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Mark Norman Sadoff, M.D.

EDUCATION

University of California, Los Angeles, CA ■ 08/1969 - 05/1973
B.A. in Zoology, Cum Laude

University of California, Los Angeles, CA ■ 07/1973 – 06/1975
M.A. in Biology

Bowman Gray School of Medicine,
Wake Forest University, Winston Salem, NC ■ 09/1975 - 05/1979
M.D.

VA Wadsworth Medical Center, Los Angeles, CA ■ 06/1979 – 06/1980
Internship, Medical

UCLA School of Medicine, Los Angeles, CA ■ 07/1980 – 06/1983
Resident, Neurology

LICENSURE

California Medical License Number - Active

CERTIFICATIONS

Diplomat, American Board of Psychiatry and Neurology ■ 1985
Qualified Medical Examiner, Industrial Medical Council ■ 1994-2000

ACADEMIC APPOINTMENTS

Attending Physician, VA Wadsworth Medical Center and St. Mary's Medical Center
Outpatient Clinics ■ 1983-1987

Clinical Assistant Professor, Neurology
UCLA School of Medicine ■ 1985-1987

Assistant Clinical Professor of Neurology
University of California, San Diego ■ 1987-2001

Clinical Instructor, VA Medical Center San Diego
Affiliated with UCSD School of Medicine ■ 1990-2005

RELATED EXPERIENCE

Investigator, Profound Research LLC, Carlsbad, CA

■ 2023 to Present

Primary and/or Sub-Investigator, Research Center, North County Neurology Associates, Carlsbad, CA

■ 2019 to 2023

Primary and/or Sub-Investigator, Research Center, The Research Center of Southern California, LLC, Carlsbad, CA
■ 01/2016 to 2023

Primary and/or Sub-Investigator, Research Center, The Research Center of Southern California, LLC, Oceanside and Encinitas, CA ■ 2007 to 01/2016

Neurologist, Private Group Practice, North County Neurology Associates dba The Neurology Center, Carlsbad, CA
■ 2016 to Present

Neurologist, Private Group Practice, North County Neurology Associates dba The Neurology Center, Oceanside, CA
■ 05/1987 to 01/2016

Private Practice of Neurology with William Gorbunoff, M.D. ■ 1983 to 1987
1045 Atlanta Avenue, Suite 619, Long Beach, California

Attending physician, VA Wadsworth Medical Center
& St. Mary's Medical Center Outpatient Clinics ■ 1983 to 1987

Tri-City Medical Center Rehabilitation Unit

- Alternate for Medical Director and Chief of Services ■ 09/1987 to 2005
- Director of Acute Rehabilitation Unit ■ 2005 to Present

Admitting physician, Scripps Memorial Hospital Encinitas, Acute Rehabilitation Unit ■ 10/1989 to 2020

- **Alternate for Rehabilitation Director** ■ 1991 to 1995
  at the multi-disciplinary conferences at Vista Knolls,
  Garden Terrace and Village Square skilled nursing facilities.

- **Medical Director for Outpatient and Inpatient Rehabilitation Services** at Pomerado Hospital and Villa Pomerado Convalescent Care Center ■1994 to 1995

- **Chief, Division of Neurosciences** ■ 1993 to 1994 and 1997 to 1998
- Tri-City Medical Center

AWARDS

Top Doctor Award featured in San Diego Magazine ■ 2019

HOSPITAL AFFILIATIONS

Palomar Medical Center, Escondido & Poway, California ■ 01/2013 to Present
Tri-City Medical Center, Oceanside, California ■ 09/1987 to Present
Scripps Memorial Hospital, Encinitas, California ■ 10/1987 to Present
UCSD, La Jolla, California, Asst. Clinical Prof. ■ 1987

HOSPITAL AFFILIATIONS *CON'T*

Scripps Memorial Hospital, La Jolla, California ■ 1993 to 2007
VA Medical Center, San Diego, California ■ 1987-2005
Fallbrook Hospital, Fallbrook, California ■ 1987-2000
San Luis Rey Hospital, Encinitas, California ■ 1987-2000

MEMBERSHIPS

American Academy of Neurology
American Association of Neuromuscular and Electro Diagnostic Medicine
San Diego Neurological Society
San Diego Medical Society

PUBLICATIONS AND PAPERS

Collaborating Clinical Centre, North County Neurology Associates, Oceanside: T Chippendale, M Lobatz, E Diamond, J Schim, **M. Sadoff**. "A randomized, blinded, trial of clopidogrel versus aspirin in patients at risk of ischemic events (CAPRIE)", CAPRIE Steering Committee. Published in *The Lancet* Vol 348 No 9038, 1329-1339, November 16, 1996.

Participating Clinical Center: Tri-City Medical Center, T. Chippendale, E. Diamond, M. Lobatz, D. Murphy, D. Rosenberg, T. Ruel, **M. Sadoff**, J. Schim, J. Schleimer. "Tissue Plasminogen Activator for Acute Ischemic Stroke," The *New England Journal of Medicine*, Vol 333 No 24, 1581-1587, December 14, 1995.

