



PACIFIC RESEARCH NETWORK, INC

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STEPHEN G. THEIN, Ph.D.

EDUCATION

1974 Ph.D: Professional Psychology, United States International University
1972 MA: Human Behavior, United States International University
1971 BA: California Western University

TRAINING

1976 – 1978 Externship: San Diego Neuropsychiatric Medical Clinic
1973 - 1976 Internship: Catholic Diocese, University of California San Diego

MEDICAL EXPERIENCE

2004 -- Present Consultant, Sleep Disorders Speakers Bureau, Sepracor Inc.
2004 -- Present Consultant, Alzheimer's Disease Speakers Bureau, Forest Research Institute
2003 -- Present Consultant, Speaker, Alzheimer's Disease Rater, Trainer, Pharmastar
1998 Consultant, Alzheimer's Disease Speakers Bureau, Novartis Pharmaceuticals
1993 -- 1996 Consultant, Alzheimer's Disease Speakers Bureau, Warner-Lambert, Parke-Davis
1989 -- 1997 Consultant and Editorial Advisory Board, CardiSense, Hoechst Marion Roussel, Inc.
1987 – 1989 Clinical Trials Consultant, Institute for Biological Research and Development
1981 – 1986 Clinical Director, Employee Assistance Program for Occupational Health Management, Inc.
1980 – 1981 Clinical Director, ADAPT (Alcohol Detoxification and Preliminary Treatment) Program
1979 – 1986 Director, Principal Investigator, Psychological Services of San Diego
1978 -- Present Director, Principal Investigator, Pacific Research Network, San Diego, California
1975 Health Consultant, San Diego Board of Supervisors
1973 – 1978 Production and Distribution of Educational and Therapy Models, Training Films and Multi-Media Presentations

CERTIFICATION AND LICENSURE

SCRIP Society for Clinical Researchers in Pharmacology-Member
American Academy of Sleep Medicine-Member
Clinical Psychologist/California Board of Psychology
National Register of Health Service Providers
American Board of Psychological Specialties, Psychopharmacology – Diplomate
American College of Advanced Practice Psychologists, Founding Fellow, Board Certified
National Institutes of Health, Human Participants Protection Education for, Research Teams- Online Course- Completed 4/25/01

Licensure: State of California
License Number: PSY 5218
Expiration Date: August 31, 2008

PROFESSIONAL ORGANIZATIONS:

American Academy of Sleep Medicine-Member
 American College of Forensic Examiners
 Alzheimer's Association- San Diego Chapter- Medical and Scientific Advisory Board
 American Psychological Association, Division 28: Clinical Psychopharmacology
 Biomedical Research Institute of America, Retired Fellow, Board of Directors, Past President
 National Register – Health Service Providers, Psychology, Psychopharmacology
 San Diego Science and Engineering Fair, Board of Governors, Judging Committee, Advisor
 Southern Caregiver Resource Center, Retired Fellow, Board of Directors, Past President
 Prescribing Psychologists' Register
 Amateur Radio Relay League and Emergency Service
 Amateur Radio Operator, Extra Class

PAPERS, JOURNAL PUBLICATIONS, AND PARTICIPATORY RECOGNITION

1. **Thein, S.G.**, et al. “*Galantamine in AD - A 6-Month Randomized, Placebo-Controlled Trial with a 6-Month Extension*”, American Academy of Neurology, June 2, 2000.
2. **Thein, S.G.**, et al. “*Reminyl Significantly Benefits the Cognitive, Functional, and behavioral Symptoms of AD*”, *Clinical Consultants Update*, Newsletter. As Presented at 52nd AAN Meeting, April 29 – May 6, 2000, San Diego, California.
3. **Thein, S.G.**, et al. “*Reminyl Produces Cognitive and Functional Benefits for 12 Months or More in Patients with AD*”, *Clinical Consultants Update*, Newsletter. As Presented at 52nd AAN Meeting, April 29 – May 6, 2000, San Diego, California
4. **Thein, S.G.**, et al. Drug: Galantamine: *U.S. Phase III Results from New Alzheimer's Drug Suggest Potential Novel Mode of Action*, International Conference on Alzheimer's Disease and Related Disorders (ICADRD), Amsterdam, The Netherlands, July 1999.
5. Adelglass, J.M., Brownstone, P., **Thein, S.G.**, et al. *Efficacy and Tolerability of the Neurogenic Inflammation Inhibitor 4991W93 in the Acute Treatment of Migraine*, Poster Form, Displayed at 9th Congress of the International Headache Society, Spain, June 1999.
6. Katz, I., Jeste, D., **Thein, S.G.**, et al. *Comparison of Risperidone and Placebo for Psychosis and Behavioral Disturbances Associated With Dementia: A Randomized, Double-Blind Trial*, Journal of Clinical Psychiatry, February 1999.
7. Fry, J., **Thein, S.G.** et al. *A Phase III, 28 Day, Multicenter, Randomized, Double-Blind Comparator-and Placebo-Controlled, Parallel-Group Safety, Tolerability and Efficacy Study of 5, 10, and 20 mg of Zaleplon, Compared with 10 mg of Zolpidem or Placebo in Adult Outpatients with Insomnia*, Sleep, 1998; 21(suppl):262.
8. Fry, J., **Thein, S.G.**, et al. *Modafinil for the Treatment of Pathological Somnolence in Narcolepsy*, Annuals of Neurology, January 1998.
9. Fry, J., Scharf, M.B., **Thein, S.G.**, et al. *Phase III, 28 Day, Multicenter, Randomized, Double-Blind Comparator – and Placebo-Controlled, Parallel-Group Safety, Tolerability and Efficacy Study of 5, 10, and 20 mg. of Zaleplon, Compared with 10 mg. of Zolpidem or Placebo, in Adult Outpatients With Insomnia*, Submitted to the APSS Meeting, 1998.

