



PACIFIC RESEARCH NETWORK

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## **JOHN J. DORIA, M.D.**

### **EDUCATION**

1958 Medical: Universidad Nationale de Mexico, Mexico,  
Degree: M. D.

1951 Undergraduate: University of Southern California, Los Angeles,  
California

Degree: B. S. in Pharmaceutical Chemistry/Pharmacist  
1947 Undergraduate: Undergraduate, San Diego State University, San  
Diego, California

Degree: B. A. in Zoology and Chemistry

### **TRAINING**

1958 - 1960 Internship: Mercy Hospital Medical, San Diego, California

### **MEDICAL EXPERIENCE**

1994 - Present Staff Physician, Pacific Research Network, San Diego,  
California

1982 - 1994 General Medicine, Senior Member, Family Practice  
Department Chairman

Sharp Rees-Stealy Medical Group, San Diego, California  
1990 - 1993 Coordinator for Spanish Speaking Medical Students,  
University of California

San Diego, San Diego, California  
1982 - 1983 Chief of Staff, Board of Directors, Family Practice Department  
Chairman

Sharp Rees-Stealy Medical Group, San Diego, California  
1960 - 1982 Private Practice, General Medicine, San Diego, California  
1974 - 1978 Deputy Medical Officer for Federal Employees, Los Angeles  
and San Diego,

California  
1972 - 1973 Chief/Medical Director, Occupational Medical Services Alert  
Health Systems

College Park Hospital, San Diego, California

### **CERTIFICATION AND LICENSURE**

2001 Certified member of the Association of Clinical Research, Professionals

**LICENSURE:** State of California

License Number: A-19433  
Expiration Date: May 31, 2014

## **PAPERS, JOURNAL PUBLICATIONS, AND PARTICIPATORY RECOGNITION**

1. S. Silberstein, MD, S. Tepper, MD, J. Brandes, MD, M. Diamond, MD, J. Goldstein, MD, P. Winner, DO, S. Venkatraman, MS, F. Vrijens, MS, W. Malbecq, Ph.D., C. Lines, Ph.D., W.H. Visser, MD, Ph.D., S. Reines, MD, Ph.D., and E. Yuen, MD: *“Randomized, Placebo-Controlled Trial of Rofecoxib in the Acute Treatment of Migraine”* May 11, 2004 Edition of the Journal of Neurology, **John J. Doria, MD, Contributor.**

## **PROFESSIONAL ORGANIZATIONS**

American Academy of Family Physicians  
American and California Medical Association – Retired 1994  
San Diego Medical Foundation – Served on Ethical Committee  
San Diego Medical Society  
State of California Pharmacy and Therapeutic Committee  
Academy of Geriatrics  
Academy of Neurosciences

## **CLINICAL RESEARCH EXPERIENCE**

1. “A Placebo-Controlled Study of XXXXXX and XXXXXX in Patients with Generalized Anxiety Disorder” (2597)  
Investigator
2. “Open-Label Safety Study of XXXXXX in Patients with Anxiety Disorders” (2387)  
Investigator
3. “A Phase III at Home Use Study Evaluating the Efficacy and Safety of Escalating Doses of XXXXXX 2, 3 and 4 mg in the Treatment of Patients with Erectile Dysfunction” (2406)
4. “A Phase III, Six-Month, Long-Term, Open Label, Flexible Dose, Safety Extension Study of XXXXXX Tablets (2, 3 and 4 mg) in the Treatment of Male Erectile Dysfunction” (2406x1)
5. “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)
6. “A Double-Blind, Placebo-Controlled Study of XXXXXX in the Treatment of Behavioral Agitation in Elderly Patients with Dementia” (2637)
7. “A Multi-Center, Double-Blind, Placebo-Controlled, Randomized Fixed Dose Study of XXXXXX in the Treatment of Depressed Patients” (2521)