D. Sherman, R. Atkinson, T. Chippendale, et al. "Intravenous Ancrod for Treatment of Acute Ischemic Stroke, The STAT Study: A Randomized Controlled Trial," *JAMA,* 2000; 283:2395-2403, May 10, 2000.

RESEARCH ACTIVITIES

Principal Investigator

Alzheimer's Disease

D97-019 "Metrifonate investigational nationwide trial (M.I.N.T)." 1997.

Protocol #14862A "Randomized, double-blind, parallel-group, placebo-controlled, fixed-dose study of Lu AE58054 in patients with mild-moderate Alzheimer's disease treated with Donepezil; Study 2 April 2015 - Present

Pain

49,774-013 "Morphine with Dextromethorphan: double-blind crossover comparison of morphine with Dextromethorphan and morphine in chronic pain." 1997

Parkinson's Disease

666E-CNS-0075-021 "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." *Principal Investigator* – 2003- 2004

M/2760/0011"PNU-95666E: Open-Label, Long Term, Flexible Dose Study of Safety, Tolerability and Therapeutic Response in Patients with Parkinson's Disease." *Principal-Investigator* – 2003- 2004

DA2APD-0075-031 "A Phase III, Double-blind, Fixed Dose Response Study Comparing the Efficacy and Safely of Sumanirole vs. Placebo in Patients with Early Parkinson's Disease." *Principal-Investigator* – 2003- 2004

RESEARCH ACTIVITIES CON'T

Sub-Investigator

Alzheimer's Disease

Suloctidil study for Alzheimer's Disease, Monsanto. 1987.

Parke-Davis 979-14 "A 26-week, randomized, double-blind, placebo-controlled, parallel-group, multicenter with a sustained active phase study of Milameline (CI-979/RU 35926) in patients with probable Alzheimer's Disease." 1995-1996.

Parke-Davis 979-16 Open label extension of "A 26-week, randomized, double-blind, placebo-controlled, parallel-group, multicenter with a sustained active phase study of Milameline (CI-979/RU 35926) in patients with probable Alzheimer's Disease." 1996.

E2020-A001-209 "A 12-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Preliminary Study to Determine the Efficacy and Safety of Donepezil Hydrochloride (E2020)

970-68-23 "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." 1996- 1997.

970-68-23 Open label extension of "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." 1996-1997.

GAL-INT-11 "A randomized double-blind placebo-controlled trial to evaluate the efficacy and safety of Galantamine in subjects with mild cognitive impairment (MCI) clinically at risk for development of clinically probable Alzheimer's disease." 2003

In Patients with Persistent Mild to Moderate Memory Impairments Resulting from a Single Closed Head Injury."
GAL-COG-3002- "An Analysis of Mortality in Subjects Who Participated in Three Studies of Galantamine in Mild Cognitive Impairment", Sub-Investigator, 2004

TVP1012-A001-201- A 1-Year, double-blind, randomized, placebo-controlled study of Rasagiline 1 mg and 2 mg added to Aricept 10 mg daily in patients with mild to moderate dementia of the Alzheimer's type. 2005.

VP-AD-301 "A Double-Blind Placebo-Controlled Study of VP4896 for the Treatment of Mild to Moderate Alzheimer's Disease". 2006.
PRX-03140 "A Randomized, Double-Blind, Placebo Controlled, Phase IIa Study to Assess the Short-Term Effects of PRX-03140 Alone and in Combination with Donepezil in Subjects with Mild Alzheimer's Disease". 2006

ELN115727-301 & 302 "A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Efficacy and Safety Trial of Bapineuzumab (AA-001, ELN115727 in Patients with Mild to Moderate Alzheimer's Disease who are Apolipoprotein Eε4 Non-Carriers (301) or Non-Carriers (302), Sub-Investigator – 2008

ELN115727-351 "A Phase 3 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" – 2009

Epilepsy

M92-813 "Tiagabine HCl administration in patients with epilepsy." 1995- 1998.

3310101018 "A multicenter, double-blind, placebo-controlled, randomized, parallel-group trail of Rufinamide as adjunctive therapy in patients with inadequately controlled primary generalized tonic-clonic seizures. 1997- 1998.

E2080-A001-301 "A Double-Blind, Placebo-Controlled, Parallel-Group Study of Rufinamide Given as Adjunctive Therapy in Patients with Refractory Partial Seizures". 2006

Migraine

S2b-350 "Imitrex (Sumatriptan Succinate) injection, post-marketing surveillance study." 1995.

CN115-0038—22 "An open label long-term trial evaluating the safety of BMS-180048 150mg in the treatment of patients with migraine headache with or without aura." 1996.

