

**David W. Brown, M.D.**

**Office**

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**Education**

St. Mary's University, San Antonio, Texas; BA in Biology, graduated Magna cum laude, 1982.

University of Texas Medical School at Houston, Houston, Texas; M.D., 1986.

**Residency**

Department of Psychiatry, University of Texas Medical School at Houston, Houston, Texas, 1986-1990.

Psychiatry Resident in Training Examination (PRITE), overall national percentile scores:  
1989: psychiatry -- 97, neurology -- 96;  
1988: psychiatry -- 97, neurology -- 98.

PGY4 activities included one year of clinical EEG interpretation, supervised by Edward L. Reilly, M.D. and Nashaat Boutros, M.D.

**Fellowship**

Biological Psychiatry Branch, National Institute of Mental Health, Bethesda, Maryland; June, 1990 – July 1991.

Fellowship provided training in conducting clinical drug trials and in the correlation of quantitative EEG with neuro-imaging and in the neuroscience of anxiety and affective disorders. Fellowship supervised by Robert M. Post, M.D.

**Board Eligibility Certification**

American Board of Psychiatry and Neurology, Board Certified, February, 1993. Board Certificate Number: 36730.  
American Medical Electroencephalographic Association, Board Eligible, July 1990.

**Professional Memberships**

American Society of Clinical Psychopharmacology

Schizophrenia International Research Society

Texas Medical Association

Travis County Medical Association

American Psychiatric Association

**Awards**

New Milestones Foundation, 2008 Champions Award; 2008  
Texas Monthly Magazine "Texas Super Doctor," 2006, 2007, 2008, 2010, 2011, 2012, 2013, 2014

**Publications**

Sand M, Brown D, Walling D, Daniels K, McGinniss J, "Prevention of Relapse in Schizophrenia: A Phase II Study Evaluating Efficacy, Safety and Tolerability of Oral BI 409306," poster originally presented at the Society of Biological Psychiatry 73rd Annual Meeting, New York, NY, USA, May 10–12, 2018.

David Brown MD, Lara Wang, Jennifer McGinniss, Michael Sand, 'Identification of meaningful cognitive endpoints in studies of pharmacological treatments for cognitive impairment in schizophrenia: an adaptive two-stage methodology' with abstract number CG16P-1183 poster presented at 29th ECNP Congress, Vienna, 2016, and published in a supplement to the journal *European Neuropsychopharmacology* (ENP) 2016.

*David Brown 8/15/18*

David Brown, MD, Kristen Daniels, Shu Zhang, Solen Pichereau, Michael Sand, "Safety, tolerability pharmacokinetics, and pharmacodynamics of BI 409306 film-coated tablets given orally qd for 14 days in patients with schizophrenia," poster originally presented at the 15<sup>th</sup> ICOSR, Colorado Springs, CO 2015.

Ryan Turncliff, PhD, Margie Hard, PhD, David Brown, MD, Mark Lerman, MD, Adam Lowry, MD, Morteza Marandi, MD, Yangchun Du, PhD, Robert Risinger, MD, Elliot Ehrich, MD, "Aripiprazole Lauroxil (ALKS 9070), a Novel Once-Monthly Prodrug of Aripiprazole, Achieves Therapeutically Relevant Levels and is Well-Tolerated in Adult Patients with Schizophrenia Following Deltoid Administration", Poster #11-137 Presented at American College of Neuropsychopharmacology 52<sup>nd</sup> Annual Meeting December, 2013.

McEvoy J, Brown D, Chamber J, Lan G, Cassone W, Forbes RH, McQuade RD, Marur R. An open-label, pilot study of aripiprazole in subjects with first-episode psychosis. Journal of Clinical Psychopharmacology; in press.

Brown D, Gopal S, Hough D, Xu H, Lull J, Gassmann-Mayor C, Eerdelkens M. Efficacy and safety of paliperidone palmitate in adult patients with schizophrenia: A randomized, double-blind, placebo-controlled, dose response study. International Clinical Psychopharmacology; September 2010, Volume 25, Issue 5.

