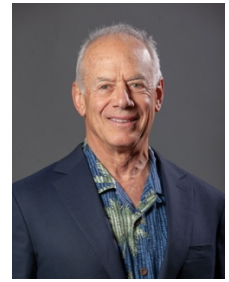


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**Jack David Schim, M.D. FAHS, FAAN**



## EDUCATION

**Chief Resident, Neurology University of California, San Diego, CA – 1985**

**Residency, Neurology University of California, San Diego, CA – 1982-1985**

**Medical School - University of California, San Diego, CA – 1977 - 1981**

**Internship, Medical Cedars Sinai, Los Angeles, CA – 1981-1982**

**Extern, Neurology, National Hospital for Neurologic Disorders, Queen Square, London – 1981**

**Master of Fine Arts, ceramics, photography, University of Miami, Miami, FL – 1973 - 1975**

**B.A. in Psychology, Philosophy, Fine Arts, Magna Cum Laude University of Miami, Miami, FL – 1969 – 1973**

## LICENSURE

California Medical License Number - G48807

NPI number 1346276375

## CERTIFICATIONS

Fellow, American Academy of Neurology – 2019

Fellow, American Headache Society – 2013

Headache Medicine Specialty Certification – 2006

Industrial Medical Council – 1993

American Society for Neurorehabilitation – 1992

Diplomate, American Board of Psychiatry and Neurology – 1987

American Society for Neuroimaging – Neurosonology MRI 1987

National Board of Medical Examiners – 1982

## AWARDS

Phi Kappa Phi – 1975

National Psychology Honor Society – 1973

National Merit Scholar – 1969

## TEACHING EXPERIENCE

Voluntary Assistant Clinical Professor of Neurology, UC, San Diego – 1985 – 2018

Veterans Hospital, La Jolla, California – 1986 – 2018

## INTERNATIONAL SPEAKING PROGRAMS

**Kingdom of Saudi Arabia Lilly Emgality & REYVOW - Real World Experience.** Virtual, January 2022

**Academia Mexicana de Neurología Congress. Lilly - Emgality & REYVOW - Real World Experience.** Virtual, November 2021

**Debate: CGRP mAbs help mood disorders. YES. Controversies in Neurology** Virtual. Dubai November 2021

**Abu Dhabi Brain Conference - Lilly - Emgality & REYVOW - Real World Experience.** Virtual - Abu Dhabi, September 2021

**Dubai Brain Conference - Lilly - Emgality & REYVOW - Real World Experience.** Virtual - Dubai, September 2021

**Scientific Exchange Meeting.** Lilly p- Virtual, Dubai, Europe. April 2021

Novartis **Scientific Session CGRPs - Real World Experience,** Virtual, Finland, December 2020

**Debate: Telemedicine will replace office visits in headache medicine. YES.** Controversies in Neurology Virtual. November 2020

**Galcanezumab Scientific Session, Cluster Headache,** Lilly - Brazil, Mexico, Columbia, Virtual, October 2020

**Erenumab launch meeting, Novartis,** Mexico City, March 2020

**EAN: Migraine Satellite Symposium.** Erenumab, Real World Experience. Novartis. EAN Oslo June 2019

**Devices will surpass medications for Cluster Headache.** Controversies in Neurology, April 2019  
Madrid

**Erenumab education programs** – Portugal March 2019, Argentina April 2019, Canada May 2019

**Erenumab education programs** – Madrid, London, Milan December 2018

**Debate: Medication overuse can be treated with preventives alone.** Controversies in Neurology. Warsaw, March 2018

**Update on Botox for Headache: Israeli Headache Society.** Tel Aviv, January 10, 2017

**Debate Host: Correcting the derangement in sleep architecture is sufficient to treat cluster and migraine headache.** Controversies in Neurology Athens March 2017

**Debate Host: Optimal sleep therapy is superior to migraine preventive medications for Migraine and Cluster.** Controversies in Neurology Lisbon March 2016

**Debate Host: CGRP antibodies will become the treatment of choice for chronic migraine**  
Controversies in Neurology Lisbon March 2016

**Botox Lectures and hands on workshops:** UAE (Abu Dhabi, Dubai), Kuwait (Kuwait City), Saudi Arabia (Riyadh, Jeddah), Egypt (Cairo, Zagazig), November 2015

**Debate: Does Migraine confer an evolutionary advantage to migraineurs?** Controversies in Neurology Berlin April 2014

**Botox Lectures and hands on workshops:** Jordan (Amman), Lebanon (Beirut, Tripoli, Byblos), Egypt (Cairo, Tanta) April 2014

**Debate: The best treatment for chronic migraine is onabotulinumtoxinA (Botox).** Controversies in Neurology Istanbul April 2013

**Debate Chairperson: Headache; Role of Imaging In Headache Management.** Controversies in Neurology Istanbul April 2013

**Debate Chairperson: Stimulating the Sphenopalatine Ganglion (Spg) In Cluster** Controversies in Neurology Istanbul April 2013

**Botox Lectures and hands on workshops:** Turkey (Istanbul, Ankara), Russia (Moscow). April 2013

**Debate: Botulinum toxin is a necessary, safe and effective treatment of chronic migraine,** Controversies in Neurology Vienna April 2012.