ALN-INT-16 "The efficacy and safety of Alniditan (1.4 or 1.8 mg SC) vs. Sumatriptan (6 mg SC) in the acute treatment of migraine: A randomized, double-blind, placebo-controlled, single-dose trial." 1996.

S2WA3003 "A randomized, double-blind, placebo-controlled, crossover study to evaluate the safety and efficacy of oral Naratriptan in the acute treatment of four migraine attacks." 1995-96.

ALN-USA-18 "Open evaluation of the long-term efficacy, safety and tolerability of 1.4 mg SC Alniditan in the acute treatment of migraine attacks." 1996-1997.

SUMA4015 "A randomized, double-blind, placebo-controlled study to evaluate the impact of sumatriptan injection on workplace productivity loss due to migraine" (Imitrex). 1996- 1997.

VML 251/96/07 "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." (Vanguard) 1997.

1042-0117.12 "A Double-Blind, Parallel, Placebo-Controlled, Single-Dose, Outpatient Study of Ganaxolone for the Treatment of Migraine With or Without an Aura." 1998

S2WA 3001 – "A Randomized, Double-Blind, Placebo-Controlled, Dose Ranging Study to Evaluate the Efficacy and Safety of Four Doses of Oral Naratriptan in the Acute Treatment of a Single Migraine Attack" – 1995

S2WA 1007 - "A Study to Evaluate the Pharmacokinetics and Pharmacodynamics of Oral Naratriptan in Migraine Subjects" **-** 1995-1996

CN102-021 - "A Randomized, Double-Blind Trial Comparing the Safety and Efficacy of Butorphanol Tartrate Nasal Spray Versus Acetaminophen and Codeine Phosphate Capsules Versus Placebo in Patients with Acute Migraine Headache Pain" - 1996

SUMA 4014 **-** "A Double-Blind, Placebo-Controlled Parallel Group Study to Evaluate the Efficacy of a Second Sumatriptan Succinate Tablet (25 or 50 mg.) In the Acute Treatment of Migraine" - 1996-1997

311c90 **-** "A Double Blind, Randomized Comparison of Zolmatriptan and Sumatriptan in the Acute Treatment of Multiple Migraine Headaches" **1997**

VML251/90/06 - "A Double Blind, Placebo Controlled, Parallel Group Study to Assess the Efficiency and Safety of a Single Dose of VML251 (2.5mg) in the Acute Treatment of Migraine". 1997

LY303870 - "Dose Comparison of LY303870 in the Long Term Prophylaxis of Migraine" 1997

RESEARCH ACTIVITIES CON'T

191622-024-00 "A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of the Safety and Efficacy of three dosages of BOTOX◆ (Botulinum Toxin, Type A) Purified Neurotoxin Complex for the Prophylactic Treatment of Migraine Headaches." 2001

A1601022 "A Multicenter Trial to Evaluate the Efficacy, Tolerability and Subject Satisfaction with Eletriptan in the Treatment of Migraine Headache Attacks in Neurology Practices." 2001

M/3275/0008 "Oral Almotriptan (LAS31416) vs. Oral Sumatriptan in a double Blind, Randomized, Parallel Group Study of Cost-Effectiveness and Quality of life in Migraine." 1988-1999

M/3275/0011 "A long-term open label safety study of Almotriptan 12.5 mg orally in migraine patients. 1988-1999

CN115-038-031 - "An Open Label Long-Term Trial Evaluating the Safety of BMS-180048 150 mg in the Treatment of Patients with Migraine Headache With or Without Aura" – 1996

191622-037-01 "A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of BOTOX® (Botulinum Toxin Type A) Purified Neurotoxin Complex for the Prophylactic Treatment of Migraine Headaches in the Episodic Migraine Population."

191622-038 "A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of BOTOX® (Botulinum Toxin Type A) Purified Neurotoxin Complex for the Prophylactic Treatment of Headaches in the Chronic Headache Population." 2003

CAPSS-155 "A Comparison of the Efficacy and Safety of TOPAMAX® (Topiramate) Tablets Versus Placebo for the Prophylaxis of Migraine." 2001

MT100-308 – "A Double Blind, Placebo-Controlled, Study to Evaluate the Safety and Efficacy of MT 100 Versus Over-Encapsulated Sumatriptan in Subjects with Acute Migraine Attacks." – Sub-Investigator – 2001

MT100-402 – "A Double Blind, Randomized Placebo-Controlled, Study to Evaluate the Safety and Efficacy of MT 100 for the Treatment of Migraine in Subjects Who Are Intolerant to 5-HT Agonists or Have Cardiovascular Risk Factors." – Sub-Investigator – 2001

MT100-401A – "A Double Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of a Two Tablet Dose of MT 100 for Treatment of Migraine in Imitrex® Non-responders." – Sub-Investigator – 2001.