10. **Thein, S.G.**, et al. *Evaluation of Efficacy and Safety Data with Long-Term Use of Modafinil in Patients with Narcolepsy*, Presented by Sahota, P. at the ANA in San Diego California, 1997.
11. **Thein, S.G.**, et al. *Risperidone in the Treatment of Psychosis and Aggressive Behavior in Patients with Dementia*, Presented by: Katz, I., Brecher, M., Clyde, C. and the Risperidone Study Group at the ACNP meeting, 1997.
12. Mathew, N., Klaussen, A., **Thein, S.G.**, et al. *Naratriptan Tablets Are Effective and Well-Tolerated in the Acute Treatment of Migraine; Results of a Double-Blind, Placebo Controlled, Parallel-Group Trial*, 49th Annual Meeting of the American Academy of Neurology, Boston, Massachusetts 1997.
13. **Thein, S.G.**, et al. *Efficacy and Tolerability of Naratriptan Tablets in the Treatment of Migraine: Results of a Double-Blind, Placebo-Controlled, Crossover Trial*, Presented by: Peykaian, M., Laurenza, A. at the 49th Annual Meeting of the American Academy of Neurology, Boston, Massachusetts, 1997.
14. **Thein, S.G.**, et al. *A Double-Blind Comparison of Nefazodone and Sertaline in Highly Anxious Patients with Major Depression*, Presented by: Feighner, J.P. at the New Clinical Drug Evaluation Unit Program Meeting, 1996.
15. Cohn, C.K., **Thein, S.G.**, et al. *A Double-Blind Comparison of Nefazodone and Sertraline in Highly Anxious Patients with Major Depression*, American Psychiatric Association Annual Meeting, New York, New York 1996.
16. Knopman, D., **Thein, S.G.**, et al. *Long-Term Tacrine (Cognex) Treatment: Effects on Nursing Home Placement and Mortality*, Neurology, Vol. 47, July 1996.
17. Ryan, R., Jr., **Thein, S.G.**, et al. *Twenty-Four Hour Effectiveness of BMS-180048 in the Acute Treatment of Migraine*, European Headache Foundation Annual Meeting, Sardinia, Italy 1996.
18. Crusey, J.E., and **Thein, S.G.**, *Sexual Issues and Alzheimer's Disease*, Caring, Vol. 1, Number 9, August 1995.
19. Feldmann, T., Tilker, H.A., and **Thein, S.G.**, *Psychopharmacology*, in R. Meyer's The Clinician's Handbook, 4th Edition, Allyn & Bacon, Boston 1995. (In Press)
20. Knapp, M., Pharm. D., **Thein, S.G.**, et al. *A 30-Week Randomized Controlled Trial of High Dose Tacrine in Patients with Alzheimer's Disease*, Journal of the American Medical Association, Vol 271, No. 13, pp. 985-991, April 1994.
21. **Thein, S.G.**, and Tilker, H.A., *The Alzheimer's Disease Assessment Scale (ADAS): A Training Video*, Somerville: Hoechst-Roussel Pharmaceuticals, Inc., 1993.
22. **Thein, S.G.**, and Tilker, H.A., *The Alzheimer's Disease Assessment Scale (ADAS): Administration Manual and Scoring Criteria*, Somerville: Hoechst-Roussel Pharmaceuticals, Inc., 1993.
23. **Thein, S.G.**, *Memory Loss, A Normal Part of Aging?*, Seniors Only, August, 1992.
24. **Thein, S.G.**, *Depression – The “Common Cold” of Our Emotions*, Seniors Only, September 1992.
25. **Thein, S.G.**, *A Hidden Hazard – Carbon Monoxide and the RV*, CardiSense, Marion Merrell Dow, Inc., Vol. II, Number 1, 1992.

26. **Thein, S.G.**, *Research Medicine: The Future is Now*, Seniors Only, October 1992.
27. Farlow, M., M.D., et al, *A Controlled Trial of Tacrine in Alzheimer's Disease*, Journal of the American Medical Association, Vol. 268, No. 18: pp. 2523-2529, November 1992.
28. *Preventing Carbon Monoxide Poisoning in Your RV or Other Vehicle*, Arizona Mobile Citizen, January, 1989.
29. *Carbon Monoxide and Your Health*, Motorhome Magazine, Trailer Life Enterprises, 1989.
30. Proceedings of the International Workshop, *Anxious Depression Assessment and Treatment*, Milan, Italy, September 22-23, 1986. Aden, G.C., Treatment of Anxious Depression: Current Models of Evaluation, Part II, Adinazolam – an Antidepressant Under Investigation, 1986.
31. Pyke, R.E., et al. **Thein, S.G.,,** Contributory Investigator; *The Effects of Adinazolam, Imipramine and Placebo in Depressed Outpatients*, An Unpublished Paper, 1986.
32. Feigner, J.P., *A Review of Control Studies of Adinazolam Mesylate in Patients with Major Depressive Disorder*, Psychopharmacology Bulletin, Vol. 22, pp. 186-192, 1986
33. Aden, G.C., **Thein, S.G.,,** et al. *Alprazolam Compared Diazepam and Placebo in the Treatment of Anxiety*, Journal of Clinical Psychiatry, 41:22-24, January 1983.
34. *Alprazolam in Clinically Anxious Patients with Depressed Mood*, Journal of Clinical Pharmacology, 44:22-24, January 1983.
35. *Comparison of Alprazolam, Imipramine, and Placebo in the Treatment of Depression*, Journal of the American Medical Association, 249:3057-3064, June 1983.
36. *Freedom is a Satiated Pigeon – Concepts and Treatment Techniques*, Paper Presented to International Conference, A.P.A. Montreal, Canada, 1974.
37. **Thein, S.G.**, *Success Factors of Methadone Maintenance*, Unpublished Doctoral Dissertation, 1974.
38. *Treatment of Phobics – A Systematic Desensitization Technique Explained*, Paper and Film Presented to A.P.A., Santa Barbara, California, 1973.
39. **Thein, S.G.**, *Graphological Indices of Personality*, Unpublished Thesis, 1972.
40. Fry, J., Scharf, M.D., Berkowitz, D.V., et al.: "*A Phase III, 28 Day, Multicenter, Randomized, Double-Blind Comparator - and Placebo-Controlled, Parallel-Group Safety, Tolerability, and Efficacy Study of 5, 10, and 20 mg of Zaleplon, Compared with 10 mg of Zolpidem or Placebo, in Adult Outpatients with Insomnia.*" Sleep. 1998; 21 (suppl): 262., **Stephen G. Thein, Ph.D. Contributor.**
41. Elaine Fuseau, Olivier Pertricoul, Antony Sabin, Adrian Pereira, Stephen O'Quinn, **Stephen Thein**, Mark Leibowitz, Helen Purdon, Scott McNeal, Reijo Salonen, Alan Metz, Peter Coates: *Effects of Encapsulation on Absorption of Sumatriptan Tablets: Data From Healthy Volunteers and Patients During Migraine*. Clinical Therapeutics Volume (issue): 23 (2) 2001, pp 242-251

42. Pierre N. Tariot, Leon Thal, Laura Jakimovich, Ronald Thomas, Rema Raman, and the ADCS Valproate Nursing Home Study Group: *“A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of Valproate Agitation Associated with Dementia”* December 2003 American College of Neuropsychopharmacology (ACNP) Poster, **Stephen G. Thein, Ph.D., Contributor.**
43. Jed Black, Max Hirshkowitz, Craig Q. Earl, for the Modafinil in Obstructive Sleep Apnea Study Group: *“Modafinil Adjunctive Therapy Improves Excessive Sleepiness and Quality of Life in Obstructive Sleep Apnea: A 12-Month Open-Label Extension Study”* June 2003 Annual Meeting Associated Professional Sleep Societies Poster, **Stephen G. Thein, Ph.D., Contributor.**
44. K. Rockwood, J. Mintzer, L. Truyen, T. Wessel, D. Wilkinson: *“Effects of a Flexible Galantamine Dose in Alzheimer’s Disease: A Randomized, Controlled Trial”* Journal of Neurology, Neurosurgery and Psychiatry; 2001; 71 pp 589-595, Contributory Investigator.
45. S.A. Reines, MD, G.A. Block, MD, J. C. Morris, MD, G. Liu, Ph.D., M. L. Nessler, MS, C.R. Lines, Ph.D., B.A. Norman, BS and C.C. Baranak, MA on behalf of the Rofecoxib Protocol 091 Study Group: *“Rofecoxib: No effect on Alzheimer’s disease in a 1-year, randomized, blinded, controlled study”*; American Academy of Neurology; Neurology 2004; 62: pp 66-71, Contributory Investigator.
46. D. Canafax, PharmD, C. Kushida, MD, Ph.D., P. Becker, MD, A. Perkins, MD, Ph.D., **S. Thein, Ph.D.**, A. Walters, MD, and T. Roth, Ph.D., *“XP13512 Improves Symptoms and Sleep Disturbance in RLS Patients: Results of a 2-Week, Randomized, Double-Blind, Placebo-Controlled Cross-Over Polysomnography Trial.”*; Sleep, Volume 29, Abstract Supplement, 2006; 20th Anniversary Meeting of the Associated Professional Sleep Societies, June 2006.