8. "Long-Term Open Label Treatment with XXXXXX for Evaluation and Safety" (1743)
9. "A Double-Blind, Placebo-Controlled, Parallel-Group Comparison of XXXXX Extended-Release Capsules and XXXXX in Outpatients with Generalized Social Anxiety Disorder" (2672)
10. "An Open-Label Study to Evaluate the Safety and Efficacy of 1.5 mg b.i.d. (3 mg/day) Through 6 mg b.i.d. (12 mg/day) of XXXXXX in Patients with Mild to Severe Probable Alzheimer's Disease in the Community Setting" (1166)
11. "A Double-Blind, Stratified, Randomized, Placebo Controlled Study of XXXXX (also known as XXXXX) in the Treatment of Influenza Infection in Elderly Adults" (2447)
12. "XXXXXX For the Treatment of Mild Cognitive Impairment and Prevention of Conversion to Alzheimer's Disease" (1160)
13. "The Safety and Efficacy of XXXXXX in Slowing the Progression of the Symptoms of Alzheimer's Disease" (2486)
14. "The Safety and Efficacy of XXXXX 25 mg in Delaying the Progression of the Symptoms of Alzheimer's Disease in Patients with Probable AD" (2855)
15. "A Phase III Double-Blind Efficacy and Safety of XXXXXX (10mg) in Addition to XXXXX in Subjects with Coronary Heart Disease or Multiple Risk Factors and with Primary Hypercholesterolemia Not Controlled by a Starting Dose (20mg) of Simvastatin" (2692)
16. "Randomized, Double-Blind, Placebo-Controlled Multicenter Trial to Demonstrate the Clinical Efficacy and Safety of Two Different Doses of XXXXXX in Patients Suffering Form Dementia of the Alzheimer's Type According to DSM-IV and NINCDS/ADRDA Criteria" (1250)
17. "Long-Term Safety and Efficacy of XXXXX in the Treatment of Alzheimer's Disease" (1138)
18. "Long-Term Safety of XXXXX in the Treatment of Alzheimer's Disease" (2485)
19. "Open-Label use of Synthetic XXXXX in the Treatment of Alzheimer's Disease" (1138x1)
20. "A Double-Blind, Placebo-Controlled Dose Finding Study Evaluating the Safety and Efficacy of XXXXX 1.5, 6 and 24 mg/day (0.5, 2, 8 mg tid) in the Treatment of Major Depressive Disorder" (2553)
21. "Safety and Efficacy of Long-Term Administration of XXXXX in the Treatment of Major Depressive Disorder: A 4 Month Double-Blind Extension to Study XXXXX" (2553x1)

22. "Safety of Open-Label Standard Antidepressant Therapy in the Treatment of Major Depressive Disorder: A 1-Month Follow-Up After Termination of Study XXXXX" (2553x2)
23. "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 XXXXX as Treatment for Adults with Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea/Hypopnea Syndrome Followed by a 9-Month Open-Label Extension" (2581)
24. "A Placebo-Controlled Study of XXXXXX in patients With Social Phobia." (2257A1) Investigator
25. "A 10-Week, Randomized, Double-Blind, Placebo-Controlled Study of XXXXXX and XXXXXX in Patients With Social Phobia." (3315) Investigator
26. "XXXXXX: Double-Blind, Placebo-Controlled, Dose-Response Study of Tolerability, Safety, and Efficacy in Patients with Early Parkinson's Disease" (3401)
27. "XXXXXX: Open-Label, Long Term, Flexible Dose Study of Safety, Tolerability, and Therapeutic Response in Patients with Parkinson's Disease." (3429)
28. "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)
29. "A 16-Week, Randomized, Double-Blind, Placebo-Controlled, Crossover, Multicenter Study of XXXXXX in Patients With Mild to Moderate Alzheimer's Disease." (2963)
30. "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)
31. "A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study to Assess the Efficacy and Safety of XXXXXX in Patients with Chronic Insomnia." (2973)
32. "Placebo Controlled Evaluation of XXXXXX in the Treatment of Alzheimer's Disease: Safety and Efficacy of a Controlled Release Formulation." (2918)
33. "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)