MT 300-302 – "A Randomized-Double-Blind, Placebo Controlled Evaluation of the Safety and Efficacy of MT 300 in the Acute Treatment of Migraine." – *Sub-Investigator*

SUM40298 – "A Randomized, Double-Blind, Placebo-Controlled, Single Attack, Parallel-Group Evaluation of the Efficacy of Sumatriptan 50mg Tablets versus Placebo in the Treatment of Self-Described and/or Physician-Diagnosed Sinus Headaches that Meet International Headache Society (HIS) Criteria for Migraine Headache." – *Sub-Investigator*

311CUS/0022 "A Multicenter, Randomized, Placebo-Controlled, Double-Blind, Parallel-Group Trial to Evaluate Early Efficacy and Tolerability of Zolmitriptan (Zomig) Nasal Spray in the Acute Treatment of Adult Subjects with Migraine" – October 2002

VML251/00/02 – "A Double-Blind, Placebo-Controlled, Three-Way Crossover Clinical Study to Assess the Safety and Efficacy of Two Dose Regimens of Frovatriptan, compared with Placebo, in Preventing Menstrually Associated Migraine (MAM) Headaches."2003.

MT 300-401 “A Multicenter Randomized, Single-Blind, Evaluation of Three Injectable Anti-Migraine Drugs” – Sub-Investigator – February 2003

RESEARCH ACTIVITIES CON’T

Migraine *Continued*

MT400-303 “An Open-label, Repeat Dose Study of the Safety of Combo Formulation in the Treatment of Multiple Episodes of Acute Migraine over 12 Months”, Sub – Investigator, 2004

065-00- (Maxalt) “A Multicenter, Double-Blind, Randomized, Parallel, Placebo-Controlled Study to Examine the Efficacy of Rizatriptan 10-mg Tablet Administered Early During a Migraine Attack While the Pain is Mild”, Sub-Investigator, 2004

MT400-301 (POZEN) “A Double-Blind, Multicenter, Randomized, Placebo-Controlled Single Dose Study To Evaluate The Safety And Efficacy Of Trexima In The Acute Treatment Of Migraine Headaches”, Sub-Investigator, 2004

VML251-3MRM/02 “A double-blind, placebo-controlled, parallel group study, with an open-label extension phase, to assess the efficacy, tolerability and safety of oral frovatriptan in the prevention of menstrually related migraine (MRM) headaches in a “difficult to treat” population. 2005.

001 – “A Randomized, Evaluator-Masked Trial to Evaluate the Efficacy of Botox Compared with Depakote in Migraine Prevention”2004

A Single-Center, Double-Blind Comparison of BOTOX® (Botulinum Toxin Type A) and DEPAKOTE® for the Prophylactic Treatment of Migraine Headaches- Pilot Study. 2004

E2007-A001-210- A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Parallel-Group Study to Evaluate the Efficacy and Safety of E2007 in Migraine Prophylaxis. 2005.

“A Single-Center, Double-Blind Comparison of Botox and Topiramate for the Prophylactic Treatment of Chronic Migraine Headache”. 2005

1602 “A Multi-Center, Randomized, Single-Blind, Controlled Study to Obtain Preliminary Safety and Efficacy Data for ONS Treatment of Chronic Migraine Headache”. 2005

191622-080 “A Multicenter Study Evaluating the Efficacy and Safety of Botox Purified Neurotoxin complex as Headache Prophylaxis In Migraine Patients with 15 or More headache Days per 4-Week Period in a 24 week, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Phase Followed by a 32 Week Open-Label Phase”. 2006

TRX103632/635 “A Randomized, Double-Blind, Multi-Center, Placebo Controlled, Cross-Over Study to Determine the Consistency of Response for TREXIMA (Sumatriptan 85mg/Naproxen Sodium 500mg) in the Acute Treatment of Multiple Migraine Attacks”. 2006

TRX106573 “A Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Cross-Over Study of Trexima® in Migraine Subjects Who Report Poor Response or Intolerance to Relpax® “, 2006

NL-2006-001 “A Phase III Randomized, Double-Blind, Parallel Group, Sham-Controlled Study Evaluating the Efficacy and Safety of Non-Invasive, Non-Repetitive Transcranial TMS Stimulation (TMS) for the Acute Preemptive Treatment of the Aura Phase of Migraine Headache”.2007

TON/03/07-CLIN “ A Multi-Centre, Parallel Group, Double-Blind, Placebo Controlled, Dose Ranging Study of the Efficacy and Tolerability of Tonabersat in the Prophylaxis of Migraine Headache and Open Label Extension” 2007

BTX0805" Safety and Efficacy of Botulinum Neurotoxin Type A in the Treatment of Forward Head Posture with Associated Chronic Tension Type Headache using a Novel Fixed sit Injection Paradigm" – 2009.