Lindenmyer JP, Brown D, Mevlin D, Liv S, Brecker M. The efficacy and tolerability of once-daily extended release quetiapine fumarate: a 6-week randomized, double-blind, placebo-controlled study. Psychopharmacology Bulletin: Vol. 41 No. 3; 2008.

Brown D, McEvoy J, Saha AR, Carson W, Stock E. Aripiprazole in patients with first episode schizophrenia [abstract]. Presented at ICOSR 2003 [poster]. Schizophrenia Res (Special Issue: TBC) 2003; Mar 03.

Saha AR, Brown D, McEvoy J, Ali M, Abou-Gharbia N, Stock E. Tolerability and efficacy of aripiprazole in patients with first-episode schizophrenia: an open-label pilot study [abstract 310]. Presented at XIIth Biennial Winter Workshop on Schizophrenia [poster]. Schizophrenia Res 2003; 67 (1 Suppl): 1-279.

Fry J, Scharf M, Berkowitz D, Brown D, Claghorn J, Ferguson, J, Karacan I, Lahmeyer H, Mendels, J, Pascualy R, Vogel G, Walsh, J, and Wooten V: 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.

Brown D, Gutierrez-Esteinou R, Hong-Lin Su, and O'Brien B: The safety and efficacy of risperidone 8mg QD and 4 mg QD compared to placebo in the treatment of schizophrenia; Presented at ACNP in San Juan, Puerto Rico, December 1996.

Brown, DW, Ketter TA, Crumlish J, Post RM: Carbamazepine induced increases in total serum cholesterol - clinical and theoretical implications; Journal of Clinical Psychopharmacology, December, 1992.

Wolfe HG, Bartke A, Amador A, Van Sickle M, Dalterio S, Brown DW: Effects of inhibitory and stimulatory photoperiods and sexual maturation on the ability of hamster testes to respond to hCG in vitro; International Journal of Andrology, 8 (1985) 232-242.

Bartke A, Matt KS, Amador AG, Klemcke HG, Brown DW, Gonzales D, Hogan MD: Testicular function of strains of mice selected for differences in gonadotropin induced ovulation rate; Journal of Endocrinology, 90 (1981) 367-373.

#### Presentations

Boehringer Ingelheim Pharma GmbH & Co. KG 1289.6 Results ICOSR 2017 oral presentation content TC (1289.6 results) San Diego, CA, March, 2017

"ARISTADA, aripiprazole lauroxil extended-release injectable suspension in the treatment of schizophrenia", for Alkermes, Temple MHMR, July 7, 2016

"ARISTADA, aripiprazole lauroxil extended-release injectable suspension in the treatment of schizophrenia", for Alkermes, Lampassas MHMR, May 26, 2016

"Abilify Maintena in the Treatment of Schizophrenia", for Otsuka, Bryan Providers of MH Services, Bryan, Texas, October 28, 2015

"Abilify Maintena in the Treatment of Schizophrenia", for Otsuka, Round Rock Providers of MH Services, Round Rock, Texas, October 28, 2015

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"Overview of Clinical Trials in Alzheimer's Disease", Austin, Texas, October 24, 2015

"Overview of Clinical Trials in Alzheimer's Disease", for residents of Sun City, Georgetown, Texas, August 6, 2015

"Overview of Clinical Trials in Alzheimer's Disease", for residents of Sun City, Georgetown, Texas, June 11, 2015

"Abilify Maintena in the Treatment of Schizophrenia", for Otsuka, Austin Providers of MH Services, Austin, Texas, March 3, 2015

"Abilify Maintena in the Treatment of Schizophrenia", for Otsuka, Bryan MHMR, Bryan Texas, December 1, 2014

"Abilify Maintena in the Treatment of Schizophrenia", for Otsuka, Department of Aging and Disability Services, Austin, Texas, November 20, 2014

"Abilify Maintena in the Treatment of Schizophrenia", for Otsuka, Temple MHMR, Temple, Texas, November, 10, 2014