34. " 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)
- 35.A Randomized, Double-Blind, Placebo-Controlled, Single-Dose Study to Assess Dose Response of XXXXXX in Subjects Transient Insomnia." (2580)
- 36.A Multi-Center, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Lipid-Altering Efficacy, Safety, and Tolerability of XXXXXX When Added to Ongoing Therapy with an HMG-CoA Reductase Inhibitor (Statin) in Patients with Primary Hypercholesterolemia, Known Heart Disease or Multiple Cardiovascular Risk Factors. (3452)
- 37.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)
- 38.A Well-Controlled Safety and Efficacy Study of XXXXXX In Subjects with Mild to Moderate Alzheimer's Disease. (3261)
- 39.Efficacy and Safety of a Flexible Dose of XXXXXX Versus Placebo in the Treatment of Psychosis of Alzheimer's Disease. (2956)
- 40.An 8-Week, Double-Blind, Randomized, Multicenter, Flexible-Dose, Placebo-Controlled Study Of XXXXXX in Patients with Panic Disorder. (3789)
- 41.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)
- 42.A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study to Assess the Efficacy and Safety of XXXXXX in Elderly Patients with Chronic Insomnia. (3927)
- 43.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)
- 44.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)

- 45.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)
46. A Phase II, Randomized, Multicenter, Double-Blind, Placebo-Controlled, Twelve-Week, Safety and Tolerability of XXXXXX in Patients with Mild-to-Moderate Dementia of the Alzheimer's Type. (3977)
47. 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)
48. 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)
49. A Long-Term, Open-Label Study of XXXXXX in Subjects with Mild to Moderate Alzheimer's Disease. (3261x1)
50. Assessment of Variance in FDG-PET Measurement of CNS Effects in Healthy Volunteers. (4082)
51. 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)
52. A Long-Term Extension Study Evaluating the Safety and Tolerability of BID and QD Administration of XXXXXX in Patients with Mild to Moderate Dementia of the Alzheimer's Type. (3811X1)
53. 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)
54. 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)
  55. 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)
  56. 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)
  57. 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)
  58. 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)
  59. 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)
  60. An Open-Label Extension Trial to Assess the Safety of XXXXXX HBr in the Treatment of Vascular Dementia. (4556)
  61. 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)
62. 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)
  63. 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)
  64. 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)
  65. A Multi-Center Study to Determine the Exposure of Adult U.S. Smokers to Cigarette Smoke. (4625)
  66. 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)
  67. 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)
  68. 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)
  69. 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)
  70. A Long-Term, Open-Label, Flexible-Dose Study of the Efficacy and Safety of XXXX in Patients with Idiopathic Restless Legs Syndrome. (4382)
  71. 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)
  72. 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)



73. Pharmacogenomics Blood Sampling Protocol to Obtain DNA in a Reference Population of Patients Diagnosed with Restless Legs Syndrome. (5152)
74. 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)
75. A 12-Month, Open-Label, Flexible-Dosage Study to Evaluate the Safety of XXXX, at Dosages up to 16 mg/day in Adults with Generalized Anxiety Disorder. (202976)
76. An Evaluation of the Long-Term Safety and Efficacy of XXXX in Patients with Moderate to Severe Dementia of the Alzheimer's Type. (202891)
77. 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)
78. 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)
79. An Open-Label Extension Study to Assess the Long-Term Safety and Tolerability of XXXX in the Treatment of Mild Cognitive Impairment. (5075)
80. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Long-Term Safety and Efficacy of Two Dose Levels of XXXX in Adult Patients with Primary Insomnia. (3934)
81. A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Obstructive Sleep Apnea/Hypopnea Syndrome. (203233)
82. 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)
83. A One year, Multicenter, Randomized, Double-Blind, Placebo-Controlled Evaluation of the Efficacy and Safety of XXXX in Subjects with Mild Cognitive Impairment. (202493)
84. 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)
85. A Randomized, Double-blind, Placebo-Controlled Trial of XXXX to Attenuate the Progression of Alzheimer's Disease. (202530)