RESEARCH ACTIVITIES CON'T

NXN-188-203 "A Phase 2 Study of the Safety and Effectiveness of a Single Oral Dose of NXN 188 for the Treatment of Moderate to Severe Migraine Headache with Aura" – 2009

NXN-188-204 "A Phase 2 Study of the Safety and Effectiveness of a Single Oral Dose of NXN 188 for the Treatment of Moderate to Severe Migraine Headache without Aura" – 2009

0462-082-00 " A Worldwide, Randomized, Double Blind, Placebo-Controlled, Parallel Group Clinical Trial to Evaluate the Safety and Efficacy of Rizatriptan for the Acute Treatment of Migraine in Children and Adolescents" - 2010

Multiple Sclerosis

ICOS Protocol AMS05- "Phase 2 Study of Hu23F2G Multi-dose in Acute Exacerbation of Multiple Sclerosis." 1998

6002i - "Phase II Study of Hu23F2G in Acute Exacerbation of Multiple Sclerosis" - 1997

Copolymer I Protocol 01-9002 - "A Long-Term Open Label Study to Evaluate the Safety of Copolymer I and to Extend Its Availability to Patients with Relapsing-Remitting Multiple Sclerosis" - 1994-1997

BL01-3112 - "Phase III, Double-Masked, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Two Doses of Betaseron in Patients with Secondary-Progressive Multiple Sclerosis" - 1996-1997

9006- (TEVA) "A Multi-Center, Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy, Tolerability, and Safety of 40mg of Copaxone in the Treatment of Relapsing-Remitting Multiple Sclerosis Patients" 2004

A 24-month double-blind, randomized, multicenter, placebo-controlled, parallel-group study comparing the efficacy and safety of 0.5 mg and 1.25 mg fingolimod (FTY720) administered orally once daily versus placebo in patients with relapsing-remitting multiple sclerosis with optional extension phase Protocol No.: CFTY720D2309

Extension to CFTY720D2309 (A 24-month double-blind, randomized, multicenter, placebo-controlled, parallel-group study comparing the efficacy and safety of 0.5mg and 1.25mg fingolimod (FTY720) administered orally once daily versus placebo in patients with relapsing-remitting multiple sclerosis, "- 2006

CFTY720D2302 "A 12-month double-blind, randomized, multicenter, active-controlled, parallel-group study comparing the efficacy and safety of 0.5 mg and 1.25 mg fingolimod (FTY720) administered orally once daily versus interferon β-1a (Avonex®) administered i.m. once weekly in patients with relapsing-remitting multiple sclerosis with optional Extension Phase " - 2007

MPB8298-SP-03 "A Double-Blind, Placebo Controlled Multi-Center Study to Evaluate the Efficacy and Safety of MPB8298 in Subjects with Secondary Progressive Multiple Sclerosis." 2007

29652 "A 12 week, Phase IIIb, Open-Label, Single-Arm, Multicenter Trial to Evaluate Ease of use of an Electronic Auto injector (RebiSmart™) for Self-Injection in Subjects with Relapsing Multiple Sclerosis (RMS) treated with Rebif® 44mcg Subcutaneously three times a week." – 2009

DRI10566 "A 14-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy, Safety, and Tolerability of Nerispirdine 50mg, 100mg, and 200mg in Patients with Multiple Sclerosis" – 2009

Nerispirdine (HP184) - Clinical Trial - ACT10573: A double-blind, placebo-controlled, randomized crossover, activity study of oral doses of 50 mg and 400 mg nerispirdine on visual function in patients with multiple sclerosis, IND # 61,494" – 2009

RESEARCH ACTIVITIES CON'T

H9B-MC-BCDJ (a) –Multiple Subcutaneous Doses of LY2127399, an Anti-BAFF Human Antibody, in Subjects with Relapsing-Remitting Multiple Sclerosis" - 2009

101MS325 "A Multicenter, Randomized, Rater-Blind, Parallel-Group, Active Controlled Study to Evaluate the Benefits of Switching Therapy (Glatiramer Acetate or Interferon β 1a) to Natalizumab in Subjects with Relapsing Remitting Multiple Sclerosis" – 2010

CFTY720DUS01 " 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) " – 2010

EFC6058 " A multi-center double-blind parallel-group placebo-controlled study of the efficacy and safety of teriflunomide in patients with relapsing multiple sclerosis who are treated with interferon-beta" – 2010

RebiDose Human Factors. A three-arm multicenter trial to preform human factors testing of the investigational RebiDose ready to use single use auto injector device including simulated injections in subjects with relapsing multiple sclerosis (RMS), caregivers, and nurses' -2011

RebiSmart Human Factors, A three-arm, multicenter trial to perform human factors testing of the investigational RebiSmart electronic auto-injector device including simulated injections in subjects with relapsing multiple sclerosis (RMS), caregivers, and nurses" – 2012

FTY Prefer 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" - 2012

Novartis Assess FTY (2312): Fingolimod vs. Glatiramer Acetate A 12-month, randomized, rater and dose-blinded study to compare the efficacy and safety of fingolimod 0.25mg and 0.5mg administered orally once daily with glatiramer acetate 20mg administered subcutaneously once daily in patients with relapsing-remitting multiple sclerosis" – 2012