**Botox Lectures and hands on workshops:** Czech Republic (Prague), Austria (Vienna), April 2012.

**Botulinum Toxin Type A Compared With Divalproex, A 3 Month Open Label Comparison Study** Oral Presentation, European Neurologic Society, Lausanne, Switzerland. May 30, 2006.

**Botulinum Toxin Type A Compared With Divalproex, A 3 Month Open Label Comparison Study,** Poster and Oral Presentation, European Federation of Neurological Societies, Glasgow Scotland, September 2006

## DOMESTIC SPEAKING PROGRAMS AND POSTERS

Moderator, Headache Cooperative of the Pacific - 14th Annual Winter Conference.

### *Presented Congress Publications*

Blumenfeld AM, Frishberg BM, Schim JD, Iannone A, Yedigiarova L, Manack Adams A. Real-World Evidence for Control of Chronic Migraine (CM) in Patients Meeting American Headache Society (AHS) Criteria Who Received Calcitonin Gene-Related Peptide Monoclonal Antibody (CGRP mAb) Therapy Added to OnabotulinumtoxinA Treatment.

- Presented at the AAN (2021) American Academy of Neurology 2021 - 73rd Annual Meeting.
- Presented at the DHCREP (2021) Diamond Headache Clinic Research and Educational Foundation - 2021 Annual Research Summit .
- Presented at the AHS (2021) American Headache Society - 63rd Annual Scientific Meeting.

Blumenfeld AM, Frishberg BM, Schim JD, Iannone A, Yedigiarova L, Manack Adams A. Real-World Evidence for Control of Patients With Chronic Migraine Who Received CGRP Monoclonal Antibody Therapy Added to OnabotulinumtoxinA Treatment.

- Presented at the HCOP (2021) Headache Cooperative of the Pacific - 14th Annual Winter Conference.
- Presented at the AMCP (2021) Academy of Managed Care Pharmacy 2021 - 33rd Annual Meeting & Expo.
- Presented at the AAN (2021) American Academy of Neurology 2021 - 73rd Annual Meeting.
- Presented at the AHS (2021) American Headache Society - 63rd Annual Scientific Meeting.
- Presented at the AANP (2021) American Association of Nurse Practitioners - 2021 National Conference.
- Presented at the EAN (2021) European Academy of Neurology - 7th Congress.
- Presented at the DHCREP (2021) Headache Update 2021.
- Presented at the EHF (2021) European Headache Federation - 15th European Headache Federation Congress.

**Changes in Acute Headache Medication Use Among Patients With Chronic Migraine and Medication-Overuse Headache: An Exploratory Analysis of PROMISE-2.** Poster. AAN 2022

**Likelihood of Response With Subsequent Dosing for Patients With Migraine and Initial Suboptimal Response With Eptinezumab.** Poster. AHS 2022

**Migraine Prevention.** American Headache Society Scottsdale Meeting. November 18, 2021

**Update on Headache Therapies 2021.** SCMG Annual Conference - 2021. September 2021

**Not All Headache is the Same. Update on Headache Therapies 2021.** Scripps Primary Care Update. August 2021

**Oral Rimegepant 75 mg is Safe and Well Tolerated in Adults With Migraine and Cardiovascular Risk Factors: Results of a Multicenter, Long-Term, Open-Label Safety Study.** IHC September 2021

**Has the pendulum swung too far regarding "Evidence based Medicine".** - Headache Cooperative of the Pacific January 2021

**Matching Treatments to Patient Profiles** - Headache Cooperative of the Pacific January 2021

**Preventive Treatment for Chronic migraine. AHS Scottsdale Virtual meeting.** November 2020

**Not All Headache is the Same. Update on Headache Therapies 2020.** Scripps Primary Care Update. September 2020

**Updates in the management of Migraine Headaches.** Practicing Clinicians Exchange, May 21, 2020

**Vestibular and Hemiplegic Migraine.** Diamond Headache Meeting, San Diego, February 2020

**Migraine with Aura.** Diamond Headache Meeting, San Diego, February 2020

**Botox for Chronic Migraine.** Diamond Headache Meeting, San Diego, February 2020

**Moving the Needle. Moderator** – Headache Cooperative of the Pacific January 2020

**Moderator, Breaking Advances** – Headache Cooperative of the Pacific January 2020

**Pain, Memory and Migraine.** Migraine World Summit, 2019, 2020

**Chronic Migraine** - Cases and Protocol, AHS Scottsdale, November 2019

**Botox for Chronic migraine – Palo Alto VAH, Stanford Residents,** August 2019

**PriMed - Migraine In Motion: Treatment Advances in Management and Prevention.** San Jose August 2019

**Real-World Evidence for Control of Patients With Chronic Migraine Who Received CGRP Monoclonal Antibody Therapy Added to OnabotulinumtoxinA Treatment.** Pain Ther. 2021 Apr 21.

