

UNIVERSITY OF MIAMI
Melissa R. Ortega, M.D.

I. PERSONAL

Current Academic Rank: Instructor
Clinical Educator Track
Primary Department: Neurology
Secondary or Joint Departmental Appointments: Multiple Sclerosis
Citizenship: United States of America

II. HIGHER EDUCATION

Institutional:
Vanderbilt University, Nashville, TN; Chief Resident: Adult Neurology; 7/2005-6/2006
Vanderbilt University, Nashville, TN; Residency: Adult Neurology; 7/2003-6/2006
Vanderbilt University, Nashville, TN; Internship: Internal Medicine; 7/2002-6/2003
University of Miami Leonard M. Miller School of Medicine, Miami, FL; MD; 8/1998-5/2002
University of Miami, Coral Gables, FL; BS cum laude in Biology; 8/1995-5/1999

Certification, Licensure:
Florida Medical License ME 97448; 11/17/2006
Diplomate of The American Board of Psychiatry and Neurology in the specialty of
Neurology; 6/2007
Certified to perform Neurostatus and EDSS assessments until 8/2012

III. EXPERIENCE

Academic: University of Miami, Instructor/Multiple Sclerosis Fellow, Department of
Neurology, 8/2010 - current
Hospital Appointments:
Tampa General Hospital 1/2007-8/2007
University of Miami Hospital 7/2010-current
Jackson Memorial Hospital 9/2010-current
Miami Veterans Administration Hospital 9/2010-current

Non-Academic:
Meridien Research, St. Petersburg, Tampa & Brooksville, FL; Sub-Investigator;
Selecting and enrolling patients in pharmaceutically sponsored clinical trials,
medically managing patients enrolled in clinical trials, following clinical trial
protocols; 9/2008-5/2009
Florida Neurovascular Institute, Tampa, FL; General Adult Neurologist; Inpatient and
outpatient neurological consults; 1/2007-8/2007

IV. PUBLICATIONS

Book Chapters:

Ortega, Melissa R. and Rammohan, Kottil W., Sarcoidosis: Neurologic Complications, In: The 5-Minute Neurology Consult. 2nd ed., Lynn DJ, Newton H, Rae-Grant A., Philadelphia: Lippincott, Williams and Wilkins, 2011.

Ortega, Melissa R. and Rammohan, Kottil W., Immunizations: Neurologic Complications, In: The 5-Minute Neurology Consult. 2nd ed., Lynn DJ, Newton H, Rae-Grant A., Philadelphia: Lippincott, Williams and Wilkins, 2011.

V. PROFESSIONAL

Professional and Honorary Organizations:

American Academy of Neurology, active member, 1/2004 to present

Honors and Awards:

Completed the Foundations of Translational Science Bootcamp, 9/2010

Alpha Omega Alpha, University of Miami Leonard M. Miller School of Medicine, 9/2001

Medical Scholars Program at the University of Miami, 8/1998-5/2002

Phi Beta Kappa, University of Miami, 4/1998

Other Professional Activities:

Clinical trials for which I am currently an evaluating physician (as of 7/2011)

GALA

A multinational, multicenter, randomized, parallel-group study performed in subjects with relapsing-Remitting multiple Sclerosis (RRMS) to assess the efficacy, safety and tolerability of Glatiramer Acetate (GA) injection administered three times a week compared to placebo in a double –blind design. Sponsor: Teva Pharmaceutical Industries, Ltd.

CombiRx (Phase III)

A multi-center, double-blind, randomized study comparing the combined use of interferon beta-1a and glatiramer acetate to either agent alone in participants with relapsing remitting multiple sclerosis. Sponsor: NIH/NINDS

Acorda trial

A double-blind, placebo-controlled, parallel-group study to evaluate the safety and efficacy of two doses of oral dalfampridine extended release tablets (5 mg and 10 mg twice daily) in patients with multiple sclerosis. Sponsor: Acorda

EPOC: CFTY720DUS01 (GILENYA™ [Fingolimod])

A 6-month, randomized, active comparator, open-label, multi-center study to evaluate patient outcomes, safety and tolerability of fingolimod 0.5 mg/day in patients with relapsing forms of multiple sclerosis who are candidates for MS therapy change from previous disease modifying therapy. Sponsor: Novartis