CLINICAL RESEARCH EXPERIENCE

1. A Multicenter Double-Blind Trial of XXXXXX and Placebo in the Treatment of Elderly Depressed Outpatients
2. An Open-Label Trial of XXXXXX in the Treatment of Elderly Depressed Outpatients
3. A Double-Blind Multicenter Trial of XXXXXX and Sertraline in the Treatment of Highly Anxious Outpatients with Major Depression
4. A Double-Blind Multicenter Trial of XXXXXX and Sertraline in the Continuation Treatment of Highly Anxious Outpatients with Major Depression
5. A Multicenter Double-Blind Trial of XXXXXX, Diazepam, and Placebo in the Treatment of Anxious Outpatients
6. An Open Multicenter Trial of XXXXXX in the Treatment of Patients with Anxiety Disorder
7. A Double-Blind Dose Response Trial of XXXXXX Compared to Placebo in the Treatment of Acute Migraine Attacks
8. An Open-Label Long-Term Trial Evaluating the Safety of XXXXXX in the Treatment of Patients with Migraine Headache With or Without Aura

9. A Nine-Week Placebo-Controlled, Double-Blind, Randomized, Parallel-Group Study of the Safety and Efficacy of Two Fixed Doses of Oral XXXXXX in Patients with Narcolepsy, Followed by a Two-Week Discontinuation Segment, Followed by a Forty-Week, Open-Label, Flexible-Fixed Dose Continuation Study
10. A Double-Blind Comparison of XXXXXX with Placebo in the Treatment of Alcohol Withdrawal in Recently Admitted Alcoholic In-Patients
11. An Open-Label Study of XXXXXX in Patients with Mild to Moderate Dementia of the Alzheimer's Type
12. Double-Blind Placebo and Diazepam Controlled Study of XXXXXX in Anxious Patients
13. A Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Two Doses of XXXXXX versus Placebo in Treatment of Social Phobia
14. Double-Blind, Placebo-Controlled, Multiple-Fixed Dose Evaluation of XXXXXX versus XXXXXX in the Treatment of Generalized Anxiety Disorder
15. A Double-Blind, Placebo-Controlled, Multiple-Fixed Dose of Evaluation of XXXXXX (GAD)
16. A Randomized Double-Blind, Placebo Controlled, Crossover Protocol to Evaluate the Safety and Efficacy of Suppositories and XXXXXX in the Acute Treatment of Multiple Migraine Attacks
17. A Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of Orally Administered XXXXXX in the Treatment of Secondary (Acquired) Erectile Disorder
18. A Multicenter, Double-Blind, Evaluation of the Efficacy and Safety of XXXXXX in the Treatment of Patients with Major Depressive Disorder
19. A Double-Blind, Placebo-Controlled, Dose-Escalation Study of the Safety and Efficacy of Oral XXXXXX in the Treatment of Patients with Panic Disorder
20. A Randomized, Double-Blind, Placebo-Controlled, Crossover Study to Evaluate the Efficacy of Oral XXXXXX in the Acute Treatment of Four Migraine Attacks
21. A Study to Evaluate the Pharmacokinetics and Pharmacodynamics of Oral XXXXXX in Migraine Subjects
22. Multi-Center, 35-Week, Double-Blind, Parallel Group Safety, Tolerance and Efficacy Comparison of Placebo and XXXXXX in Outpatients with Alzheimer's Disease
23. Multi-Center, Double-Blind, Parallel Group, Safety, Tolerance and Efficacy Comparison of Placebo and XXXXXX in Outpatients with Alzheimer's Disease
24. Forty-Eight Week Efficacy and Safety Study of XXXXXX in Patients with Alzheimer's Disease
25. Twenty-Four Week Efficacy and Safety Study of XXXXXX in Patients with Vascular Dementia

26. A Comparison of the Efficacy and Safety of XXXXXX with Nifedipine GITS in an 8-Week Treatment of Patients with Chronic Stable Angina Pectoris
27. A Placebo-Controlled Study to Determine the Effects of XXXXXX in Ischemic Stroke Patients
28. Long Term XXXXXX versus Hydrochlorothiazide Double-Blind Parallel in Patients with Hypertension
29. Clinical Evaluation of the Efficacy and Safety of XXXXXX in the Treatment of Alzheimer's Disease
30. A Randomized, Double-Blind, Placebo Controlled Study of XXXXXX for Treatment of Behavioral Disturbances in Subjects with Dementia
31. Safety of XXXXXX in the Long-Term Treatment of Alzheimer's Disease
32. The Efficacy and Safety of XXXXXX versus Sumatriptan in the Acute Treatment of Migraine: A Randomized Double-Blind, Placebo-Controlled, Single Dose Trial
33. A Randomized, Double-Blind Placebo Controlled Trial to Evaluate the Efficacy and Safety of XXXXXX Given Subcutaneously in the Acute Treatment of Migraine
34. Open Evaluation of the Long-Term Efficacy, Safety and Tolerability of XXXXXX in the Acute Treatment of Migraine Attacks
35. Efficacy, Tolerability and Safety of XXXXXX in the Treatment of Alzheimer's Disease
36. XXXXXX in the Treatment of Alzheimer's Disease: Flexible Dose Range Trial
37. Long-Term Safety and Efficacy of XXXXXX in the Treatment of Alzheimer's Disease (1138)
38. Long-Term Safety and Efficacy of XXXXXX in the Treatment of Alzheimer's Disease (2485)
39. Long-Term Safety and Efficacy of XXXXXX in the Treatment of Alzheimer's Disease
40. Placebo-Controlled Evaluation of XXXXXX in the Treatment of Alzheimer's Disease: Safety and Efficacy Under a Slow-Titration Regimen
41. Safety and Efficacy of XXXXXX During Withdrawal in the Treatment of Alzheimer's Disease: Blinded Withdrawal Trial
42. A Double-Blind Pilot Study to Evaluate the Safety and Efficacy of XXXXXX Therapeutic Implant XXXXXX as Compared to XXXXXX When Administered to Patients with External Condylomata Acuminata
43. A Randomized Double-Blind Controlled Study to Evaluate the Contribution of Components in the Therapeutic Implant XXXXXX When Administered to Patients with External Condylomata Acuminata
44. Open-Label Re-Treatment Study Describing and Evaluating the Safety and Efficacy of the XXXXXX in the Treatment of Condylomata Acuminata