**Diamond Headache Meeting Summer 2020 - Eptinezumab Reduces the Frequency of Headaches and Migraines in Patients With Episodic or Chronic Migraine: Results From the PROMISE-1 and PROMISE-2 Trials**

**AHS June 2020 Virtual Meeting Poster: Rimegepant is Safe and Tolerable for the Acute Treatment of Migraine in Patients Using Preventive. Migraine Medications: Results from a Long-Term Open-Label Safety Study**

**AHS June 2020 Virtual Meeting Poster: Oral Rimegepant 75 mg is Safe and Well Tolerated in Adults With Migraine and Cardiovascular Risk Factors: Results of a Multicenter, Long-Term, Open-Label Safety Study**

**AHS Poster and Oral Presentation. New Therapeutic Options for Treating Migraine.** AAPA Denver May 2019

**AAN: Poster presentation. Eptinezumab Increases Days Free from Canonical Migraine-Associated Symptoms Within 1 Month of Treatment in Patients with Chronic Migraine.** AAN Meeting, Philadelphia May 2019

**Rethinking Migraine Treatment.** California Neurologic Society, Cupertino March 2019

**Migraine with Aura.** Diamond Headache Meeting, Carlsbad, February 2019

**Devices and Procedures for Headache.** Diamond Headache Meeting –February 2019

**Botox for Chronic Migraine.** Diamond Headache Meeting –February 2019

**Moderator, Breaking Advances** – Headache Cooperative of the Pacific January 2019

**Expanding Horizons in the Management of Migraine Headache** - PCE program. November 2018, Atlanta

**Migraine with Aura** – Cases. AHS Scottsdale, November 2018

**Chronic Migraine** - Cases and Protocol, AHS Scottsdale, November 2018

**Update on Migraine Therapeutics.** California Neurologic Society, San Diego, October 2018

**Botox for Chronic Migraine.** Diamond Headache Meeting –February 2018

**Promotional presentations on migraine**

- ~ 60 programs in 2021: Abbvie, Amgen, Biohaven, Lilly, Novartis, Teva
- ~ 50 programs in 2020: Allergan, Amgen, Biohaven, Lilly, Novartis, Teva, Theranica
- ~ 80 programs in 2019: Allergan, Amgen, Electrocore, Lilly, Novartis, Teva, Theranica
- ~ 50 programs in 2018: Allergan, Amgen, Avanir, Depomed, Electrocore, Lily, Novartis, Pernix, Promius, Supernus, Teva, Upshire-Smith,

**Promotional presentations and hands on workshops on Botox for chronic migraine** - > 80 programs over the last 10 years.

**Cluster – Patient interview** – Headache Cooperative of the Pacific January 2018

**Secondary Headaches Mimicking Migraine.** Southern Clinical Neurologic Society, Naples Florida. January 16, 2018

**Update on migraine therapies.** California Neurology Society. San Diego, September 2018

**CME and Grand Rounds** – 12 programs 2017-2018 through Potomac Center for Medical Education, Practicing Clinician Exchange and Rockpointe.; Steering Committee and content development faculty with Dr Steven Silberstein and Dr Susan Burke

**Procedures and Injections for Headache** – Headache Cooperative of the Pacific January 2017

**The ADVANCES Initiative: New Advances in Headache Diagnosis and Treatment,** Los Angeles, Chicago, Atlanta, Miami, St Louis, Philadelphia, Nashville. Fall 2017

**Stroke 101.** June 2017, September 2018

**Stroke Critical Care Update.** April 2017

**Diagnose these interesting headache patients, Figure out the best treatments,** Southern Clinical Neurology Society, January 2017

**Botulinum toxin for Chronic Migraine - Skills Workshop.** American Academy of Neurology: April 2016

**Botulinum toxin for Chronic Migraine** – Southern Clinical Neurology Society, January 2016

**Botulinum toxin for Chronic Migraine** – American Headache Society, Scottsdale, November 2016

**Improving Migraine Treatment: A Collaborative Care Approach.** PCE Workshops, 2015-2016

**Speaker on headache, stroke, dementia, neuropathy, pain,** Scripps Primary Care in Paradise – 2010-2016

**EMR – A Great Tool for your Practice.** American Academy of Neurology. April 4 2005, May 3 2006, May 4 2007

**Stroke Prevention Issues in Women:** Women’s Healthcare Forum: Anaheim:, March 15, 2007, Chicago, April 20, 2007, Houston, May 18, 2007, Baltimore, Jun 15, 2007

**Treatment of Alzheimer's Disease.** Women’s Healthcare Forum: Anaheim:, March 15, 2007, Chicago, April 20, 2007, Houston, May 18, 2007, Baltimore, Jun 15, 2007

**Stroke Update. Advances in Neurology 2007:** Chicago September 8 2007, New York September 15 2007, New Orleans. October 20 2006.

