#### **CURRICULUM VITAE**

# JONATHAN OREN HARRIS, M.D. Neurology and Internal Medicine

## **POST-GRADUATE TRAINING:**

National Institute of Health, Bethesda, MD. Senior Staff Fellow, Neuroimmunology, (7/1988 – 10/1990).

## **EDUCATION:**

University of Miami Affiliated Hospitals, Miami, FL.

Internal Medicine internship (7/1982 – 6/1983)

Internal Medicine residency (7/1983 - 6/1985)

Neurology residency (7/1985 - 6/1988)

Board Certified Internal Medicine (1985) Board Certified Neurology (1988).

University of Pennsylvania, Philadelphia, PA., M.D. Degree, 9/1978 – 5/1982.

University of Chicago, Chicago, IL., BA Degree, 9/1970 – 5/1974. Post baccalaureate premed courses, 1976.

#### **NEUROLOGY PRACTICE**

BocaCare Inc. Boca Raton Regional Hospital Marcus Neuroscience Institute 800 Meadows Rd, Boca Raton, FL 33486 June 2017 – October 2019

Neurologic Consultants P.A., 1841 N.E. 45th Street, Fort Lauderdale, Florida 33308 October, 1990 – June 2017

## **RESEARCH EXPERIENCE:**

PHARMACEUTICAL RESEARCH: See page five.

Cerebral Vascular Research Center, University of Miami, Miami, FL. (1987-1988) Immunosuppression in experimental stroke.

Laboratory of CNS Studies, NINCDS, NIH, Bethesda, MD. Epidemiology of slow virus infections of the CNS, 1977-1978.

Gerontological Research Institute, Philadelphia, PA. Environmental influences on behavior of demented old people, 1974-1975.

## **CURRENT APPOINTMENTS**

Broward Medical Reserve Corps – Safety Officer Clinical Assistant Professor of Neurology - Nova Southeastern University Clinical Associate – Florida Atlantic University

# **RECENT ACTIVITIES**

Course Director – Florida Stroke Symposium 2013 - 2017

Course Director – Marcus Neuroscience Institute Annual Cerebrovascular Symposiums 2018-2019

Course Director – Practical Neuroscience for the non-neurologist, 2019

## **HOSPITAL AFFILIATIONS:**

None, currently

## **PERSONAL:**

Date of birth: December 12, 1952 Marital status: Married, five children

## **MEDICAL LICENSES:**

Florida: Available on Request

#### **RECENT HONORS**

America's Most Honored Professionals 2019 Castle Connolly Regional Top Doctor 2019 Gold Coast Magazine "Top Doctors" 2006 -2020 South Florida Super Doctors® 2008-2014 The Leading Physicians of the World 2011 Miami Metro Magazine "Top Doctors" 2000-2001

## **RECENT PRESENTATIONS:**

- "Stroke is bad, but worsening in the hospital is worse" 2nd Annual Cerebrovascular Symposium Marcus Neuroscience Institute 2018
- "Memory loss and the diagnosis of common dementias" Practical Neuroscience for the non-neurologist, 2019
- "Altered mental status, Coma, & Brain Death" Nova Southeastern University 2020
- "Multiple Sclerosis 2020" Nova Southeastern University 2020

#### PLATFORM PRESENTATIONS

Harris JO, Patronas NJ, Frank JA, et al., "The natural history of multiple sclerosis lesions in relapsing-remitting patients between clinical relapse by serial Gd-DTPA", Society of Magnetic Resonance in Medicine, 9th Annual Scientific Meeting, New York, NY, 1990.

#### **POSTERS**

Harris JO, Berger JR, Gregorios JB, Norenberg M, "The spectrum of cerebrovascular disease in the acquired Immunodeficiency syndrome", 113th Annual meeting of the American Neurological Association, Philadelphia, PA, 1988.

Harris JO, Dietrich WD, Busto R, Ginsberg M, "Busulfan immunosuppression in

experimental thrombotic stroke." 14th International Joint Conference on Stroke and Cerebral Circulation, San Antonio, TX, 1989.

Harris JO, Jacobson S, Mcfarlin DE, "Cutaneous anergy in chronic progressive myelopathy associated with Human T-Lymphotropic Virus Type I in a Caucasian male and his asymptomatic seropositive wife", 114th Annual meeting of the American Neurological Association, New Orleans, LA, 1989.