45. Phase II Double-Blind Controlled Study of XXXXXX and Placebo to Establish Efficacy in the Treatment of Outpatients with Depression
46. Safety and Efficacy versus XXXXXX in Outpatients with Recurrent Depression
47. Efficacy and Safety in Outpatients with Major Depression, 5 ½ Month, Phase III Study
48. Efficacy and Safety in Outpatients with Major Depression, 6 Month, Phase III Study
49. Long-Term Safety in Patients with Chronic Non-Malignant Pain
50. XXXXXX for the Treatment of Mild Cognitive Impairment and Prevention of Conversion to Alzheimer's Disease (1160)
51. The Safety and Efficacy of XXXXXX in Slowing the Progression of the Symptoms of Alzheimer's Disease (2486)
52. A Phase II Study of the Efficacy and Safety of XXXXXX in Patients with Primary Degenerative Dementia (PDD)
53. An Open-Label Study to Evaluate the Safety and Efficacy of XXXXXX Through XXXXXX of XXXXXX in Patients with Mild to Severe Probable Alzheimer's Disease in the Community Setting (1166)
54. A Randomized, Double-Blind, Dose-Range Finding, Multicenter, Parallel-Group, Active and Placebo-Controlled Trial of the Safety and Efficacy of XXXXXX in Patients with Moderate to Severe Major Depressive Disorder.
55. A Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Dose-Range Finding Trial to Evaluate the Safety and Efficacy of Four Doses of XXXXXX in Patients with Social Phobia.
56. A Double-Blind, Placebo Controlled, High Dose Study of XXXXXX in Patients with Alzheimer's Disease
57. An Open-Label, High Dose Study of XXXXXX in Patient's With Alzheimer's Disease
58. A Double-Blind, Placebo Controlled Study of XXXXXX with and Open-Label Extension and Compassionate Use (AD)
59. A 12-Week, Double-Blind, Placebo-Controlled; Parallel-Group, Dose-Response, Multicenter Study of XXXXXX in Patients with Alzheimer's Disease
60. A 16-Week, Open-Label Safety Study of XXXXXX with Monitoring of XXXXXX at Weeks 4, 6, 8, 12, and 16 (AD)
61. 16-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose Response Multicenter Study of XXXXXX with a 16-Month Open-Label Extension in Patients with Dementia of the Alzheimer's Type

62. A 26-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study of XXXXXX in Patients with Probable Alzheimer's Disease
63. A Non-Randomized Open-Label Extension, Multicenter Study of XXXXXX in Patients with Probable Alzheimer's Disease
64. A Double-Blind, Placebo-Controlled, Parallel 3-Day Treatment and 3-Month Follow-up, Multicenter Study to Evaluate the Safety and Efficacy of Intravenous XXXXXX in Patients with Acute Ischemic Stroke
65. Phase II, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Three Doses of XXXXXX Administered for 12 Weeks to Subjects with Alzheimer's Disease
66. Phase II, Open-Label, Multicenter Extension Study of the Safety and Efficacy of XXXXXX Administered for Twenty-Six Weeks to Subjects with Alzheimer's Disease
67. A Six-Week, Double-Blind, Placebo- and Fluoxetine-Controlled Multicenter Study to Evaluate the Safety and Efficacy of Oral XXXXXX in Outpatients with Major Depressive Disorder
68. A Double Blind, Placebo-Controlled, Parallel Design Study to Determine the Effects of Orally Administered XXXXXX versus Placebo on Survival I Recent Post-Myocardial Infarction Patients at Risk of Sudden Death
69. A Randomized, Double-Blind, Multicenter Progestin Efficacy Study of Three Doses of XXXXXX Patches in Continuous Wear Compared to an Estradil 50 Patch
70. Double-Blind Study of XXXXXX and Placebo (GAD)
71. Randomized, Double-Blind, Placebo-Controlled Multicenter Trial to Demonstrate the Clinical Efficacy and Safety of Two Different Doses of XXXXXX in Patients Suffering from Dementia of the Alzheimer's Type According to DSM-IV and NINCDS/ADRDA Criteria (1250)
72. A Dose-Titration, Safety and Efficacy Study of XXXXXX in the Treatment of Erectile Dysfunction in Diabetic and Non-Diabetic Patients Followed by 48 Weeks of Open-Label Treatment
73. A Double-Blind, Placebo Controlled, Parallel Group Study to Assess the Safety, Tolerability and Pharmacokinetics Following Repeated-Dose Up Titration of XXXXXX in Patients with Mild to Moderate Dementia of the Alzheimer's Type
74. An Open-Label Administration Study of XXXXXX In Patients Suffering From Dementia of the Probable Alzheimer's Type
75. A 48 Week Double-Blind, Placebo Controlled, Parallel Group, Fixed Dose Study of the Efficacy, Safety and Cost-Effectiveness of XXXXXX in Patients Suffering from Dementia of the Probable Alzheimer's Type
76. A Twelve Month, Double-Blind, Placebo-Controlled, Investigation of the Safety and Efficacy of XXXXXX Transdermal System XXXXXX in Patients with Dementia of the Alzheimer's Type
77. A Study to Evaluate the Effects of XXXXXX on Acute Duodenal Ulcer

78. A Study to Evaluate the Effects of XXXXXX on Acute Gastric Ulcer
79. A Study to Evaluate the Effects of XXXXXX on Acute Gastroesophageal Reflux Disease
80. A Randomized, Double-Blind, 12-Month Safety and Efficacy Trial of XXXXXX in Patients with Probable Alzheimer's Disease
81. A Randomized, Double-Blind, 12-Month Safety and Efficacy Study of XXXXXX or Placebo Added to Treatment with Donepezil HCl 10 mg qd in Patients with Probable Alzheimer's Disease
82. A Double-Blind, Placebo-Controlled, Randomized Study of the Safety and Efficacy of a Combination of Insulin and Two Doses of XXXXXX in the Treatment of Patients with Non-Insulin Dependent Diabetes Mellitus (NIDDM)
83. A Double-Blind Randomized Trial Comparing Four Doses of XXXXXX and Placebo in the Treatment of Outpatients with Migraine Headaches
84. A Fixed-Dose, Placebo-Controlled, Dose-Response Study of XXXXXX in the Treatment of Mixed Anxiety and Depressive Disorder
85. Comparison of XXXXXX, Valium, and Placebo in the Treatment of Anxiety
86. Comparison of XXXXXX versus Valium versus Placebo (GAD)
87. Comparison of Therapeutic Effect, Tolerance and Safety of XXXXXX and Diazepam Administered Six Months to Outpatients with Chronic Anxiety Neurosis
88. Comparison of XXXXXX, Imipramine, and Placebo in the Treatment of Neurotic Depression
89. Comparison of Long Term Efficacy and Tolerance of XXXXXX and Diazepam in Outpatients with Chronic Generalized Anxiety Disorder or Minor Depressive Disorder
90. Double-Blind Efficacy and Safety Study Comparing XXXXXX, Imipramine and Placebo in Depressed Outpatients
91. Efficacy Study for XXXXXX in Patients with Exertional Angina Pectoris – BID Dosing
92. Efficacy Study for XXXXXX in Patients with Exertional Angina Pectoris- TID Dosing
93. Collaborative Fixed –Dose Study of the Efficacy and Safety of XXXXXX Tablets in Generalized Anxiety Disorder
94. Comparison of XXXXXX and Certrioxone in the Treatment of Uncomplicated Gonococcal Infection
95. Treatment of Gonococcal Infections with Intramuscular XXXXXX or Certrioxone Sodium (Rocephin)
96. XXXXXX Treatment of Insomnia in Depressed Patients Receiving Selected Antidepressants