**Stroke Update 2007:** U.S. Psychiatric & Mental Health Congress Orlando. October 14, 2007

**Pearls of the Neurologic Exam** U.S. Psychiatric & Mental Health Congress Orlando October 14, 2007

**Botulinum toxin for Dystonia - Skills Workshop.** American Academy of Neurology: May 7, 2006

**Stroke Update 2006** U.S. Psychiatric & Mental Health Congress. New Orleans. October 20 2006

**Pearls of the Neurologic Exam.** U.S. Psychiatric & Mental Health Congress, New Orleans. October 20 2006

## **PUBLICATIONS AND PAPERS**

Blumenfeld AM, Frishberg BM, Schim JD, Iannone A, Schneider G, Yedigarova L, Manack Adams A. Real-World Evidence for Control of Chronic Migraine Patients Receiving CGRP Monoclonal Antibody Therapy Added to OnabotulinumtoxinA: A Retrospective Chart Review. Pain Ther. 2021 Apr 21.

Faust E, Pivneva I, Yang K, Betts KA, Ahmed Z, Joshi S, Hogan R, Blumenfeld A, Schim J, Feoktistov A, Carnes K, Bensink M, Wu EQ, Chou DE, Chandler D. Real-World Treatment Profiles, Clinical Outcomes, and Healthcare Resource Utilization of Patients with Migraine Prescribed Erenumab: A Multicenter Chart-Review Study of US Headache Centers. Neurol Ther. 2021 Jun;10(1):293-306.

Nerivio-Migra for Preventive effect in Chronic Migraine. For submission

Schim J. Moving the Needle, the Clinical Perspective. Headache. 2020 Oct;60(9):2042-2048.

Hutchinson, S, Schim, J, Lipton, R. Rimegepant 75 mg Demonstrates Safety and Tolerability Similar to Placebo With No Effects of Age, Sex, or Race in 3 Phase 3 Trials. Virtual poster, AAN 2020

Rimegepant is Safe and Tolerable for the Acute Treatment of Migraine in Patients Using Preventive Migraine Medications: Results from a Long-Term Open-Label Safety Study (Study 201). Susan Hutchinson, MD; Jack Schim, MD; Richard B. Lipton, MD et al. Virtual poster, AAN 2020

Loo LS, Ailani J, Schim J, Baygani S, Hundemer HP, Port M, Krege JH. Efficacy and safety of lasmiditan in patients using concomitant migraine preventive medications: findings from SAMURAI and SPARTAN, two randomized phase 3 trials. *J Headache Pain*. 2019 Jul 24;20(1):84.

Liu E, Schmidt ME, Margolin R, Sperling R, Koeppe R, Mason NS, Klunk WE, Mathis CA, Salloway S, Fox NC, Hill DL, Les AS, Collins P, Gregg KM, Di J, Lu Y, Tudor IC, Wyman BT, Booth K, Broome S, Yuen E, Grundman M, Brashear HR; Bapineuzumab 301 and 302 Clinical Trial Investigators. Amyloid- $\beta$  11C-PiB-PET imaging results from 2 randomized bapineuzumab phase 3 AD trials. *Neurology*. 2015 Aug 25;85(8):692-700.

Salloway S, Sperling R, Fox NC, Blennow K, Klunk W, Raskind M, Sabbagh M, Honig LS, Porsteinsson AP, Ferris S, Reichert M, Ketter N, Nejadnik B, Guenzler V, Miloslavsky M, Wang D, Lu Y, Lull J, Tudor IC, Liu E, Grundman M, Yuen E, Black R, Brashear HR; Bapineuzumab 301 and 302 Clinical Trial Investigators. Two phase 3 trials of bapineuzumab in mild-to-moderate Alzheimer's disease. *N Engl J Med*. 2014 Jan 23;370(4):322-33.

Blumenfeld A, Ashkenazi A, Napchan U, Bender SD, Klein BC, Berliner R, Ailani J, Schim J, Friedman DI, Charleston L 4th, Young WB, Robertson CE, Dodick DW, Silberstein SD, Robbins MS. Expert consensus recommendations for the performance of peripheral nerve blocks for headaches--a narrative review. *Headache*. 2013 Mar;53(3):437-46.

Blumenfeld A, Schim J, Brower J. Pure tension-type headache versus tension-type headache in the migraineur. *Curr Pain Headache Rep*. 2010 Dec;14(6):465-9.

Lees KR, Bluhmki E, von Kummer R, Brott TG, Toni D, Grotta JC, Albers GW, Kaste M, Marler JR, Hamilton SA, Tilley BC, Davis SM, Donnan GA, Hacke W; ECASS, ATLANTIS, NINDS and EPITHET rt-PA Study Group, Allen K, Mau J, Meier D, del Zoppo G, De Silva DA, Butcher KS, Parsons MW, Barber PA, Levi C, Bladin C, Byrnes G. Time to treatment with intravenous alteplase and outcome in stroke: an updated pooled analysis of ECASS, ATLANTIS, NINDS, and EPITHET trials. *Lancet*. 2010 May 15;375(9727):1695-703.

