 1993 Complete February 1994	Open parallel group study	Duloxetine: 10-mg capsules taken once per day after breakfast	N=83 44.8 years (19-69)	Classified as having depression or depressive conditions according to DSM-III-R classifications of: Major depression, single episode; major depression, recurrent; bipolar disorder, depressive. Total score of ≥17 on items 1-17 of HAMD.	6 weeks	Global severity, global improvement

(continued)

Table I.C.3.3. Listing of Clinical Studies (continued)

Study Identifier; Location; Status; Report Type	Objective(s)	Enrollment Start Status and End	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	# Patients (M/F) Mean Age (Range) years	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint
F1J-JE-1009 Section IV.B.1.8.2.13; Complete, Full	Safety and efficacy	September 1994 Complete December 1995	Double-blind intergroup comparison study	Duloxetine: Formulation A: 10 mg/day Formulation B: 20 mg/day Formulation C: 30 mg/day administered twice per day after breakfast and before bed Imipramine: Formulation A: 50 mg/day Formulation B: 100 mg/day Formulation C: 150 mg/day administered twice per day after breakfast and before bed	N=176 Efficacy Analysis N=149 (Efficacy Analysis M=70; F=79) 20-70	Pre-administration total score of 17 points or more on item Nos. 1-17 on the HAMD. DSM-III-R classifications of: major depression, single episode; major depression, recurrent; or bipolar depressive disorder.	6 weeks	HAMD

(continued)

Table I.C.3.3. Listing of Clinical Studies (concluded)

Abbreviations: AUA = American Urological Association; BID = twice daily; BPI = Brief Pain Inventory; CGI-Improvement = Clinical Global Impression of Improvement; CGI-Severity = Clinical Global Impression of Severity; DAI = Detrusor Activity Index; DSM-III-R = Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised; DSM-IV = Diagnostic and Statistical Manual of Mental Disorders, Four Edition; F = female; $HAMD_{17}$ = 17-Item Hamilton Depression Rating Scale; I-QOL = Incontinence Quality of Life; M = male; MADRS = Montgomery Asberg Depression Rating Scale; MDD = major depressive disorder; N = total population; PFMT = Pelvic Floor Muscle Training; PO = administered orally; QD = once daily.