97. A Dose Response Study of XXXXXX in the Treatment of Generalized Anxiety Disorder with Associated Depressive Symptoms
98. A Multicenter, Double-Blind Comparison of Efficacy and Safety of XXXXXX, Haloperidol, and Placebo in the Treatment of Elderly Subjects Residing in Nursing Homes or Assisted Care Facilities and Presenting with Alzheimer's Dementia and Psychoses or Other Selected Psychoses
99. A Multicenter, Double-Blind, Placebo-Controlled, Randomized Fix Dose Study of XXXXXX in the Treatment of Depressed Patients (2521)
100. Long-Term Open Label Treatment with XXXXXX for Evaluation and Safety (Depression) (1743)
101. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Investigate the Tolerability and Efficacy of 12-Week XXXXXX Once Daily Compared to Placebo in the Prophylaxis of Migraine Headache Attacks in Adult Subjects with Migraine
102. Long-Term Safety of XXXXXX in the Treatment of Alzheimer's Disease
103. A Double-Blind, Placebo-Controlled Dose Finding Study Evaluating the Safety and Efficacy of XXXXXX in the Treatment of Major Depressive Disorder (2553)
104. Safety and Efficacy of Long-Term Administration of XXXXXX in the Treatment of Major Depressive Disorder: A 4-Month Double-Blind Extension to Study XXXXXX (2553X1)
105. Safety of Open-Label Standard Antidepressant Therapy in the Treatment of Major Depressive Disorder: A 1-Month Follow-Up After Termination of Study XXXXXX (2553X2)
106. A Placebo-Controlled Study of XXXXXX and Alprazolam In Patients with Generalized Anxiety Disorder (2597)
107. Open-Label Safety Study of XXXXXX In Patients with Anxiety Disorders (2387)
108. A Phase III at Home Use Study Evaluating the Efficacy and Safety of Escalating Doses of XXXXXX in the Treatment of Patients with Erectile Dysfunction (2406)
109. A Phase III Six Month, Long-Term, Open-Label, Flexible Dose, Safety Extension Study of XXXXXX in the Treatment of Males Erectile Dysfunction (2406X1)
110. A Multicenter, Double-Blind Comparison of Efficacy and Safety of XXXXXX, Haloperidol, and Placebo in the Treatment of Elderly Subjects Residing in Nursing Homes or Assisted Care Facilities and Presenting with Alzheimer's Dementia and Psychoses or other Selected Psychoses"
111. An Open-Label Long-Term, Safety Study of Transdermal XXXXXX in the Treatment of Anxious Outpatients
112. Evaluation of the Clinical Safety and Efficacy of XXXXXX In Patients with Intermittent Claudication

113. Effects of Prolonged Administration of XXXXXX and Progesterone on the Incidence of Endometrial Hyperplasia in Postmenopausal Patients
114. Comparative Study of XXXXXX and Ampicillin in the Treatment of Outpatients with an Acute Bacterial Exacerbation of Chronic Bronchitis
115. XXXXXX in Rheumatoid Arthritis
116. A Phase III, 28-Day, Multicenter, Randomized, Double-Blind, Comparative-and Placebo-Controlled, Parallel-Group Safety, Tolerance and Efficacy Study of 5, 10 and 20 mg of XXXXXX, Compared with 10 mg of Zolpidem or Placebo, in Adult Outpatients with Insomnia
117. A Study to Evaluate the Safety and Tolerance of Long-Term Use of XXXXXX in the Treatment of Patients with Insomnia
118. An Open-Label, Long-Term, Safety Study of Transdermal XXXXXX in the Treatment of Anxious Outpatients
119. A Double-Blind, Randomized Trial of Three Fixed Doses of Transdermal XXXXXX Compared to Placebo in the Treatment of Anxious Outpatients
120. A Double-Blind, Randomized, Flexible Dose Trial of XXXXXX Transdermal or Alprazolam Compared to Placebo in the Treatment of Anxious Outpatients
121. A Placebo-Controlled Study of XXXXXX in patients With Social Phobia (2257A1)
122. A 10-Week, Randomized, Double-Blind, Placebo-Controlled Study of XXXXXX and XXXXXX in Patients With Social Phobia (3315)
123. A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Safety and Efficacy of XXXXXX Therapy for Agitation in Nursing Home Residents with Probable or Possible Alzheimer's Disease (2860)
124. XXXXXX: Double-Blind, Placebo-Controlled, Dose-Response Study of Tolerability, Safety, and Efficacy in Patients with Early Parkinson's Disease (3401)
125. XXXXXX: Open-Label, Long Term, Flexible Dose Study of Safety, Tolerability, and Therapeutic Response in Patients with Parkinson's Disease (3429)
126. A Double-Blind, Placebo-Controlled, Parallel-Group Comparison of XXXXXX Extended-Release Capsules and XXXXXX in Outpatients with Generalized Social Anxiety Disorder. (2672)
127. A Randomized, Double-Blind, Placebo-Controlled, Single-Attack, Parallel Group Evaluation of XXXXXX 50mg and 100mg Versus Placebo During a Migraine Headache at the First Sign of Pain (2840)
128. A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of 12 Weeks of 2 Oral Doses (200 mg and 400 mg Once Daily) of XXXXXX as Treatment for Adults with Excessive Daytime Sleepiness Associated with

- Obstructive Sleep Apnea/Hypopnea Syndrome Followed by a 9-Month Open-Label Extension (2581)
129. Prospective, Randomized, Double-Blind, Multi-Center Comparison of the safety and Efficacy of XXXXXX 400mg QD Five Days Versus XXXXXX 500mg QD for Seven Days in the Treatment of Patients with Acute Exacerbation of Chronic Bronchitis (2444)
 130. A Randomized, Single-Dose, Double-Blind, Parallel Study Comparing XXXXXX 20 mg, XXXXXX 10 mg and Placebo in Preventing Heartburn When Administered Immediately Prior to a Provocative Breakfast Meal (2666)
 131. “A Double-Blind, Placebo-Controlled Study of XXXXXX in the Treatment of Behavioral Agitation in Elderly Patients with Dementia (2637)
 132. A Multicenter, Randomized, Double-Blind, Placebo Controlled Flexible Dose Study of XXXXXX in the Treatment of Institutionalized Patients with Psychosis Associated with Dementia of the Alzheimer’s Type (2721)
 133. A 1-Year, Double-Blind, Placebo-Controlled, Parallel Group Study to Determine the Safety and Efficacy of XXXXXX in Patients With Effort-Induced Chronic Stable Angina (2622)
 134. Open-Label use of Synthetic XXXXXX in the Treatment of Alzheimer’s Disease (1138X1)
 135. The Safety and Efficacy of XXXXXX 25 mg in Delaying the Progression of the Symptoms of Alzheimer’s Disease in Patients with Probable AD (2855)
 136. XXXXXX: A 16-Week, Randomized, Double-Blind, Placebo-Controlled, Crossover, Multicenter Study of XXXXXX in Patients With Mild to Moderate Alzheimer’s Disease (2963)
 137. A Phase III Double-Blind Efficacy and Safety Study of XXXXXX (10mg) in Addition to XXXXXX Compared to Placebo in Subjects with Primary Hypercholesterolemia (2532)
 138. A Double-Blind, Stratified, Randomized, Placebo-Controlled Study of XXXXXX (also known as XXXXXX) in the Treatment of Influenza Infection in Elderly Adults (2447)
 139. A Phase III Double-Blind Efficacy and Safety Study of XXXXXX (10mg) in Addition to XXXXXX in Subjects with Coronary Heart Disease or Multiple Risk Factors and with Primary Hypercholesterolemia Not Controlled by a Starting Dose (20mg) of XXXXXX (2692)
 140. A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of 12 Weeks of 2 Oral Doses (200 mg and 400 mg Once Daily) of XXXXXX as Treatment for Adults with Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea/Hypopnea Syndrome Followed by a 9-Month Open-Label Extension (2581)
 141. Efficacy and Safety of a Flexible Dose of XXXXXX Versus Placebo in the Treatment of Psychosis of Alzheimer’s Disease (2956)
 142. A Dose-Ranging, Double-Blind, Placebo-Controlled, Safety, Tolerability, and Efficacy Study of XXXXXX in Patients with Major Depressive Disorder By DSM-IV Criteria. (3348)