Diener HC, Dodick DW, Aurora SK, Turkel CC, DeGryse RE, Lipton RB, Silberstein SD, Brin MF; PREEMPT 2 Chronic Migraine Study Group. OnabotulinumtoxinA for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 2 trial. *Cephalalgia*. 2010 Jul;30(7):804-14.

Aurora SK, Dodick DW, Turkel CC, DeGryse RE, Silberstein SD, Lipton RB, Diener HC, Brin MF; PREEMPT 1 Chronic Migraine Study Group. OnabotulinumtoxinA for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 1 trial. *Cephalalgia*. 2010 Jul;30(7):793-803.

Teal P, Davis S, Hacke W, Kaste M, Lyden PD; Modified Randomized Exposure Controlled Trial



Study Investigators, Fierus M; Bayer HealthCare AG. 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: modified Randomized Exposure Controlled Trial (mRECT). *Stroke*. 2009 Nov;40(11):3518-25. doi: 10.1161/STROKEAHA.109.551382.

Diener HC, Sacco RL, Yusuf S, Cotton D, Ounpuu S, Lawton WA, Palesch Y, Martin RH, Albers GW, Bath P, Bornstein N, Chan BP, Chen ST, Cunha L, Dahlöf B, De Keyser J, Donnan GA, Estol C, Gorelick P, Gu V, Hermansson K, Hilbrich L, Kaste M, Lu C, Machnig T, Pais P, Roberts R, Skvortsova V, Teal P, Toni D, VanderMaelen C, Voigt T, Weber M, Yoon BW; Prevention Regimen for Effectively Avoiding Second Strokes (PRoFESS) study group. Effects of aspirin plus extended-release dipyridamole versus clopidogrel and telmisartan on disability and cognitive function after recurrent stroke in patients with ischaemic stroke in the Prevention Regimen for Effectively Avoiding Second Strokes (PRoFESS) trial: a double-blind, active and placebo-controlled study. *Lancet Neurol*. 2008 Oct;7(10):875-84.

Yusuf S, Diener HC, Sacco RL, Cotton D, Ounpuu S, Lawton WA, Palesch Y, Martin RH, Albers GW, Bath P, Bornstein N, Chan BP, Chen ST, Cunha L, Dahlöf B, De Keyser J, Donnan GA, Estol C, Gorelick P, Gu V, Hermansson K, Hilbrich L, Kaste M, Lu C, Machnig T, Pais P, Roberts R, Skvortsova V, Teal P, Toni D, VanderMaelen C, Voigt T, Weber M, Yoon BW; PRoFESS Study Group. Telmisartan to prevent recurrent stroke and cardiovascular events. *N Engl J Med*. 2008 Sep 18;359(12):1225-37.

Sacco RL, Diener HC, Yusuf S, Cotton D, Ounpuu S, Lawton WA, Palesch Y, Martin RH, Albers GW, Bath P, Bornstein N, Chan BP, Chen ST, Cunha L, Dahlöf B, De Keyser J, Donnan GA, Estol C, Gorelick P, Gu V, Hermansson K, Hilbrich L, Kaste M, Lu C, Machnig T, Pais P, Roberts R, Skvortsova V, Teal P, Toni D, Vandermaelen C, Voigt T, Weber M, Yoon BW; PRoFESS Study Group. Aspirin and extended-release dipyridamole versus clopidogrel for recurrent stroke. *N Engl J Med*. 2008 Sep 18;359(12):1238-51.

Mayer SA, Brun NC, Begtrup K, Broderick J, Davis S, Dinger MN, Skolnick BE, Steiner T; FAST Trial Investigators. Efficacy and safety of recombinant activated factor VII for acute intracerebral hemorrhage. *N Engl J Med*. 2008 May 15;358(20):2127-37.

Blumenfeld AM, Schim JD, Chippendale TJ. Botulinum toxin type A and divalproex sodium for prophylactic treatment of episodic or chronic migraine. *Headache*. 2008 Feb;48(2):210-20. doi: 10.1111/j.1526-4610.2007.00949.x.

Schim JD, Stang P. Overview of pain management. *Pain Pract*. 2004 Mar;4 Suppl 1:S4-18.

Schim J. Effect of preventive treatment with botulinum toxin type A on acute headache medication usage in migraine patients. *Curr Med Res Opin*. 2004 Jan;20(1):49-53.

Lyden P, Jacoby M, Schim J, Albers G, Mazzeo P, Ashwood T, Nordlund A, Odergren T. The Clomethiazole Acute Stroke Study in tissue-type plasminogen activator-treated stroke (CLASS-T): final results. *Neurology*. 2001 Oct 9;57(7):1199-205.

CAPRIE Steering Committee. A randomised, blinded, trial of clopidogrel versus aspirin in patients at risk of ischaemic events (CAPRIE). CAPRIE Steering Committee. *Lancet*. 1996 Nov 16;348(9038):1329-39..