A multicenter, open-label phase IV study to evaluate whether a Medication Event Monitoring System (MEMS®) can improve adherence to Tecfidera® (delayed-release dimethyl fumarate) treatment in multiple sclerosis patients. 2015-present

Parkinson's Disease

HL18317 "An open, randomized, multicenter study to assess the efficacy and safety of 1.25mg O.D. and 5 mg B.D. (or 10mg O.D.) Zydis Selegiline in the control of symptoms of Parkinson's Disease in patients stabilized in a regimen including Selegiline." 1996

NR15440/M35016 **"**Non-comparative Open Label Study to Identify Tasmar Dosage Regimen in Non-Fluctuating Parkinson's Disease Patients Treated with Sinemet; with Follow-Up Extension of Tasmar" 1997

A/SEL/97/026, "A randomized, double-blind, parallel-group study to compare the safety and efficacy of Zydis Selegiline 1.25 to 2.5 mg Q.D. with placebo as an adjunct in the management of Parkinsonian patients being treated with Levodopa who exhibit deterioration in the quality of their response to this therapy. "1998

Z/SEL/97/027 “An Open Extension Study of the Safety and Efficacy of Zydis Selegiline 1.25 to 2.5 mg Q.D. as an Adjunct in the Management of Parkinsonian Patients being treated with Levodopa.”

Z/SEL/95/008 EXTENSION – “An open, multicenter parallel group continuation study to assess the safety of 1.25mg qd and 10mg qd Zydis Selegiline in the control of symptoms of Parkinson’s disease in patients stabilized on a regimen including selegiline.” 1998

RESEARCH ACTIVITIES CON’T

RP54274X-320 “A Phase III Multicenter, Double-Blind, Parallel-Group, Placebo Controlled Study of the Effect of Riluzole 50 mg BID or 100 mg BID for Two Years on the Progression of Parkinson’s Disease in 1050 Patients.” - 2001

RP54274X-321 “A Phase III Multicenter, Double Blind, Parallel-Group Placebo Controlled Study of the Effect of Riluzole 50 mg Bid of 100 mg Bid on the Progression of Parkinson’s Disease in Patients Treated With L-Dopa or Dopamine Agonist.” 2001

1198.100 “A 14-week placebo-controlled dose-response efficacy and safety study of NS 2330 in Early Parkinson’s Disease patients (Study of the Concept of treating Early Parkinson’s Disease with a Triple Reuptake inhibitor, NS 2330) [SCEPTRE]” 2004

S308-3-003 “A Multi-Centre, Randomized, Double-Blind, Parallel-Group Placebo and Pramipexole Controlled Study to Assess Efficacy and Safety of SLV308 Monotherapy in the Treatment of Patients with Early Stage Parkinson’s Disease”. 2006

S308-3-008 “An extension of SLV308, A multicenter, randomized, double-blind, parallel-group placebo and pramipexole controlled study to assess efficacy and safety of monotherapy in the treatment of patients with early stage Parkinson’s disease.” 2007

Droxidopa NOH306 “A Multicenter, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled Study to Assess the Clinical Effect of Droxidopa in the Treatment of Symptomatic Neurogenic Orthostatic Hypotension in Patients with Parkinson’s Disease” – 2010

S187.3.002 “A Randomized, Double-Blind, Double-Dummy, Efficacy, Safety and Tolerability Study of Levodopa-Carbidopa Intestinal Gel in Levodopa-Responsive Parkinson's Subjects Receiving Optimized Treatments with Parkinson Medicinal Products, who Continue to Experience Persistent Motor Fluctuations” – 2010.

S187.3.003 “Open-Label, 12-Month Safety and Efficacy Study of Levodopa – Carbidopa Intestinal Gel in Levodopa-Responsive Parkinson’s Disease Subjects.” – 2010.

S187.3.004 “An Open-Label, 12 Month Safety and Efficacy Study of Levodopa-Carbidopa Intestinal Gel in Levodopa-Responsive Subjects with Advanced Parkinson’s Disease and Severe Motor-Fluctuations Despite Optimized Treatment with Available Parkinson’s Disease Medications” – 2010

S187.3.005 “Open-Label Contiuation Treatment Study With Levodopa – Carbidopa Intestinal Gel In Subjects With Advanced Parkinson’s Disease And Severe Motor-Fluctuation Who Have Exhibited A Persistent And Positive Effect To Treatment in Previous Studies.” – 2010.

M12-920 “An Open-Label, Two part, Multicenter Study to Assess the Safety and Efficacy of Levodopa Carbidopa Intestinal Gel (LCIG) for the Treatment of Non-Motor Symptoms in subjects with Advanced Parkinson’s Disease 3/12/13- present

Pain

BTOX 144-8051 “A multicenter, double-blind, placebo-controlled, parallel, graduated-dose clinical trial of Botox (Botulinum toxin type A) purified neurotoxin complex for the treatment of chronic low back muscle spasm.” 1996-1997.