143. A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Lipid-Altering Efficacy, Safety, and Tolerability of XXXXXX When Added to Therapy with an HMG-CoA Reductase Inhibitor XXXXXX in Patients with Primary Hypercholesterolemia with Known Heart Disease or Multiple Cardiovascular Risk Factors.” (3452)
144. A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study to Assess the Efficacy and Safety of XXXXXX in Patients with Chronic Insomnia. (2973)
145. Evaluation of XXXXXX Placebo Controlled in the Treatment of Alzheimer’s Disease: Safety and Efficacy of a Controlled Release Formulation. (2918)
146. A Randomized, Double-Blind, Placebo-Controlled, Dose Finding Study of XXXXXX (Topical Gel Formulation of XXXXXX and XXXXXX) for the Treatment of Male Erectile Dysfunction in an At-Home Setting. (3601)
147. An Open-Label Continuation Trial of 1% XXXXXX (Topical Gel Formulation of 1% XXXXXX and 5% XXXXXX) in Male ED Patients Who Previously Participated in XXXXXX Study XXXXXX. (3601X1)
148. A Randomized, Double-Blind, Placebo-Controlled, Single-Dose Study to Assess Dose Response of XXXXXX in Subjects Transient Insomnia. (2580)
149. A Randomized Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of XXXXXX in Subjects with Mild Cognitive Impairment (MCI) Clinically at Risk for Development of Clinically Probable Alzheimer’s Disease. (2919)
150. An 8-Week, Double-Blind, Randomized, Multicenter, Flexible-Dose, Placebo-Controlled Study of XXXXXX in Patients with Panic Disorder. (3789)
151. A Randomized, 26-Week, Double-Blind, Placebo-Controlled Trial to Evaluate the Safety And Efficacy of XXXXXX in the Treatment of Dementia Secondary to Cerebrovascular Disease. (3666)
152. A Well-Controlled Safety and Efficacy Study of XXXXXX In Subjects with Mild to Moderate Alzheimer’s Disease. (3261)
153. A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study to Assess the Efficacy and Safety of XXXXXX in Elderly Patients with Chronic Insomnia. (3927)
154. A 6-Week, Double-Blind, Randomized, Multicenter, Fixed-Dose, Placebo-Controlled Study of XXXXXX Dosed Twice a Day in Patients with Generalized Anxiety Disorder. (3979)
155. An Open-Label Extension Trial to Assess the Long-Term Safety of a Controlled Release Formulation of XXXXXX HBr in the Treatment of Alzheimer’s Dementia. (2918x1)
156. A Double-Blind, Randomized, Placebo-Controlled Surveillance Study of Asthma Event Outcomes in Subjects Receiving Either Usual Pharmacotherapy of Asthma or Usual Pharmacotherapy Plus XXXXXX 42mcg (2 Puffs) Twice Daily. (3963)
157. A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of XXXXXX in Subjects with Mild Cognitive Impairment (MCI) Clinically at Risk

- For Development of Clinically Probable Alzheimer's Disease. (2920)
158. A Phase II, Randomized, Multicenter, Double-Blind, Placebo-Controlled, Twelve-Week, Safety and Tolerability Study of XXXXXX in Patients with Mild-to-Moderate Dementia of The Alzheimer's Type. (3977)
 159. A Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXXXXX in Patients with Mild to Moderate Dementia of the Alzheimer's Type. (3811)
IND#: 33,392
 160. A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study to Assess the Efficacy and Safety of Modified Release Formulation of XXXXXX in Elderly Patients with Chronic Sleep Maintenance Insomnia. (4097)
 161. A Long-Term, Open-Label Study of XXXXXX in Subjects with Mild to Moderate Alzheimer's Disease. (3261x1)
 162. Assessment of Variance in FDG-PET Measurement of CNS Effects in Healthy Volunteers. (4082)
 163. A Long-Term Extension Study Evaluating the Safety and Tolerability of BID and QD Administration of XXXXXX in Patients with Mild to Moderate of the Alzheimer's Type. (3811X1)
 164. An Eight-Week, Double-Blind, Placebo-Controlled Multicenter Study to Evaluate the Safety and Efficacy of 2 Doses of XXXXXX (1.5mg and 3.0mg) and XXXXXX in Subjects With Major Depressive Disorder. (3495)
 165. A Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXXXXX in Patients with Mild to Moderate Dementia of the Alzheimer's Type. IND#: 33,392 (4441)
 166. A Phase II, Randomized, Double-Blind, 5-Way Cross-Over Study to Evaluate the Efficacy and Safety of XXXXXX (5,10 and 15 mg) and XXXXXX (10 mg) Versus Placebo in a Model of Transient Insomnia. A sleep Laboratory Study in Healthy Subjects. (4485)
 167. XXXXXX 60 mg (or 30 mg) Once Daily in the Treatment of Generalized Anxiety Disorder. An Open Multicenter Safety Study of 5 Months, Including a 1-Month Drug-Free Follow-Up Period. Follow-Up to Studies 3013023 and 3013025. (4458)
 168. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Multicenter Study to Assess the Efficacy and Safety of XXXXXX in Adults with Primary Insomnia. (4310)
 169. XXXXXX 30 mg and 60 mg Once Daily Versus Placebo in Generalized Anxiety Disorder. A Randomized Double-Blind Placebo and XXXXXX-Controlled Fixed-Dose Parallel-Group Multicenter Study of 10 Weeks (Including a 2-Week Single-Blind Placebo Period). (4128)
 170. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Efficacy and Safety of XXXXXX for the Treatment of Transient Insomnia in