Schim J, Lyden P, Sharp FR. Increased subcortical and laminar cortical 2-deoxy[14C]glucose

uptake during cerebellar stimulation. *Exp Neurol.* 1981 Nov;74(2):499-518.

## SUBMITTED ABSTRACTS:

Accepted to IHS: Eptinezumab Increases Days Free from Canonical Migraine-Associated Symptoms Within 1 Month of Treatment in Patients with Chronic Migraine

Accepted to AHS: Efficacy and safety of lasmiditan in patients on concomitant migraine preventive medications: findings from SAMURAI and SPARTAN Phase 3 trials

Accepted to AHS: Eptinezumab Reduces the Frequency of Headaches and Migraines in Patients with Episodic or Chronic Migraine: Results from the PROMISE 1 and PROMISE 2 Trials

Accepted to AAN: Eptinezumab Reduces the Frequency of Headaches and Migraines in Patients with Episodic or Chronic Migraine: Results from the PROMISE-1 and PROMISE-2 Trials

## ADVOCACY

**Alliance for Patient Access** – President, California Chapter. Board member since 2005

**Lobbying** with American Heart Association to Congress regarding stroke care - You're the Cure on the Hill 2009

**Lobbying** with BioCom to Congress regarding biosimilars – April 2014

## CLINICAL EXPERIENCE

**Senior Partner Neurologist, Private Group Practice, North County Neurology Associates**

dba The Neurology Center, Carlsbad, CA – 1985 – Present.

**Neurologist, Research Center,** The Research Center of Southern California, LLC. Carlsbad, CA 2007 – Present

**Staff Neurologist:** Critical Care Neurology, Emergency Care, Neurology, Clinical Consultation, Electrodiagnostic Studies, Rehabilitation Neurology – 1985 – Present

Scripps Memorial Hospital, Encinitas Scripps Memorial Hospital, La Jolla Tri-City Medical Center, Oceanside

## HOSPITAL AFFILIATIONS

**Tri-City Medical Center,** Vista, California, Active Privileges – 1985- Present, Chief of

Neuroscience Division – 1995-1997

**Scripps Memorial Hospital**, Encinitas, California, Active Privileges – 1985- Present, Chief of Neurology Division – 1992-1994, 2000-2015

**Scripps Memorial Hospital**, La Jolla, California, Active Privileges – 1985 – 2015, Chief of Neurology Division – 1997-2000

**UCSD**, La Jolla, California, Asst. Clinical Prof. – 1986 – Present

**VA Medical Center**, San Diego, California, Active Privileges – 1986 – Present

## PROFESSIONAL MEMBERSHIPS

**Medical Director**, Tri-City Medical Center Stroke Program – 2005 –2019

**Member**, American Academy of Neurology – 1983 – Present **President**, Headache Cooperative of the Pacific – 2016-2018 **Board Member**, Alliance for Patient Access – 2005- present

**Member**, San Diego Neurologic Society – 1981 – Present, **President** – 1992 – 1995

**Secretary/Treasurer** – 1990 – 1992

**Neurology Advisor**, California Medical Society – 1992 – 1995

**Neurology Advisor**, Blue Shield/Medicare Carrier Advisory Committee – 1996 – 2010

**Board Member**, California Neurologic Society – 1997 – Present, **Secretary/Treasurer** – 2000 – 2002, **President** – 2003- 2006

**Chairperson**, San Diego Metro Stroke Task Force – 1999 – 2004 **President**, American Heart Association San Diego – 2002 – 2004 **President**, San Diego Stroke Council – 1998 – 2004

**Member**, American Society of Neurorehabilitation – 1998 – 2010

**Member**, American Association of Electrodiagnostic Medicine – 1990 – 2010

**Member**, American Society of Neuroimaging – 1987 – 2010

## RESEARCH ACTIVITIES

### Principal Investigator

#### **Alzheimer's Disease**

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

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

#### **Migraine**

Allergan- ACHIEVE - A Phase 3, Multicenter, Randomized, Double-Blind, Placebo Controlled

Single Attack Study to Evaluate the Efficacy, Safety, and Tolerability of Oral Ubrogapant in the Acute Treatment of Migraine.

Lilly – GLADIATOR - A Study of Two Doses of LAsMiditan (100 mg and 200 mg) Compared to Placebo in the Acute Treatment of Migraine: A Randomized, Double-blind, Placebo-controlled Parallel Group Study

Alder - Promise 2 study. Evaluation of ALD403 (Eptinezumab) in the Prevention of Chronic Migraine. 2019

Alder – RELIEF study. Evaluate Efficacy & Safety of Eptinezumab Administered Intravenously in Subjects Experiencing Acute Attack of Migraine. 2020

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ElectroCore – Premium 2 - A Randomized, Multicenter, Double-Blind, Parallel, Sham-Controlled Study Of Non-Invasive Vagus Nerve stimulation (nVNS) For The Prevention Of Migraines. 2019

Satsuma – EMERGE. A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate STS101 in the Acute Treatment of Migraine. 2019