Harris JO, Frank JA, Patronas NJ, <u>et al.</u>, "Serial Gadolinium enhanced MRI scanning in patients with early relapsing-remitting multiple sclerosis", 115th Annual meeting of the American Neurological Association, Atlanta, GA, 1990.

## **PUBLICATIONS:**

Berger JR, Harris JO, Gregorios J, Norenberg M, "Cerebrovascular disease in AIDS: a case-control study." AIDS, 4(3):239-44 1990 Mar

Bernoulli C, Masters CL, Gajdusek DC, Gibbs CJ, Harris JO, "Early clinical features of Creutzfeldt - Jakob Disease (Subacute spongiform encephalopathy) In: Prusiner SB and Hadlow WJ, (eds.) Slow transmissible diseases of the nervous system, Academic Press: New York, 1979, Volume 1, pages 229-251.

Burke A, Harris JO, Younkin D, et al., "Focal diaschisis and bilateral homologous hyperemia after acute stroke", Neurology 32(4): A196, 1982.

Harris JO, "Proposal to increase the number of physicians providing care to elderly Americans", Joint hearing before the Subcommittee on Health and Long-term Care and the Subcommittee on Human Services of the select Committee on Aging. House of Representatives May 17, 1978. Comm. Pub. No. 95-151. U.S. Government Printing Office: Washington D.C., 1978.

Harris JO, and Berger JR, "Clinical approach to stupor and coma", Chapter 5 in Bradley WG, Daroff RB, Fenichel GM, and Marsden CD, (eds.), <u>Neurology in clinical practice</u>, Butterworth Publishers: Stoneham, MA., 1991.

Harris JO, Frank JA, Patronas N, McFarlin DE, McFarland HF, "Serial gadolinium-enhanced magnetic resonance imaging scans in patients with early relapsing-remitting multiple sclerosis: implications for clinical trials and natural history." Ann Neurol, 29(5):548-55 1991

Harris JO, Marquez J, Swerdloff MA, Magana IA, "Listeria brain abscess in the acquired immunodeficiency syndrome" [letter] Arch Neurol, 46(3):250 1989

Masters CL, Harris JO, Gajdusek DC, et al., "Creutzfeldt - Jakob Disease: Patterns of

worldwide occurrence and the significance of familial and sporadic clustering", Ann Neurol 5(2): 177-188, 1979.

Masters CL, Harris JO, Gajdusek DC, <u>et al.</u>, "Creutzfeldt - Jakob Disease: Patterns of worldwide occurrence" In: Pruisner SB and Hadlow WJ, (eds.) <u>Slow transmissible</u> <u>diseases of the nervous system</u>, Academic Press: New York, 1979, Volume 1, pages 113-142.

McFarland HF, Frank JA, Albert PS, Smith ME, Martin R, Harris JO, Patronas N, Maloni H McFarlin DE, "Using gadolinium-enhanced magnetic resonance imaging lesions to monitor disease activity in multiple sclerosis." Ann Neurol, 32(6):758-66 1992

Smith ME, Katz DA, Harris JO, Frank JA, Kufta CV, McFarlin DE, "Systemic histiocytosis presenting as multiple sclerosis." Ann Neurol, 33(5):549-54 1993

#### PHARMACEUTICAL CLINICAL TRIALS EXPERIENCE:

## **Principal Investigator**

#### Alzheimer's Disease

Alzheimer 's Disease - - "Protocol 979-14: A 26-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study of Milameline (CI-979/RU35926) in Patients with Probable Alzheimer's Disease (to be read in conjunction with Protocol 979-16)"

*Alzheimer's Disease* - - "Protocol 979-16: A nonrandomized, Open-Label Extension, Multicenter Study of Milameline (CI-979/RU35926) in Patients with Probable Alzheimer's Disease."

Alzheimer's Disease - - "Protocol 970-68: A 16-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response Multicenter Study of Tacrine (CI-970) Once-A-Day Formulation (Tacrine GITS) with a 16-Month Open-Label Extension in Patients with Dementia of the Alzheimer's Type."

*Alzheimer's Disease* - - Protocol 97-019: Metrifonate Investigational Nationwide Trial (M.I.N.T.)