BTOX-145-8051 “A multicenter, double-blind, placebo-controlled, parallel, graduated-dose clinical trial of Botox (Botulinum Toxin Type A) purified neurotoxin complex for the treatment of chronic low back muscle spasm” 1997.

NAL0396 – “A multicenter, randomized, double-blind, placebo-controlled, phase IIb study of oral Naloxone for the treatment of opioid-induced constipation in patients with chronic, non-malignant pain.” 1997-1998.

RESEARCH ACTIVITIES CON’T

Pain *Continued*

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.” May 1997.

97040B- “A Double Blind Randomized, Placebo Controlled Multicenter Study to Evaluate the Efficacy and Safety of 4 Doses of Intramuscular Phenoxybenzamine Hydrochloride Injection versus Placebo in Chronic Muscle Pain.” 1998

191622-013-01 “A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Clinical Study of the Safety and Efficacy of BOTOX◆ (Botulinum Toxin Type A) Purified Neurotoxin complex Injections into Areas of Focal Tenderness in subjects with Chronic Low Back Pain.” 2001

Stroke

CAPRIE/P-1633 “Clopidogrel vs. aspirin in patients at risk of ischemic events” 1993-1996.

510.1067 “Double-blind, randomized, placebo-controlled parallel-group trial of the efficacy and safety of Enlimomab Anti-Icam-1 compared to placebo administered within 6 hours of the onset of stroke symptoms, for treatment of acute ischemic stroke.” 1995-1996.

534.11 “A phase II/III Multicenter, double-blind, placebo-controlled, parallel group study to evaluate the efficacy, safety, tolerability, and pharmacokinetics of intravenous aptiganel hydrochloride in patients with an acute ischemic stroke” (Cerestat). 1996-1997.

IP302-007 “A placebo-controlled study to determine the effects of 500mg of Citicoline in ischemic stroke patients.” 1996-1997.

A-120-A “S*T*A*T stroke treatment with Ancrod (Arvin) trial, parallel, group sequential, double-blind, randomized, placebo-controlled study of the safety and efficacy of IV Ancrod (Arvin) given within 3 hours after the onset of acute ischemic stroke.” 1993-1998.

981-124 “A Double-Blind, Randomized, Placebo-Controlled Study of Atorvastatin as Prevention of Cerebrovascular Events in Patients with a Previous Transient Ischemic Attack (TIA) or Stroke” Present

SB 214857/030 BRAVO “Blockade of the GP IIB/IIIA Receptor to Avoid Vascular Occlusion.” 2000

03062k1-200-US “A randomized, double-blind, placebo-controlled parallel group multicenter trial of Fiblast®.” October 1997-1998.

SA-CMZ-009 “The Clomethiazole Acute Stroke Study in Ischemic Stroke (CLASS-I): A double blind, parallel group, multinational, multicenter study of the efficacy and safety of i.v. Clomethiazole compared to placebo in patients with acute ischemic stroke.” 1998-Present

SA-CMZ-0010 “The Clomethiazole Acute Stroke Study in acute intracerebral hemorrhage (CLASS-H): A double blind, parallel group, multinational, multicenter study of safety of i.v. Clomethiazole compared to placebo in patients with acute intracerebral hemorrhage.” 1998-1999

Stroke *Continued*

SA-CMZ-0011 "The Clomethiazole Acute Stroke Study in t-PA Treated Ischemic Stroke (CLASS-T): A double blind, parallel group, multinational, multicenter study of safety of i.v. Clomethiazole compared to placebo in patients treated with t-PA (tissue Plasminogen activator) for acute ischemic stroke." 1998-1999

YM872 "A Randomized, Double-Blind, Placebo-Controlled, Sequential Dose-Escalation Study to Evaluate the Safety of YM872 in Patients with Acute Ischemic Stroke." 1998-Present

CP101-606 MRI/DIFF/Perf. Stroke "A Double-Blind, Placebo Controlled, Multi-Center Study to Evaluate the Safety and Efficacy of a 72-hour Infusion of CP-101, 606 in Subjects with Acute Ischemic Stroke in the Forebrain, Study #:161-106-5078." 2000

GAIN-America- 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 800mg Loading Dose and Five 200mg Maintenance Doses of GV150526 in the Treatment of Patients with a Clinical Diagnosis of Acute Stroke." 2000

NF 198, 003 "A Double-Blind, Placebo Controlled, Dose-Ranging Study of Nefiracetam in Patients With Post-Stroke Depression." 2001

CHARISMA EFC4505 "Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management and Avoidance (CHARISMA)." 2002

BOTOX vs. Zanaflex " Placebo Controlled Trial of Botox® versus Zanaflex® for the Treatment of Subjects with Post-Stroke Upper Limb Spasticity" March 2003