- Adult Subjects. (4311)
171. An Open-Label Extension Trial to Assess the Safety of XXXXXX HBr in the Treatment of Vascular Dementia. (4556)
 172. A Randomized, Double-Blind, Single-Dose, Double-Dummy Evaluation of the Efficacy, Safety and Pharmacokinetics of the Adenosine A1 Agonist, XXXXXX 100 mg, and XXXXXX 50 mg Versus Placebo in the Acute Treatment of Migraine. (4452)
 173. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Long-Term Safety and Efficacy of Two Dose Levels of XXXXXX in Adult Patients with Primary Insomnia. (3934)
 174. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Assess the Efficacy and Safety of a Modified Release Formulation of XXXXXX In Elderly Primary Insomnia Patients with Sleep Maintenance Difficulties. (4315)
 175. A Multi-Center Study to Determine the Exposure of Adult U.S. Smokers to Cigarette Smoke. (4625)
 176. A Double-Blind, Placebo-Controlled Dose-Finding Study Evaluating the Safety and Efficacy of XXXXXX, 80 mg bid, and 20 and 80 mg QD in the Treatment of Mild to Moderate Alzheimer's Disease. (4807)
 177. A Long-term, Open-label, Flexible-Dose Study of the Efficacy and Safety of XXXX in Patients with Idiopathic Restless Legs Syndrome. (4382)
 178. A Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXXX in Patients with Moderate to Severe Dementia of the Alzheimer's Type. (4887)
 179. A Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXXX in Patients with Moderate to Severe Dementia of the Alzheimer's Type. (4988)
 180. Pharmacogenomics Blood Sampling Protocol to Obtain DNA in a Reference Population of Patients Diagnosed with Restless Legs Syndrome. (5152)
 181. An 8-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dosage Study to Evaluate the Efficacy and Safety of XXXX, at Dosages up to 16mg/day, in the Treatment of Generalized Anxiety Disorder in Adults. (202359)
 182. A 12-Month, Open-Label, Flexible-Dosage Study to Evaluate the Safety of XXXX, at Dosages up to 16mg/day in Adults with Generalized Anxiety Disorder. (202976)
 183. An Evaluation of the Long-Term Safety and Efficacy of XXXX in Patients with Moderate to Severe Dementia of the Alzheimer's Type. (202891)
 184. A Multicenter, Randomized, Double-Blind, Active and Placebo Controlled 5-Way Crossover Study of the Safety and Efficacy of XXXX, Zolpidem, and Placebo in Primary Insomnia. (5076)

185. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Efficacy and Safety of Two Dose Levels of XXXX in Elderly Patients with Primary Insomnia. (3931)
186. A Phase III, Double-Blind, Outpatient, Extension Study to Assess the Long-Term Safety of Two Dose Levels of XXXX in Elderly Patients with Primary Insomnia. (3931x1)
187. A Randomized, Double-Blind, Placebo-Controlled, 4-Period-Cross-Over Pilot Study of the Safety and Efficacy of Multiple Doses of XXXX in Subjects with Alzheimer's Disease. (202856)
188. An Open-Label Extension Study to Assess the Long-Term Safety and Tolerability of XXXX HBr in the Treatment of Mild Cognitive Impairment. (5075)
189. A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of XXXX (150 and 250 mg/day) as Treatment for Adults with Residual Excessive Sleepiness Associated with Obstructive Sleep Apnea/Hypopnea Syndrome. (203233)
190. A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of XXXX (150 and 250 mg/day) as Treatment for Adults with Excessive Sleepiness Associated with Narcolepsy. (203231)
191. A One Year, Multicenter, Randomized, Double-Blind, Placebo-Controlled Evaluation of the Efficacy and Safety of XXXX in Subjects with Mild Cognitive Impairment. (202493)
192. A Randomized, Multicenter, Double-Blind, Placebo-Controlled, 18-Month Study of the Efficacy of XXXX in Patients with Mild-To-Moderate Dementia of the Alzheimer's Type. (202793)
193. A Randomized, Double-Blind, Placebo-Controlled Trial of XXXX to Attenuate the Progression of Alzheimer's Disease. (202530)
194. A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter, Fixed-Dose, Polysomnographic Study of XXXX in Patients with Primary Insomnia. (202700)
195. A Multicenter, Randomized, Open-Label Study Evaluating the Effects of XXXX, 80 mg b.i.d., vs. XXXX, 5 or 10 mg, on Adrenal Function in Patients with Mild Alzheimer's Disease. (202538)
196. A 12-Month, Open-Label, Flexible-Dosage (100-250 mg/day) Extension Study of XXXX in the Treatment of Patients with Excessive Sleepiness Associated with Narcolepsy, Obstructive Sleep Apnea/Hypopnea Syndrome, or Chronic Shift Work Sleep Disorder. (203903)
197. A Double-Blind, Phase II, Safety and Efficacy Evaluation of XXXX in Patients with Mild to Moderate Alzheimer's Disease. (203096PRN)
198. A Phase III Study of the Efficacy and Safety of XXXX in Patients with Mild to Moderate Alzheimer's Disease. (203077PRN)
199. A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of Once Daily XXXX in Patients with Restless Legs Syndrome. (00036)

200. A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Safety and Efficacy of XXXX 25 mg in Slowing the Progression of Alzheimer's Disease. (202531)
201. A Long-Term Safety and Efficacy of Open-Label XXXX, 80 mg b.i.d. in the Treatment of Probable Alzheimer's Disease: A 18-month Follow-Up After Completion of Study XXXX. (202859)
202. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase II Study of Efficacy and Safety of XXXX in Subjects with Mild to Moderate Alzheimer's Disease. (00012)
203. A Study To Define The Non-Restorative Sleep Population. (00010)
204. A Randomized, Double-Blind, Placebo-Controlled Trial of XXXX to Attenuate the Progression of Alzheimer's Disease. (00026)
205. A 6-Month Safety Follow-Up Study of Select Patients Previously Enrolled and Randomized to XXXX in Studies XXXX, XXXX or XXXX. (00028)
206. Evaluation of the Long-Term Efficacy and Safety of XXXX 12.5 mg Compared to Placebo, When Both are Administered Over a Long-Term Period "as needed", in Patients with Chronic Primary Insomnia. (A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter, Phase IIIb Clinical Study). (00007)
207. A Randomized, Double-Blind, Placebo-Controlled, Crossover Study to Assess the Efficacy and Safety of XXXX in Patients with Restless Legs Syndrome. (203812PRN)
208. A Phase IIa, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Multiple Ascending Dose, Safety, Tolerability, Pharmacokinetic, Pharmacodynamic, and Immunogenicity Trial of XXXX in Patients with Mild to Moderate Alzheimer's Disease. (00025)
209. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group study of the efficacy, safety and tolerability of XXXX in Patients with Generalized Anxiety Disorder. (00054)
210. A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Five-Arm Parallel-Group Trial to Investigate the Efficacy and Safety of Four Different Transdermal Doses of XXXX in Subjects with Idiopathic Restless Legs Syndrome. (00046)
211. A 12 Week, Double-Blind, Placebo Controlled, Parallel Group to Assess the Efficacy and Safety of XXXX XR (Extended Release) in Patients with Restless Legs Syndrome. (00059)
212. Phase 3 Multicenter, Randomized, Double Blind, Placebo Controlled Study of the Effect of Daily Treatment with XXXX on Measures of Cognition, Activities of Daily Living and Global Function in Subjects with Mild Dementia of the Alzheimer's Type. (00023)
213. The Efficacy of XXXX 3mg as Adjunctive Therapy in Subjects with Insomnia Related to Generalized Anxiety Disorder. (00057)
214. A Double Blind, Placebo Controlled Study of XXXX for the Treatment of Mild-To-Moderate Alzheimer's Disease. (00065)