Alzheimer's Disease - - Protocol CV-2619/PNFP-008: "A Randomized, Double-Blind, 12-Month Safety and Efficacy Study of Idebenone (CV-2619) 360 mg tid or Placebo Added to Treatment with Donepezil HCL 10 mg qd in Patients with Probable Alzheimer's Disease.

Alzheimer's Disease - - Protocol CV-2619/PNFP-005 "A Randomized, Double-Blind, Placebo-Controlled, 12-Month Safety and Efficacy Trial of Idebenone (CV-2619) 360 mg tid in Patients with Probable Alzheimer's Disease."

Alzheimer's Disease - - Protocol MEM-MD-10: "A randomized, double-blind, placebo-controlled evaluation of the safety and efficacy of Memantine in patients with mild to moderate Dementia of the Alzheimer's type.

Alzheimer's Disease - - Protocol MEM-MD-11 "A Long – Term Extension Study Evaluating the Safety and Tolerability of BID and QD Administration of Memantine In Patients with Mild to Moderate Dementia of the Alzheimer's Type.

Alzheimer's Disease - - Protocol GAL-INT-10: "A placebo controlled evaluation of Galantamine in the treatment of Alzheimer's Disease: Safety and efficacy of a controlled release formulation.

Alzheimer's Disease - - Protocol GAL-INT-21: "An open label extension trial to assess the long term safety of a controlled released formulation of Galantamine HBR in the treatment of Alzheimer's Dementia.

Alzheimer's Disease - - Protocol #1198.052: "A Phase II Double Blind, Randomized, Dose Ranging, Placebo Controlled, Multicenter, Safety and Efficacy Evaluation of Three Doses of Ns 2330 in Patients with Mild To Moderate Dementia of the Alzheimer's Type."

Alzheimer's Disease- - Protocol # ONO-2506POU010: A double-blind, phase II, safety and efficacy evaluation of ONO-2506PO in patients with mild to moderate Alzheimer's Disease.

Alzheimer's Disease - - Protocol CENA713D2340: "A 48-Week, Multicenter, Randomized, Double –Blind, Parallel-Group Evaluation of the Comparative Efficacy, Safety, and Tolerability of Exelon 10 and 15 cm2 Patch in patients with Alzheimer's Disease Showing Cognitive Decline during an initial Open-Label Treatment Phase".

Alzheimer's disease - - Protocol ELN115727-301: "A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Efficacy and Safety Trial of Bapineuzumab (AAB-001, ELN115727) in Patients with Mild to Moderate Alzheimer's disease who are Apolipoprotein E e4 Non-Carriers".

Alzheimer's Disease - - Protocol ELN115727-302: "A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Efficacy and Safety Trial of Bapineuzumab (AAB-001, ELN115727) in Patients with Mild to Moderate Alzheimer's Disease who are Apolipoprotein E e4 Carriers".

*Alzheimer's Disease* - - Protocol H6L-MC-LFAN: "Effect of y-Secretase Inhibition on the Progression of Alzheimer's Disease: LY450139 versus Placebo"

Alzheimer's Disease - - Protocol CENA713DUS44: "A 24 Week, Prospective, Randomized, Parallel-Group, Double-Blind, Multi-Center Study Comparing the Effects of Rivastigmine Patch 15 cm2 vs. Rivastigmine Patch 5 cm2 on **ACT**ivities of Daily Living and Cognit**ION** in Patients with Severe Dementia of the Alzheimer's Type (ACTION)".

Alzheimer's Disease - - Protocol CENA713DUS44E1: "A 24 Week, Open-Label Extension to Study CENA713DSU44: A 24 Week, Prospective, Randomized, Parallel-Group, Double-blind, Multi-Center Study Comparing the Effects of Rivastigmine Patch 15 cm2 vs. Rivastigmine patch 5 cm2 on ACTivities of Daily Living and CognitiON in Patients with Severe Dementia of the Alzheimer's Type (ACTION).