EFC7331 - ***MATCH*** – "**M**anagement of **At**herthrombosis with **C**lopidogrel in **H**igh-Risk Patients with Recent Transient Ischemic Attack or Ischemic Stroke: A Randomized, Double-Blind Study, with 18 months of Follow-up." 2001-2002

100282 Bayer Study "A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy, Safety, Tolerability, and Pharmacolkinetic/Pharmacodynamic Effects of a Targeted Exposure of Intravenous Repinotan in Patients with Acute Ischemic Stroke", 2003

9.159 "PRoFESS – Prevention Regimen for Effectively avoiding Second Strokes: A double-blind, active and placebo controlled study of Aggrenox vs. clopidogrel, with and without Micardis" 2004

SA-NXY-0007: "A Double-Blind, Randomized, Placebo Controlled, Parallel Group, Multicenter, Phase IIb/III Study to Assess the Efficacy and Safety of Intravenous NXY-059 in Acute Ischemic Stroke" – 2004

SA-NXY-0012- (CHANT) "A Double-Blind, Randomized, Placebo Controlled, Parallel Group, Multicenter, Phase IIb Study to Assess The Safety And Tolerability Of 72 Hours Intravenous Infusion of NXY-059 In Adult Patients with Intracerebral Hemorrhage (ICH)", 2004

RESEARCH ACTIVITIES CON'T

Stroke *Continued*

Ptcl-01213: "A Randomized, Double-blind, Placebo-controlled, Multicenter, Parallel study to evaluate the effects of DP-b99 on Neurologic Function and Disability in subjects with Acute Ischemic Hemispheric Stroke", 2004

F7ICH-1641 A Randomized, Double-Blind, Placebo Controlled, Multi-Centre, Parallel Groups Confirmatory Efficacy and Safety Trial of Activated Recombinant Factor VII (NovoSeven®/Niastase® in Acute Intracerebral Hemorrhage, 2005

NTI-ASP-0502 "A Randomized, Double-Blind, Placebo Controlled Study of Ancrod (Viprinex) in Subjects Beginning Treatment within 6 Hours of the Onset of Acute Ischemic Stroke". 2006

CD-0125 "Safety and Efficacy of NeuroFlo Technology in Ischemic Stroke". 2006

NTS-INT06-007 "A Double-Blind, Randomized, Controlled, Parallel Group, Multi-Centre, 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". Principal Investigator, 2007

A Multicenter Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of SCH530348 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 2°P - TIMI 50) P04737-3694, 2007

P04737 "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", Sub-Investigator 2008

NTS-INT08-009 " A double-blind, randomized, sham-controlled, parallel group, multicenter, pivotal study to assess the safety and efficacy of transcranial laser therapy with the NeuroThera® Laser System for the treatment of acute ischemic stroke within 24 hours of stroke onset." – 2010.

01373 "A double blind, randomized, placebo-controlled, parallel group, multicenter Phase 3 pivotal study to assess the safety and efficacy of 1mg/kg/day intravenous DP-b99 over 4 consecutive days versus placebo when initiated within nine hours of acute ischemic stroke onset." – 2010.

Other Studies

"Schneider (USA) Inc. Carotid Stent Therapy vs. Carotid Endarterectomy."

DVT TRG004-02 & TRG004-03 "Prospective Study of Venous Thromboembolism (VTE) Patient Characteristics, Diagnostic Methods and Treatment Plans in Preparation for a Phase III Study" 2000

GAL-IV-201-201X "A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Clinical Study of Galantamine/Chronic Fatigue." 2000

Other Studies

SR 90107A/ORG 31540 "A Multicenter, randomized, parallel, double-blind, dose ranging study of subcutaneous SR 90107 A/ORG 31540 with an assessor blind, comparative control group of subcutaneous LMWH in the prevention of deep vein thrombosis after elective total hip replacement." 1997

101468/205: A 12-Week, Double-Blind, Placebo Controlled, Parallel Group Study to Assess the Efficacy and Safety of Ropinirole XR (Extended Release) in Patients with Restless Legs Syndrome, Sub-Investigator, 2005

E2020-A001-412: A One Year, Multicenter, Randomized, Double-Blind, Placebo-Controlled Evaluation of the Efficacy and Safety of Donepezil Hydrochloride (E2020) in Subjects with Mild Cognitive Impairment, Sub-Investigator, 2005

"A Randomized, Double-blind, Placebo Controlled Multi-Center Study to Evaluate the Safety and Efficacy of Botulinum Neurotoxin Type A in the Treatment of Forward Head Posture with Associated Chronic Tension Type Headache using a Novel Fixed site Injection Paradigm" Sub-Investigator 2009

PrecisionMed 4800: A single or multiple visit protocol for collection of DNA/RNA/SERUM/PLASMA/CSF in Amyotrophic Lateral Sclerosis and related disorders," Sub-Investigator 2012