215. A Double-Blind, Randomized, Placebo-Controlled, Phase IIa, Multiple Dose, Multicenter Study in Patients with Mild to Moderate Dementia of the Alzheimer's Type to Evaluate the Safety and Tolerability of Two 10-Week Dose Regimens of Orally-Administered XXXX. (00063)
216. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Polysomnographic Study to Assess the Efficacy and Safety of a Modified Release Formulation of XXXX in Primary Insomnia Patients with Sleep Maintenance Difficulties. (00047)
217. An Open-Label Extension of the Phase III Study XXXX with XXXX in Patients with Alzheimer's Disease. (00107)
218. A 52-Week, Open-Label Study to Assess the Long-Term Safety of XXXX Extended Release (XR) in Patients with Restless Legs Syndrome (RLS). (00075)
219. A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Parallel-Group Study to Evaluate the Efficacy and Safety of XXXX in Migraine Prophylaxis. (00082)
220. A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Effects of XXXX on Cognitive Functions in the Elderly. (00058)
221. A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXXX in Patients with Restless Legs Syndrome. (00056)
222. An Open-Label, 52-Week Extension Study Assessing XXXX Safety and Efficacy in Patients with Restless Legs Syndrome. (00114)
223. A 54-Week , Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Investigate the Effects of XXXX (extended release tablets) as Adjunctive Therapy to Acetylcholinesterase Inhibitors on Cognition and Overall Clinical Response in APOE E4-Stratified Subjects with Mild to Moderate Alzheimer's Disease. (00123)
224. A Multi-Center, Double-Blind, Parallel Group, Fixed Dose, 4-Arm, Placebo and Paroxetine Controlled 8-Week Efficacy Study of 2 Oral Doses of XXXX (175mg or 350mg, bid) in Adult Outpatients with Major Depressive Disorder. (00022)
225. Phase 3 Multinational, Randomized, Double-Blind, Placebo-Controlled Study of the Effect of Daily Treatment with XXXX on Measures of Cognition, Activities of Daily Living and Global Function in Subjects with Mild Dementia of the Alzheimer's Type. (00128)
226. A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study to Assess the Efficacy, Safety and Pharmacokinetics of XXXX in Patients with Restless Legs Syndrome. (00141)
227. Open Label Study of the Effect of Daily Treatment with XXXX in Subjects with Dementia of the Alzheimer's Type. (00139)
228. An 8-Week, Randomized, Double-Blind, Fixed-Dosage, Placebo-Controlled, Parallel-Group, Multi-Center Study of the Efficacy, Safety and Tolerability of XXXX 25 mg and 50 mg in the Treatment of Major Depressive Disorder (MDD) Followed by a 52-Week, Open-Label Extension (XXXX). (00125)

229. An Open-Label Extension Trial to Investigate the Safety and Tolerability of Long-Term Treatment with Transdermal XXXX in Subjects with Idiopathic Restless Legs Syndrome. (00093)
230. A 28-Week Open Label Extension Study Evaluating the Safety and Tolerability of XXXX (XXXX) in Subjects with Mild Cognitive Impairment. (00105)
231. A Randomized, Double-Blind, Placebo-Controlled, Cross-Over Study to Evaluate the Effects of XXXX (2.5, 10 and 30mg) on Polysomnographic Sleep Recordings, Subjective Sleep Assessment, and Daytime Cognitive Function in Elderly and Non-Elderly Subjects with Primary Insomnia. (00088)
232. A Randomized, Double-Blind, Placebo Controlled, Cross-Over Study to Evaluate Effects of the XXXX in Patients with Insomnia. (00077)
233. A Randomized, Double-Blind Comparison of 5mg of XXXX, 15 mg of XXXX, and Placebo in the Treatment of Patients with Primary Insomnia. (00076)
234. A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Demonstrate the Subjective Treatment Effects of XXXX on Sleep Using a Post Sleep Questionnaire-Interactive Voice Response System (PSQ-IVRS) in an “At-Home Setting” in an Adult Population with Chronic Insomnia. (00145)
235. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Study to Investigate the Efficacy and Safety of a Single Oral Dose of XXXX (20, 50, and 100 mg) and Matching Placebo in Healthy Male and Female Subjects with Induced Transient Insomnia. (00107)
236. Efficacy and Safety of XXXX 5mg/day on Sleep Maintenance Insomnia: A 6-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study. (00103)
237. A Randomized, Double-Blind, Placebo and Active Controlled, Multi-Center, Proof of Concept Trial of XXXX in Subjects with Non-Restorative Sleep. (00095)
238. Effect of XXXX in Slowing the Progression of Alzheimer’s Disease. (00134)
239. A Double-Blind, Randomized, Placebo-Controlled Study of the Efficacy, Safety and Tolerability of 8 Week Treatment of XXXX 8 mg (QHS) in Sleep Disturbed, Mild to Moderately Severe Alzheimer’s Disease Subjects. (00090)
240. A Phase 2, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Effect on Cognitive Function of XXXX After 12 Weeks of Intranasal Administration in Subjects with Mild Cognitive Impairment. (00163)
241. A Six-Week, Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Efficacy and Safety, Sleep Lab Trial with XXXX in Patients with Chronic Primary Insomnia. (00118)
242. A Randomized, Double-Blind, Placebo-Controlled, Parallel, Proof of Concept Study to Evaluate the Effectiveness of XXXX to Advance the Timing of Sleep in Individuals with Delayed Sleep Phase Syndrome (DSPS). (00198)

243. A Randomized, Double-Blind, Placebo-Controlled, Phase IIa Study to Assess the Short-Term Effects of XXXX Alone and in Combination with Donepezil in Subjects with Mild Alzheimer's Disease. (00144)
244. Efficacy and Safety of 2 mg/Day XXXX on Sleep Maintenance Insomnia: A 6-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Polysomnographic Study. (00192)
245. A Phase II, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Dose-Ranging Study Assessing the Efficacy and Safety of XXXX Tablets Twice Daily in Adults with Mild to Moderate Alzheimer's Disease. (00214)
246. Fifty-Two Weeks, Open-Label Extension Trial to Evaluate Safety and Efficacy of XXXX in Outpatients with Chronic Primary Insomnia Who Completed Clinical Trial Protocol 176001 or 176002. (00217)
247. A Randomized, Double-Blind, Active- and Placebo-Controlled, Parallel Group Safety Study Assessing Simulated Driving Performance in XXXX- Treated Patients with Restless Legs Syndrome. (00227)
248. XXXX Dose-Ranging Trial: A Randomized, Double-Blind, Placebo-Controlled, 5-Way Crossover, Multicenter Polysomnography Trial of XXXX in Adults with Primary Insomnia. (00284)
249. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Study to Investigate the Efficacy and Safety of XXXX (20 MG/Day and 50 MG/Day) in the Treatment of Primary Insomnia. (00273)