86. A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter, Fixed-Dose, Polysomnographic Study of XXXX in Patients with Primary Insomnia. (202700)
87. 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)
88. 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)
89. A Double-Blind, Phase II, Safety and Efficacy Evaluation of XXXX in Patients with Mild to Moderate Alzheimer's Disease. (203096PRN)
90. A Phase III Study of the Efficacy and Safety of XXXX in Patients with Mild to Moderate Alzheimer's Disease. (203077PRN)
91. 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)
92. 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)
93. A Study to Define the Non-Restorative Sleep Population. (00010)
94. A Randomized, Double-Blind, Placebo-Controlled Trial of XXXX to Attenuate the Progression of Alzheimer's Disease. (00026)
95. A 6-Month Safety Follow-Up Study to Select Patients Previously Enrolled and Randomized to XXXX in Studies XXXX, XXXX or XXXX. (00028)
96. 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)
97. A Randomized, Double-Blind, Placebo-Controlled, Crossover Study to Assess the Efficacy and Safety of XXXX in Patients with Restless Legs Syndrome. (203812PRN)
98. A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of Once Daily XXXX in Patients with Restless Legs Syndrome. (00036)

99. 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 & 00100)
100. 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)
101. A Double Blind, Placebo Controlled Study of XXXX for the Treatment of Mild-To-Moderate Alzheimer's Disease. (00065)
102. A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXXX in Patients with Restless Legs Syndrome. (00056)
103. A Randomized, Double-Blind, Placebo-Controlled, Cross-Over Study to Evaluate the Effects of XXX (2.5, 10 and 30 mg) On Polysomnographic Sleep Recording, Subjective Sleep Assessment and Daytime Cognitive Function in Elderly and Non-elderly Subjects with Primary Insomnia. (00088)
104. A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Effects of XXXX on Cognitive Functions in the Elderly. (00058 & 00228)
105. A Randomized, Double-Blind, Placebo Controlled, Cross-Over Study to Evaluate the Effects of the XXXX in Patients with Insomnia. (00077)
106. A Randomized, Double-Blind Comparison of 5 mg of XXXX, 15 mg of XXXX, and Placebo in the Treatment of Patients with Primary Insomnia. (00076)
107. A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Parallel-Group Study to Evaluate the Efficacy and Safety of XXXX in Migraine Prophylaxis. (00082)
108. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy, Safety and Tolerability of XXXX in Patients with Generalized Anxiety Disorder. (00054)
109. 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)
110. 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)
111. 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)
112. The Efficacy of XXXX 3 mg as Adjunctive Therapy in Subjects with Insomnia Related to Generalized Anxiety Disorder. (00057)
  113. A 12 Week, Double-Blind, Placebo Controlled, Parallel Group Study to Assess the Efficacy and Safety of XXXX XR (Extended Release) in Patients with Restless Legs Syndrome. (00059)
  114. 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)
  115. An Open-Label Extension of the Phase III Study XXXX with XXXX in Patients with Alzheimer's Disease. (00107)
  116. A 28-Week Open Label Extension Study Evaluating the Safety and Tolerability of XXXX XXXX (XXXX) in Subjects with Mild Cognitive Impairment. (00105)
  117. A Randomized, Double-Blind, Placebo and Active-Controlled, Multicenter, Proof of Concept Trial of XXXX in Subjects with Non-Restorative Sleep. (00095)
  118. Efficacy and Safety of XXXX 5mg/day on Sleep Maintenance Insomnia: A 6-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study. (00103)
  119. 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)
  120. An Open-Label, 52-Week Extension Study Assessing XXXX Safety and Efficacy in Patients with Restless Legs Syndrome. (00114)
  121. Open Label Study of the Effect of Daily Treatment with XXXX in Subjects with Dementia of the Alzheimer's Type. (00139 & 00189)
  122. An 8-Week, Randomized, Double-Blind, Fixed-Dosage, Placebo-Controlled, Parallel-Group, Multicenter 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. (00125)
  123. 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)