*Alzheimer's Disease* - - Protocol H6L-MC-LFBF: "Open-label Extension for Alzheimer's Disease Patients Who complete One of Two Semagacestat Phase 3 Double-Blind Studies (H6L-MC-LFAN or H6L-MC-LFBC"

*Alzheimer's Disease* - - Protocol ELN115727 – 351: "A phase III Extension, Multicenter, Double – Blind, Long Term Safety and Tolerability Treatment Trial of Bapineuzumab (AAB-001, ELN115727) in Subjects with Alzheimer's Disease who participated in Study ELN115727-301 or in Study ELN115727-302

Alzheimer's Disease - - Protocol 3133K1-3000-US: "A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Efficacy and Safety Trial of Bapineuzumab (AAB-001, ELN115727) in Subjects With Mild to Moderate Alzheimer Disease Who Are Apolipoprotein E4 Non-Carriers"

Alzheimer's Disease - - Protocol BP28248: "A Phase II, Multicenter, Randomized, double-Blind, Parallel-Group. Placebo-Controlled Study to Investigate the Efficacy And Safety Of RO4602422 Added To the Background Therapy Of The Acetylcholinesterase Inhibitors Donepezil Or Rivastigmine In Patients With Moderate Severity Alzheimer's Disease."

## **Assessment Scale Validity**

Protocol Number CENA713B2314: "A 4-Week, Non-Interventional, Cross-Sectional, Multicenter Study to Assess the Validity of Various Assessment Scales Measuring Cognition, Executive Function, Attention, Behavior, and Activities of Daily Living (ADL) in Patients with Mild to Moderate Parkinson; Disease Dementia (PDD) or Vascular Dementia (VaD).

#### Cerebrovascular disease

Acute Ischemic Stroke - - Protocol IX-103-002 "Cervene (Nalmefene) Modification of Outcome in Patients with Acute Ischemic Stroke: A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Dose-Comparison Study by 24 Hour Infusion."

Acute Ischemic Stroke - - Protocol IX-004-002 "A Phase III, Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of a 24-Hour Infusion of Cervene in Patients with Acute Ischemic Stroke.

Acute Ischemic Stroke - - Protocol LES02: "Assessment of the Efficacy and Safety of Eliprodil in Patients with Acute Ischemic Stroke."

Acute Ischemic Stroke - - Protocol 534.11 "A Phase II/III Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy. Safety, Tolerability, and Pharmacokinetics of Two Doses of Intravenous Aptiganel Hydrochloride Verses Placebo In Patients with An Acute Ischemic Stroke."

Acute Ischemic Stroke - - Protocol CMZ 009 The Clomethiazole Acute Stroke Study in Ischemic Stroke (Class-I): A Double Blind, Parallel Group, Multinational, Multicenter

Study of the Safety of IV Clomethiazole Compared to Placebo in Patients with Acute Ischemic Stroke.

Acute Ischemic Stroke - - Protocol CMZ 010 The Clomethiazole Acute Stroke Study in Acute Intracerebral Hemorrhage (Class-H): A Double Blind, Parallel Group, Multinational, Multicenter Study of the Safety of IV Clomethiazole Compared to Placebo in Patients with Acute Intracerebral Hemorrhage.

Acute Ischemic Stroke - - Protocol CMZ 011 The Clomethiazole Acute Stroke Study in t-PA Treatment Ischemic Stroke (Class -T): A Double Blind, Parallel Group, Multinational, Multicenter Study of the Safety of IV Clomethiazole Compared to Placebo in Patients Treated with t-PA for Acute Ischemic Stroke.

Acute Ischemic Stroke - - Protocol GLYA3002, An International, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess Over 3 Months the Safety, Efficacy and Pharmacoeconomics of an 800 mg Loading Dose and Five 200 mg Maintenance Doses of GV150526 in the Treatment of Patients with a Clinical Diagnosis of Acute Stroke.

Acute Ischemic Stroke - - Protocol CN123-011 "A Double-Blind, Placebo-Controlled, Safety, Efficacy and Dose Response Trial of Three Intravenous Doses of BMS 204352 in Patients with acute Stroke."

Antiplatelet Drug - - Protocol SB 214857 Lotrafiban: "Blockade of the GP IIB/IIIA Receptor to Avoid Vascular Occlusion (BRAVO)"

Stroke - - Protocol GLY30009: "A six-month post-stroke follow-up protocol for subjects who have previously completed clinical trial protocol GLYA3002 (an International, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess over Three Months the Safety, Efficacy and Pharmacoeconomics of an 800mg Loading Dose and Five 200mg Maintenance Doses of GV150526 in the Treatment of Subjects with a Clinical Diagnosis of Acute Stroke)."