A long-term, multicenter, non-interventional, observational study monitoring long-term safety and effectiveness of GILENYA™ (fingolimod 0.5 mg) in patients with multiple sclerosis who have participated in the fingolimod clinical development program. Sponsor: Novartis

Stratify-2 (101jc402)

JCV antibody assay in patients with relapsing multiple sclerosis receiving or considering treatment with natalizumab. Sponsor: Biogen idec)

(109MS303[Extension Study])

A dose-blind, multicenter, extension study to determine the long-term safety and efficacy of two doses of BG00012 monotherapy in subjects with relapsing-remitting multiple sclerosis. Sponsor: Biogen Idec

Clinical trials I have participated in as a Sub-Investigator (9/2008 to 5/2009):

A multi-center double-blind parallel-group placebo-controlled study of the efficacy and safety of teriflunomide in patients with relapsing multiple sclerosis

A randomized, multinational, double-blind, placebo-controlled, parallel-group design pilot study to estimate the tolerability, safety, pharmacokinetics, and pharmacodynamic effects of teriflunomide for 24 weeks when added to treatment with interferon- β in subjects with multiple sclerosis

A randomized, multinational, double-blind, placebo-controlled, parallel-group design pilot study to estimate the tolerability, safety, pharmacokinetics, and pharmacodynamic effects of teriflunomide for 24 weeks when added to treatment with glatiramer acetate in subjects with multiple sclerosis

A phase 3, randomized, double-blind, placebo-controlled, parallel-group trial to study the effect of γ -secretase inhibition on the progression of Alzheimer's disease: ly450139 versus placebo

A randomized, double-blind, placebo-controlled study using a bayesian adaptive design to evaluate the efficacy and safety of abt-089 in subjects with mild-to-moderate alzheimer's disease on stable doses of acetylcholinesterase inhibitors

A global phase 3, double-blind, placebo-controlled safety and efficacy study of oral dimebon in patients with mild-to-moderate Alzheimer's disease

A phase 3, multi-center, randomized, double-blind, placebo-controlled study to investigate the safety and efficacy of gabapentin extended release (g-er) tablets in the treatment of vasomotor symptoms in postmenopausal women

A phase 3, randomized, double-blind, placebo-controlled, parallel-group trial of linaclotide administered orally for 12 weeks in patients with chronic constipation

A phase 3, randomized, double-blind, placebo-controlled, parallel-group trial of linaclotide administered orally for 12 weeks in patients with chronic constipation

A phase 3, randomized, double-blind, placebo-controlled, parallel-group trial of linaclotide administered orally for 12 weeks followed by a 4-week randomized withdrawal period in patients with irritable bowel syndrome with constipation

A randomized, double-blind, placebo-controlled subjective study to assess the efficacy of apd125 in patients with primary insomnia characterized by difficulty maintaining sleep

A 52-week, double-blind, randomized, placebo-controlled, parallel-group study to assess the safety and efficacy of lorcaserin hydrochloride in overweight and obese patients with type 2 diabetes mellitus managed with oral hypoglycemic agent(s)

A randomized, double-blind, parallel group study evaluating the efficacy and safety of co-administration of a triple combination therapy of olmesartan medoxomil, amlodipine besylate and hydrochlorothiazide in subjects with hypertension

A double-blind, randomized, placebo-controlled study assessing the safety and efficacy of desvenlafaxine sustained release for the treatment of vasomotor symptoms associated with menopause

VI. TEACHING

“Multiple Sclerosis: Diagnosis, Clinical Presentation, and Medical Management” lecture given to University of Miami Physical Therapy graduate students, 7/2011

Presentation for VA Nurses on Revised 2010 McDonald Criteria, 4/2011

Facilitator for Problem-Based Learning Modules for University of Miami second-year medical students, 4/2011

“Case Presentations” in the University of Miami Department of Neurology, Neurology Update and Stroke Intensive, 2/2011

Facilitator for Case-Based Learning Modules for University of Miami second-year medical students, 1/2011

VII. SERVICE

Patient education program for not-for-profit organization MS Views and News “MS Treatment Therapies,” 7/2011

Patient education program for veterans at the Miami VA: “Memory and Mood in MS,” 12/2010