124. 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)
125. A Multi-Center, Double-Blind, Parallel Group, Fixed Dose, 4-Arm, Placebo and XXXX Controlled 8-Week Efficacy Study of 2 Oral Doses of XXXX (175mg or 350mg, bid) in Adult Outpatients with Major Depressive Disorder. (00022)
126. A 51-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 ε4-Stratified Subjects with Mild to Moderate Alzheimer's Disease. (00123)
127. 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)
128. Effect of XXXX in Slowing the Progression of Alzheimer's Disease. (00134)
129. A Randomized, Double-Blind, Placebo-Controlled, Phase IIa Study to Assess the Short-Term Effects of XXXX Alone and in Combination with XXXX in Subjects with Mild Alzheimer's Disease. (00144)
130. 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)
131. 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)
132. 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)
133. Efficacy and Safety of 2 mg/day XXXX on Sleep Maintenance Insomnia: a 6-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Polysomnographic Study. (00192)
134. A 52-Week Open-Label Extension Study of the Long-Term Safety and Efficacy of XXXX Extended-Release (RSGXR) as Adjunctive Therapy to Acetylcholinesterase inhibitors in Subjects with Mild-to-Moderate Alzheimer's Disease (AVA102675, REFLECT-4) (00220)

135. XXXX Dose-Ranging Trial: A Randomized, Double-Blind, Placebo-Controlled, 5-Way Crossover, Multicenter Polysomnography Trial of XXXX in Adults with Primary Insomnia. (00284)
136. 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)
137. 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)
138. 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)
139. 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)
140. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 3 Study of XXXX in Adult Migraineurs For a Single Migraine Followed by Open-Label Extensions to 26/52 Weeks. (00219)
141. 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)
142. A Double-Blind, Randomized, Placebo-Controlled Study Examining, the Safety, Efficacy, and Tolerability of XXXX in Subjects with Major Depressive Disorder (Including Atypical and Melancholic Features). (00230)
143. A Phase 3, Randomized, Double-Blind, Placebo Controlled, Parallel Group, 10-Week Study Evaluating the Efficacy and Safety of XXXX for the Treatment of Generalized Anxiety Disorder. (00275)
144. A Randomized, Long-Term Safety Study of XXXX in Elderly Outpatients with Chronic Primary Insomnia Examining the Effects of 1.5 mg or 3.0 mg of XXXX. (00226)
145. A Randomized, Double-Blind, Placebo-Controlled Subjective Study to Assess the Efficacy of XXXX in Patients with Primary Insomnia Characterized by Difficulty Maintaining Sleep. (00324)
146. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of XXXX at a Target Dosage of 200 mg/day as Treatment for Adults With Excessive Sleepiness Associated With Obstructive Sleep Apnea/Hypopnea Syndrome With Comorbid Major Depressive Disorder or Dysthymic Disorder. (00323)

147. Effect of  $\gamma$ -Secretase Inhibition on the Progression of Alzheimer's Disease: XXXX Versus Placebo. (00294)
148. XXXX Dose-Ranging Trial: A Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multicenter Outpatient Trial of XXXX in Adults with Non-Restorative Sleep. (00321)
149. A Phase 2a Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of XXXX in Patients with Mild to Moderate Alzheimer's Disease. (00318)
150. A Double-Blind, Placebo-Controlled, Randomized, Multicenter Study Evaluating the Efficacy and Safety of Eighteen Months of Treatment with XXXX (XXXX) in Participants with Mild-To-Moderate Alzheimer's Disease. (00355)
151. A Polysomnography Study of XXXX (XXXX) Extended Release Tablets Versus Placebo in the Treatment of Restless Legs Syndrome (RLS) and Associated Sleep Disturbance. (00338)
152. A Randomized, Double-Blind, Placebo-Controlled, Ascending-Dose Phase 1b Study of Three Different Doses of an Alpha-7 Nicotinic Acetylcholine Receptor Agonist (XXXX) or Placebo in Patients with Mild to Moderate Probable Alzheimer's Disease. (00343)
153. A 52 Week Open Label Safety Study of XXXX in Subjects with Generalized Anxiety Disorder. (00305)
154. Efficacy and Safety of XXXX 5mg/Day in Insomnia Characterized by Sleep Maintenance Difficulties: A 6-Week, Randomized, Double-Blind, Placebo-Controlled, Polysomnography Study. (00350)
155. A Phase 2 Study of XXXX Compared with Placebo for the Treatment of Alcohol Dependence. (00347)
156. A Randomized, Double-Blind, Placebo-Controlled, Functional Neuroimaging Study of the Effects of XXXX (200mg/Day) Treatment on Prefrontal Cortical Activation in Patients with Residual Excessive Sleepiness Associated with Obstructive Sleep Apnea/Hypopnea Syndrome. (00407)
157. A Phase 3 Multicenter, Randomized, Placebo-Controlled, Twelve-Month Safety and Efficacy Study Evaluating XXXX in Patients with Mild-To-Moderate Alzheimer's Disease on Donepezil. (00404)
158. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Tolerability, Pharmacodynamic and Pharmacokinetic Effects of XXXX in the Treatment of Patients With Mild to Moderate Alzheimer's Disease. (00341)