Acute Ischemic Stroke - - Protocol GLY30011: "A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess over 3 Months the Efficacy, using the Stroke Impact Scale, and Safety of an 800mg Loading Dose and Five 200mg Maintenance Doses of GV150526 in the Treatment of Patients with a Clinical Diagnosis of Acute Stroke."

*Post Stroke Study* - - Protocol 981-124-97 SPARCL: "A Double-Blind, Randomized, Placebo-Controlled Study of Atorvastation as Prevention of Cerebrovascular Events in Patients with a previous transient Ischemic Attack (TIA) or Stroke."

Acute Ischemic Stroke - -Protocol ARG 251: "Randomized, Placebo-Controlled, Three-Treatment Arm Study To Determine The Safety and Efficacy of Argatroban Injection in Patients With Acute Ischemic Stroke (ARGIS –1)"

Acute Ischemic Stroke - - Protocol 872-CL-004: ARTIST +: A Multicenter, Stratified, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Neurologic Function and Disability in Patients with Active Ischemic Stroke Given Tissue Plasminogen Activator Plus YM872 or Tissue Plasminogen Activator Plus Placebo."

Post Stroke Study - - MATCH Protocol Number EFC7331: "Management of Atherothrombosis with Clopidogrel in High-risk Patients With Transient Ischemic Attack or Ischemic Stroke."

Post Stroke Study - - Protocol number EFC4505: "Clopidogrel For High Atherothrombotic Risk and Ischemic Stabilization, Management and Avoidance." (Charisma)

Acute Ischemic Stroke - - Protocol 100282: "A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy, Safety, Tolerability, and Pharmacokinetic/Pharmacodynamic Effects of a Targeted Exposure of Intravenous Repinotan in Patients with Acute Ischemic Stroke." (mRECT)

Acute Ischemic Stroke - - protocol Number SA-NXY-0007 titled: "SAINT II (Stroke-Acute Ischemic-NXY Treatment) A double-blind, randomized, placebo controlled, parallel group, multicenter, phase IIb/II Study to assess the efficacy and safety of intravenous NXY-059 in acute ischemic stroke."

*Stroke-* - Protocol # ONO-2506: A Randomized, double-blind, placebo controlled, multicenter study of the effects of ONO-2506 intravenous infusion on the amelioration of neurological damage and improvement of stroke assessment of scales in patients with acute ischemic stroke.

*Stroke-* - Protocol # SA-NXY-0012: A double-blind, randomized, placebo-controlled, parallel-group, multi-center, phase IIb study to assess the safety and tolerability of 72 hours intravenous infusion of NXY-059 in adult patients with acute intracerebral hemorrhage.

*Stroke-* - Protocol # 9.159: PRoFESS- Prevention Regimen for Effectively avoiding Second Strokes: A Double-blind and placebo-controlled study of Aggrenox vs. Clopidogrel, with and without Micardis.

*Stroke* - - Protocol NTI-ASP-0502: "A Randomized, Double-Blind, Placebo-Controlled Study of Viprinex<sup>™</sup> (Ancrod Injection) in Subjects Beginning Treatment within 6 Hours of the Onset of Acute, Ischemic Stroke."

Post Stroke Apathy - - Protocol HPI-001 "A Randomized, Controlled Comparison of Nefiracetam with Placebo In The Treatment Of Patients With Post-Stroke Apathy"

Acute Ischemic Stroke - - Protocol No. NTI-AST-0502 "Study of Acute Viprinex for Emergency Stroke: A Randomized, Double-Blind, Placebo-Controlled Study of Ancrod

(Viprinex) in Subjects Beginning Treatment within 6 Hours of the Onset of Acute, Ischemic Stroke.

Acute Ischemic Stroke - - Protocol NTS-INT06-007: "NeuroThera Effectiveness and Safety Trial-2 (NEST-2) A Double Blind, randomized, controlled, parallel group, multicenter, pivotal study to assess the safety and effectiveness of the treatment of acute ischemic stroke with the NeuroThera Laser System within 24 hours from stroke onset".