Zosano – ZOTRIP. Safety and Efficacy of ZP-Zolmitriptan Intracutaneous Microneedle Systems for the Acute Treatment of Migraine 2017

Co-Lucid - SPARTAN study – A multicenter, randomized, double-blind, placebo-controlled, parallel- group, study comparing the efficacy and safety of lasmitidan for acute treatment of migraine. 2016

Allergan. COMPEL. A Long-term Efficacy, Safety, and Tolerability Study of BOTOX® in Patients With Chronic Migraine. 2016

Labrys: A multicenter, randomized, double-blind, double-dummy, placebo-controlled, parallel group, multi-dose study comparing the efficacy and safety of subcutaneous LBR-101 with placebo for the preventive treatment of chronic migraine. 2014

Labrys: A multicenter, randomized, double-blind, placebo-controlled, parallel-group, study comparing the efficacy and safety of two doses of subcutaneous LBR-101 with placebo for the preventive treatment of high frequency episodic migraine. 2014

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

Allergan – PREEMPT “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

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

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

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 (Frovatriptan ) in the acute treatment of migraine." (Vanguard) 1997

### **Multiple Sclerosis**

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

MPB8298-SP-03 "A Double-Blind, Placebo Controlled Multi-Center Study to Evaluate the Efficacy and Safety of MBP8298 in Subjects with Secondary Progressive Multiple Sclerosis." 2007

### **Parkinson's Disease**

"A/SEL/97/026, A randomized, double-blind, parallel-group study to compare the safety and efficacy of Zydys 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." 1998-2003

### **Stroke**

Study Ptcl-01373 entitled: 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." 201

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

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

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

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 – 2006

Ptcl-01213 entitled: "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

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 Inter-cerebral Hemorrhage (ICH)." 2004

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

100282 Bayer Study "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." 2003

YM872 "A Randomized, Double-Blind, Placebo-Controlled, Sequential Dose-Escalation Study to Evaluate the Safety of YM872 in Patients with Acute Ischemic Stroke." 1998-2003

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." 1998-2000

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

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

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

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 03062k1-200-US "A randomized, double-blind, placebo-controlled parallel group multicenter trial of Fiblast®." October 1997- 1999

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." 1995-96

### **Sub-Investigator**

#### **Alzheimer's Disease**

AAB-001-SC-ALZ-2003 " A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi- Center, Biomarker, Safety, and Pharmacokinetic Study of Bapineuzumab (AAB-001) Administered Subcutaneously at Monthly Intervals in Subjects with Mild to Moderate Alzheimer's Disease." 2010

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

ELN115727-301 & 302 "A Phase III, Multicenter, Randomized, Double-Blind, Placebo Controlled, Parallel Group, Efficacy and Safety Trial of Bapineuzumab ( AAB-0001, ELN115727 in Patients with Mild to Moderate Alzheimer's Disease who are Apolipoprotein E ε4 Non-Carriers (301) or Carriers (302)" 2008

VP-AD-301 "A Double-Blind Placebo-Controlled Study of VP4896 for the Treatment of Mild to

Moderate Alzheimer's Disease". 2006.

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.

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

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.

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

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.

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.

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

## **Epilepsy**

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**

Electrocore: Non-invasive Neurostimulation of the vagus nerve with the GammaCore device for the treatment of cluster headache. 2013

COMPEL An open-label, multicenter study of the long-term efficacy, safety and tolerability of BOTOX for the prophylaxis of headaches in adult patients with chronic migraine" – 2012

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

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

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.

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

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

"The Effect of BOTOX® for the Treatment of Episodic Migraine Headaches in Patients who Demonstrate Poor Response to Triptans." 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

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

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

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® (Botulinum Toxin Type A) and DEPAKOTE® for the Prophylactic Treatment of Migraine Headaches- Pilot Study." 2004

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." 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." 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." 2004

CL1776-005 – "A Phase 2 Safety and Efficacy Study of NPS 1776 for the Acute Treatment of Migraine Headaches." 2004

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

MT 300-401 " A Multicenter Randomized, Single-Blind, Evaluation of Three Injectable Anti-Migraine Drugs." 2003

3420AG1 – "Program to Assess Treatment Strategies: A Botox Observational Program." 2003

MT 300-302 – "A Randomized-Double-Blind, Placebo Controlled Evaluation of the Safety and Efficacy of MT 300 in the Acute Treatment of Migraine." 2003

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." 2003

191622-037-01 "A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of BOTOX<sup>®</sup> (Botulinum Toxin Type A) Purified Neurotoxin Complex for the Prophylactic Treatment of Migraine Headaches in the Episodic Migraine Population." 2003

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

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." 2002

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

MT 100-308 "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." 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." 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<sup>®</sup> Nonresponders." 2001

191622-024-00 "A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of the Safety and Efficacy of three dosages of BOTOX<sup>®</sup> (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