159. A Double-Blind, Placebo-Controlled Preliminary Study of the Efficacy, Safety and Tolerability of XXXX in the Treatment of Alzheimer's Disease. (00382)
160. A Double-Blind, Placebo-Controlled Preliminary Study of the Efficacy, Safety and Tolerability of XXXX in the Treatment of Alzheimer's Disease in Subjects Concurrently Receiving Donepezil (Aricept®). (00403)
161. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Tolerability, Pharmacodynamic and Pharmacokinetic Effects of XXXX in the Treatment of Patients with Prodromal Alzheimer's Disease. (00412)
162. Randomized, Double-Blind, 12-Month Study of XXXX in Subjects with Restless Legs Syndrome. (00418)
163. An Open Label Study of the Safety and Tolerability of XXXX in Subjects with Alzheimer's Disease. (00446)
164. A Phase 2 Multicenter, Double-Blind, Placebo-Controlled, Parallel Group Study of XXXX in Subjects with Mild to Moderate Alzheimer's Disease. (00440)
165. A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dosage Study to Evaluate the Efficacy and Safety of XXXX (50, 150 and 250 mg/day) as Treatment for Patients with Excessive Sleepiness Associated with Mild to Moderate Closed Traumatic Brain Injury. (00397)
166. A 12-Month, Open-Label Study to Evaluate the Safety, Tolerability, and Efficacy of XXXX (150 and 250 mg/Day) as Treatment for Patients With Excessive Sleepiness Associated With Mild or Moderate Closed Traumatic Brain Injury. (00506)
167. Open-Label Extension for Alzheimer's Disease Patients Who Complete One of Two XXXX Phase 3 Double-Blind Studies (H6L-MC-LFAN or H6L-MC-LFBC). (00516)
168. A Randomized, Double-Blind, Placebo-Controlled, 3-Way Crossover, Multicenter Polysomnography Study of XXXX and XXXX in Adults With Restless Legs Syndrome. (00457)
169. Effect of Passive Immunization on the Progression of Alzheimer's Disease: XXXX (XXXX) Versus Placebo. (00503)
170. A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Long-Term Safety Study of XXXX in Patients With Primary Insomnia. (00448)



171. A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Study to Evaluate the Safety and Efficacy of XXXX in Patients With Primary Insomnia - Study A. (00514)
172. An Open-Label Extension of the CONCERT Protocol (DIM18) Evaluating XXXX (XXXX) in Patients With Alzheimer's Disease. (00529)
173. A Worldwide, Randomized, Double Blind, Placebo-Controlled, Parallel Group Clinical Trial to Evaluate the Safety and Efficacy of XXXX for the Acute Treatment of Migraine in Children and Adolescents. (00502)
174. A Worldwide, Open Label, Clinical Trial to Examine the Long Term Safety and Tolerability of XXXX in Pediatric Migraineurs for the Treatment of Migraine With or Without Aura. (00469)
175. Randomized, Double-Blind, 12-Week Study of XXXX in Subjects With Restless Legs Syndrome. (00515)
176. A Multiple Dose Study of the Safety, Tolerability, Pharmacokinetic and Pharmacodynamic Effects of XXXX Administered Once Daily to Subjects with an Excessive Daytime Sleepiness Disorder. (00541)
177. Continued Efficacy and Safety Monitoring of XXXX, an Anti-Amyloid  $\beta$  Antibody in Patients with Alzheimer's Disease. (00565)
178. A Randomized, Double-Blind, Placebo-Controlled, Combined Single Ascending Dose and Multiple Ascending Dose Study to Assess Safety, Tolerability, Immunogenicity, Pharmacodynamic Response, and Pharmacokinetics of Intravenous Infusions of XXXX in Subjects with Mild to Moderate Alzheimer's Disease. (00582)
179. A Phase 2, 24-Month, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Amyloid-Imaging Positron Emission Tomography (PET) and Safety Study of XXXX and XXXX Adjuvant in Subjects with Mild to Moderate Alzheimer's Disease. (00591)
180. A 4-Week, Randomized, Double-Blind, Parallel Group, Placebo Controlled Study to Investigate the Safety and Efficacy of XXXX as Monotherapy in Patients with Treatment-Resistant Major Depression. (00585)
181. A Multicenter, Randomized, Double-Blind, Active-Controlled Study of the Efficacy and Safety of Flexibly-Dosed XXXX in Patients with Treatment Resistant Major Depression. (00571)
182. A Phase 2, Multicenter, Open-Label Study to Assess the Safety and Tolerability of Oral XXXX as Adjunctive Therapy in Adult Patients with Major Depressive Disorder. (00416)
183. A Randomized, Double Blind, Placebo-Controlled Efficacy and Safety Study of XXXX in Subjects with Spasticity Due to Multiple Sclerosis. (00595)