Acute Ischemic Stroke - - Protocol Albumin in Acute Stroke (ALIAS) Trial: "A Phase III Randomized Multicenter Clinical Trial of High-Dose Human Albumin Therapy for Neuroprotection in Acute Ischemic Stroke".

*Post Stroke* - - Protocol 20071259 - - "A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of SCH 530348 in Addition to Standard of care in Subjects With a History of Atherosclerotic Disease: Thrombin Receptor Antagonist in Secondary Prevention of Atherothrombotic Ischemic Events (TRA 2P – TIMI 50)".

*Post Stroke* - - Protocol DALF-PS-1003: "A Phase 2b Study of Dalfampridine 10 mg Extended Release Tablet in Subjects with Chronic Deficits After Ischemic Stroke."

Acute Ischemic Stroke - - Protocol ASBI 801: "A Multicenter Observational Study toate the Simplified-Stroke Rehabilitation Assessment of Movement (S\_STREAM) Scale in Subjects Obtained Between 24 and 48 Hours of a Nonhemorrhagic Ischemic Stroke."

*Acute Ischemic Stroke* - - Protocol A9541004: "A Phase 2 Multicenter, Randomized, Double-Blind, Placebo Controlled Study Of The Safety And Efficacy Of PF-03049423 In Subjects With Ischemic Stroke."

#### **Migraine**

Migraine - - Protocol VML251/96/07: "A Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Efficacy and Safety of Up To Two Doses of VML251 in the Acute Treatment of Migraine."

*Migraine* - - Protocol CAPSS-223; Phase IV: "A Comparison of the Efficacy and Safety of ULTRACET™ (Tramadol HCL/Acetaminophen versus Placebo for the Acute Treatment of Migraine Headache Pain."

#### Mild Cognitive Impairment

Mild Cognitive Impairment - - Protocol GAL-INT-18: "A randomized double blind placebo-controlled trial to evaluate the efficacy and safety of Galantamine in subjects with Mild Cognitive Impairment clinically at risk for development of clinically probable Alzheimer's Disease

Mild Cognitive Impairment - - Protocol GAL-MCI-301: "An Open-Label Extension Study to Assess the Long-Term Safety and Tolerability of Galantamine HBr in the Treatment of Mild Cognitive Impairment."

*Mild Cognitive Impairment*- - Protocol # E2020-A001-412: A one-year, multi-center, randomized double-blind, placebo-controlled evaluation of the efficacy and safety of donepezil hydrochloride {E2020} in subjects with mild cognitive impairment.

*Mild Cognitive Impairment (MCI)* - - Protocol No. E2020-A001-414 "Open Label Extension Study of the E2020-A001-412 Protocol"

#### **Multiple Sclerosis**

Multiple Sclerosis - - Protocol EPOC: "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 (EPOC)"

Multiple Sclerosis - - Protocol CFTY720DUS09: "A 12-Month, Prospective, Randomized, Active-Controlled, Open-label Study to Evaluate The Patient Retention Of Fingolimod vs. Approved First-Line Disease Modifying Therapies In Adults Who Are In Early Stages Of Treatment For Relapsing Remitting Multiple Sclerosis (PREFERMS)."

*Multiple Sclerosis* - - Protocol CFTY720D2404: "the Multi-National Gilenya Pregnancy Exposure Registry in Multiple Sclerosis."

#### Pain

Low Back Pain - - Protocol 1008-104-431: "An 8-Week, Randomized, Double-Blind, Placebo-Controlled, Monotherapy Trial of Pregabalin for Treatment of Chronic Low Back Pain"

Low Back Pain - - Protocol 1008-033-431: "Pregabalin Open-Label, Extension Safety Trial in Patients with Chronic Pain."

#### Parkinson's Disease

Parkinson's Disease - - Protocol NR154401/M35016:m A Noncomparative Open-Label Study to Evaluate TASMAR Dosage Regimen in Nonfluctuating Parkinson's Disease Patients Treated with Sinemet, with Follow-up Treatment of Tasmar.

Parkinson's Disease - - OPRC 352-E-00 "A Prospective, Randomized, Parallel-Group, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Short-Term Efficacy and Safety of Entacapone Administered Together with Levodopa in Subjects with Parkinson's Disease Without Motor Fluctuations."