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

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

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

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." 1996-97

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

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

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

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

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

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

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

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

### **Multiple Sclerosis**

CBAF312A2304: A multicenter, randomized, double-blind, parallel-group, placebo-controlled variable treatment duration study evaluating the efficacy and safety of Siponimod (BAF312) in patients with secondary progressive multiple sclerosis. 2013

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

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

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

101MS325 "A Multicenter, Randomized, Rater-Blind, Parallel-Group, Active Controlled Study to Evaluate the Benefits of Switching Therapy (Glatiramer Acetate or Interferon  $\beta$  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

Nerispiridine (HP184) - Clinical Trial - ACT10573: A double-blind, placebo-controlled, randomized crossover, activity study of oral doses of 50 mg and 400 mg nerispiridine on visual function in patients with multiple sclerosis IND # 61,494." 2010

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 Nerispiridine 50mg, 100mg, and 200mg in Patients with Multiple Sclerosis." 2009

CFTY720D2302 "A 12-Month Double-Blind, Randomized, Multi-Centre, 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  $\beta$ -1a (Avonex®) Administered I.M. Once Weekly in Patients with Relapsing-Remitting Multiple Sclerosis." 2007

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  $\beta$ -1a (Avonex®) administered i.m. once weekly in patients with relapsing-remitting multiple sclerosis with optional Extension Phase." 2007

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

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

CAMMS223 – "A Phase II, Randomized, Open-Label, Three-Arm Study Comparing Low and High Dose CAMPATH (MABCAMPATH) and High Dose Rebif in Patient with Early, Active Relapsing-Remitting Multiple Sclerosis." 2003 – 2004

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

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

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

### **Parkinson's Disease**

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 Parkinsons disease (M12-920) 2013

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 Continuation 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

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

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

DA2APD-0075-031 "A Phase III, Double-blind, Fixed Dose Response Study Comparing the Efficacy and Safety of Sumanriole vs. Placebo In Patients with Early Parkinson's Disease." 2004

1198.100 NS2330 "A Fourteen-Week Placebo-Controlled Dose-Response Efficacy and Safety Study of NS 2330 in Early Parkinson's Disease Patients (Study for Proof of Concept in Early Parkinson's Disease of a Triple Reuptake Inhibitor, NS2330 / SCEPTRE)." 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." 2003

Z/SEL/97/027 "An Open Extension Study of the Safety and Efficacy of Zydys Selegiline 1.25 to 2.5 mg

Q.D. as an Adjunct in the Management of Parkinsonian Patients being treated with Levodopa." 2003

666E-CNS-0075-021 "A Phase III, Double-Blind, Placebo-Controlled, Randomized Study Comparing the Efficacy, Safety, and Tolerability of Sumanitrole Versus Placebo or Ropinirole in Patients with Early Parkinson's Disease." 2002

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." 2002

RP54274X-321 "A Phase III Multicenter, Double Blind, Parallel-Group Placebo Controlled Study of the Effect of Riluzole 50 mg BID or 100 mg BID on the Progression of Parkinson's Disease in Patients Treated With L-DOPA or Dopamine Agonist." 2002

Z/SEL/95/008 EXTENSION – "An open, multicenter parallel group continuation study to assess the safety of 1.25mg qd and 10mg qd Zydys Selegiline in the control of symptoms of Parkinson's disease in patients stabilized on a regimen including Selegiline." September 1997 – November 1998

NR15440/M35016 "Noncomparative 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

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.) Zydys Selegiline in the control of symptoms of Parkinson's Disease in patients stabilized in a regimen including Selegiline." 1996

## **Stroke**

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

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

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." 2008

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. 2007

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.

BOTOX vs ZANAFLEX "Placebo Controlled Trial of BOTOX versus Zanaflex for the Treatment of Subjects with Post- Stroke Upper Limb Spasticity" – March 2003- 2004

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

CHARISMA EFC4505 "Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management and Avoidance (CHARISMA)." 2002-2003

EFC7331 - MATCH – "Management of Atherothrombosis with Clopidogrel in High-Risk Patients with Recent Transient Ischemic Attack or Ischemic Stroke: A Randomized, Double-Blind Study, with 18 months of Follow-up." 2003

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

NF 198,003 "A Double-Blind, Placebo-Controlled, Dose-Ranging Study of Nefiracetam in Patients with Post-Stroke Depression." 2000

SB 214857/030 BRAVO "Blockade of the GP IIB/IIIA Receptor to Avoid Vascular Occlusion." 1999

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." 1999

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 - 1994

CAPRIE/P-1633 "Clopidogrel vs. Aspirin in patients at risk of ischemic events" 1993-96

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." 2009

## **Other**

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

FHP: "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." 2008

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." 2005

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." 2005

GAL-COG-3002- "An Analysis of Mortality in Subjects who participated in Three Studies of Galantamine in Mild Cognitive Impairment." 2004

E2020-A001-209 "A 12-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Preliminary Study To Determine The Efficacy and Safety of Donepezil Hydrochloride (E2020) In Patients With Persistent Mild to Moderate Memory Impairments Resulting From a Single Closed Head Injury." 2003

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" 2002

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