184. An Open Label, 26-Week Study Assessing XXXX Safety and Efficacy in Subjects with Spasticity Associated with Multiple Sclerosis. (00614)
185. A Phase 1b, Multicenter, Double-Blind, Randomized, Placebo-Controlled, Sequential Dose Study of the Safety and Tolerability of XXXX in Subjects with Alzheimer's Disease on Donepezil. (00618)
186. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Phase II Study to Evaluate the Efficacy and Safety of XXXX in Patients with Mild to Moderate Alzheimer's Disease. (00579)
187. A Multicenter, Double-Blind, 58-Week Rollover Study to Assess the Safety and Tolerability of XXXX in Patients with Treatment Resistant Major Depression. (00583)
188. A Study to Evaluate the Effects of XXXX in Patients with Chronic Obstructive Pulmonary Disease. (00619)
189. A Double-Blind, Parallel Group, Randomized, Placebo Controlled Sleep Laboratory Study of Efficacy and Safety of XXXX in Insomnia Patients Aged 18-80. (00635)
190. A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Effectiveness of XXXX (Human), 10 % Solution (XXXX, 10%) for the Treatment of Mild to Moderate Alzheimer's Disease (AD). (00626)
191. A Phase IIa Safety and Tolerability Study to Investigate the Effect on Sleep of 3 Doses of XXXX and Placebo in Patients with Mild Alzheimer's Disease and Mild Cognitive Impairment During 4 Weeks of Treatment, Designed as a Randomized, Double-Blind, Multi-Center, Parallel Group, Placebo-Controlled Study. (00658)
192. Effect of XXXX in Obese Subjects with Moderate or Severe Obstructive Sleep Apnoea A 32- Week Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Centre and Multinational Trail. (00696)
193. A Phase 2, Randomized, Double-Dummy, Double-Blind, Placebo-Controlled Study to Assess the Efficacy, Safety and Tolerability of XXXX (XXXX/XXXX) for the Treatment of Symptoms of Agitation in Patients with Alzheimer's Disease. (00697)
194. A Randomized, Double-Blinded, Placebo-Controlled Multiple Dose Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXXX in Subjects with Prodromal or Mild Alzheimer's Disease. (00700)
195. A Multicenter, Open-Label, Long-Term Safety Extension of Phase II Studies ABE4869g and ABE4955g in Patients with Mild to Moderate Alzheimer's Disease. (00729)

196. A Twelve-Week, Double-Blind, Placebo-Controlled, Randomized, Parallel-Group, Multi-Center Study of the Safety and Efficacy of XXXX in the Treatment of Excessive Daytime Sleepiness in Subjects with Narcolepsy. (00733)
197. A 26-Week, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Investigate the Effects of Daily Administration of XXXX in Participants with Mild to Moderate Alzheimer's Disease (AD) with an Optional 26-Week Open-Label Extension. (00731)
198. Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 18-Month Safety and Efficacy Study of XXXX in Subjects with Mild Alzheimer's Disease. (00722)