Parkinson's Disease - - Protocol RP54274X-320: "A Phase III Multicenter, Double-Blind, Parallel-Group, Placebo-Controlled Study of the Effect of Riluzole 50mg bid or 100 mg bid on the Progression of Parkinson's Disease for Two Years in 1050 Patients."

Parkinson's Disease - - Protocol RP54274X-321: "A Phase III Multicenter, Double Blind, Parallel-Group, Placebo Controlled Study of the Effect of Riluzole 50mg bid or 100mg bid on the Progression of Parkinson's Disease in Patients Treated With L-Dopa or Dopamine Agonist"

*Parkinson's Disease* - - Protocol CCOM 998 US01: "A Multicenter, Double-Blind, Placebo-Controlled Study to Assess the Tolerability and Effect of Entacapone on the Quality of Life in Parkinson's Disease Patients Treated with Levodopa/Carbidopa Experiencing End-of-Dose Wearing-Off."

Parkinson's Disease - - Protocol PNU – 95666E:" A Double-Blind, Placebo-Controlled, Dose-Response Study of Tolerability, Safety, and Efficacy in Patients with Early Parkinson's Disease.

*Parkinson's Disease* - - Protocol PNU-95666E: "Open-label, Long Term, Flexible Dose Study of Safety, Tolerability, and Therapeutic Response in Patients with Parkinson's Disease.

Parkinson's Disease - - Protocol 666E-CNS-0075: "A Phase III, Double-blind, Placebo-Controlled, Randomized Study Comparing the Efficacy, Safety, and Tolerability of Sumanirole versus Placebo or Ropinirole in Patients with Early Parkinson's Disease.

Parkinson's Disease - - Protocol 666E-CNS-0614-001: "Pharmacogenomics Blood Sampling Protocol for Sumanirole."

Parkinson's Disease - - Protocol DA2APD-0075-031: "A Phase III, Multi-center, Randomized, Double-blind, Placebo-controlled, Fixed Dose Response Study Comparing the Efficacy and Safety of Sumanirole Versus Placebo in Patients With Early Parkinson's Disease."

Parkinson's Disease - - Protocol CELC200AUS11: A prospective, multi-center, randomized, open-label study with blinded raters to evaluate the effects of immediate versus delayed switch to Stalevo on motor function and quality of life in patients with Parkinson's disease with end-of-dose wearing off."

Parkinson's Disease - - Protocol No. CELC200A "A Prospective, Multi-Center, Randomized, Open-Label Study With Blinded Raters To Evaluate The Effects of Immediate Versus Delayed Switch To Stalevo On Motor Function And Quality Of Life In Patients With Parkinson's Disease With End-Of-Dose Wearing Off."

Parkinson's Disease - - Protocol No. S308.3.001 "The Rembrandt Study" A Randomized, Double-blind, Placebo Controlled Parallel-group fixed and Flexible SLV308 Dose Arm Study to Assess Efficacy and Safety of SLV308 Monotherapy in the Treatment of Patients with Early Stage Parkinson's Disease."

Parkinson's Disease - - S187.3.004 "Open-Label, 6-12 Months Safety and Efficacy Study of Levodopa – Carbidopa Intestinal Gel in Levodopa-Responsove Subjects with Advanced Parkinson's Disease and Severe Motor-Fluctuations."

Parkinson's Disease - - S187.3.005 "Open-Label Continuation Treatment Study with Levidopa-Carbidopa Intestinal Gel in Subjects with Advanced Parkinson's Disease and Severe Motor-Fluctuations Who Have Exhibited a Persistent and Positive Effect to Treatment in Previous Studies."

#### **Peripheral Neuropathy**

Diabetic Peripheral Neuropathy - - Protocol K0718g "A Phase III Multicenter, Double-Blind, Placebo Controlled, Parallel-Group Study of the Efficacy and Safety of Recombinant Human Nerve Growth Factor (rhNGF) in Subjects with Diabetic Neuropathy."

Diabetic Peripheral Neuropathy - - Protocol K0807g: "A Phase III Open-Label Extension Study of the Long-Term Safety of Recombinant Human Nerve Growth Factor (rhNGF) in the Treatment of Subjects with Diabetic Peripheral Neuropathy."

*Diabetic Peripheral Neuropathy* - - Protocol MEM-MD-06A: "A Double-Blind comparison of Memantine and placebo in the treatment of chronic pain in patients with Diabetic Neuropathy.

*Diabetic Peripheral Neuropathy* - - Protocol MEM-MD-06B: "An open-label extension of Memantine treatment in patients with painful Diabetic Neuropathy.

Diabetic Peripheral Neuropathy - - Protocol NPP30004: "A Multicenter, Double-Blind, Randomized Study to Evaluate the Safety and Efficacy of Lamotrigine 200 mg/day, 300 mg/day, and 400 mg/day Compared With Placebo in Subjects With painful Diabetic Neuropathy."

Diabetic Peripheral Neuropathy - - Protocol Number NPP30006: "An Open-Label Study to Evaluate the Safety of Lamotrigine in Subjects with Painful diabetic Neuropathy."

*Diabetic Neuropathy*- - Protocol # SP742: A multi-center, randomized, double-blind, placebo-controlled trial to assess the efficacy and safety of 200, 400, and 600mg/day SPM 927 in subjects with painful distal diabetic neuropathy.

*Peripheral Neuropathy*- - Protocol # NPP30010: A multicenter, randomized, doubleblind, placebo-controlled, parallel group to evaluate the safety and efficacy of lamotrigine in subjects with neuropathic pain and inadequate pain relief with gabapentin, tricyclic antidepressants or non-narcotic analgesics.

Herpatic Neuropathy - - Protocol A1A20004: "A Multicenter Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Tolerability of a 14 Day Treatment Course of CW493838 50mg Compared to Placebo in Subjects with Peripheral Neuropathic Pain."

*Postherpetic Neuropathy*--Protocol # CXA 20009: A multi-center, randomized, double-blind, placebo controlled, parallel group study to assess the safety and efficacy of GW406381 25mg and 50mg, administered once daily for 21 days to subjects with postherpetic neuralgia.

Postherpetic Neuralgia - - Protocol No. 81-0045 "A Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Gabapentin Extended Release (G-ER) Tablets in the Treatment of Patients with Postherpetic Neuralgia."

Diabetic Peripheral Neuropathy - - Protocol R331333-PAI-3015: "A Randomized-Withdrawal Phase III Study Evaluating the Safety and Efficacy of CG5503 Extended-Release (ER) in Subjects with Painful Diabetic Peripheral Neuropathy".

### Vascular Dementia

*Vascular Dementia* - - Protocol GAL-INT-26: "A randomized 26-week, double blind placebo controlled trial to evaluate the safety and efficacy of Galantamine in the treatment of Dementia secondary to Cerebrovascular Disease.

*Vascular Dementia* - - Protocol GAL-INT-22: "An Open-Label Extension to Assess the Safety of Galantamine HBr in the treatment of Vascular Dementia.

## **Sub-Investigator:**

Acute Ischemic Stroke - - Protocol LUB-INT-9: "Lubeluzole: Effects of Intravenous Therapy in Subjects With Acute Ischemic Stroke, A Placebo-Controlled, Double-Blind, Randomized, Multicenter, Trial."

Painful Diabetic Peripheral Neuropathy—Protocol Prosaptide TX14-004: "A Four-Week, Double-Blind, Randomized, Placebo-Controlled, Multicenter, Phase II Study to Evaluate the Safety, Tolerability, and Efficacy of Three Subcutaneous Doses of Prosaptide (TX14(A) when Administered Daily for 28 days on Diabetic Painful Neuropathy in Patients with Type 1 and Type 2 Diabetes Mellitus."

Painful Diabetic Peripheral Neuropathy - - Protocol PRI/TOP-INT-30:(TOPMAT-NP-003) "A Double-Blind, Placebo-Controlled, Parallel Group, Dose-Response Study to Evaluate the Efficacy and Safety of Topiramate Versus Placebo in the Treatment of Pain Associated with Diabetic Peripheral Polyneuropathy.

*Migraine* - - Protocol PRI/TOP-INT-48 (TOPMAT-MIGR-002): "A randomized, double-blind, placebo-controlled, parallel group, dose-response study to evaluate the efficacy and safety of Topiramate in the prophylaxis of migraine."