"Abilify Maintena in the Treatment of Schizophrenia", for Otsuka, Bryan Texas, February 19, 2014

"Limited Overview of Psychiatric Drugs in Development", Blue Bonnet Trails, Round Rock Texas, October 3, 2013

"Abilify Maintena in the Treatment of Schizophrenia", for Otsuka, Austin, Texas, September 25, 2013

"Abilify Maintena in the Treatment of Schizophrenia", for Otsuka, Austin, Texas, September 24, 2013

"Abilify Maintena in the Treatment of Schizophrenia", for Otsuka, Gatesville, Texas, September 20, 2013

"Abilify Maintena in the Treatment of Schizophrenia", for Otsuka, Rockwall Texas, September 11, 2013

"Glutamate Hypothesis of Schizophrenia", CME Lecture, Seton Medical Center, Austin, Texas, September, 2013

"Abilify Maintena in the Treatment of Schizophrenia", for Otsuka, New Braunfels, Texas, August 27, 2013

"Abilify Maintena in the Treatment of Schizophrenia", for Otsuka, Austin, Texas, August 22, 2013

"Limited Overview of Psychiatric Drugs in Development" South Austin Medical Center, Austin, Texas, February 13, 2013

"The Role of Atypical Antipsychotic Long-Acting Therapies in the Treatment of Schizophrenia and Maintenance Treatment of Bipolar 1 Disorder" for Janssen, Austin, Texas, June 12, 2012

"The Role of Atypical Antipsychotic Long-Acting Therapies in the Treatment of Schizophrenia and Maintenance Treatment of Bipolar 1 Disorder", Central Counties MHMR, Killeen, Texas, September 7, 2011

"Clinical Trials for L42140023 in Schizophrenia: Practical Considerations" for Eli Lilly and Company, Dallas, Texas, February 10, 2011

"Use of Invega Sustenna" for Janssen, San Antonio, Texas, November 18, 2010

"Abilify for Major Depression" for Bristol-Myer Squibb, MHMR, Bryan, Texas, July 24, 2010

"Abilify for Major Depression" for Bristol-Myer Squibb, MHMR, Bryan, Texas, July 7, 2010

"Abilify for Major Depression" for Bristol-Myer Squibb, MHMR, Temple, Texas, June 11, 2010

"An Important Treatment Option for Schizophrenia" for Janssen, Austin, Texas, November 5, 2009

"An Important Treatment Option for Schizophrenia" for Janssen, Temple, Texas, October 8, 2009

"An Important Treatment Option for Schizophrenia" for Janssen, Austin, Texas, August 28, 2009

"Abilify for Major Depression" for Bristol-Myer Squibb, Bryan, Texas, August 26, 2009

"An Important Treatment Option for Schizophrenia" for Janssen, Marble Falls, Texas, August 4, 2009

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"An Important Treatment Option for Schizophrenia" for Janssen, Marble Falls, Texas, July 28, 2009

"Abilify for Major Depression" for Bristol-Myer Squibb, Temple, Texas, May 22, 2009

"Abilify for Major Depression" for Bristol-Myer Squibb, Killeen, Texas, May 8, 2009

"An Important Treatment Option for Schizophrenia" for Janssen, Lubbock, Texas, December 18, 2008.

"An Important Treatment Option for Schizophrenia" for Janssen, Big Spring, Texas, December 18, 2008.

"An Important Treatment Option for Schizophrenia" for Janssen, Austin, Texas, December 17, 2008.

"An Important Treatment Option for Schizophrenia" for Janssen, Marble Falls, Texas, November 12, 2008.

"An Important Treatment Option for Schizophrenia" for Janssen, Temple, Texas, March 7, 2008.

"Update on Genetics of Schizophrenia and Bipolar Disorder" for National Alliance for Mental Illness, Austin, Texas, February, 2008.

"An Important Treatment Option for Schizophrenia" for Janssen, Waco, Texas, December, 2007.

"Clinical Case Discussion" for Janssen, Houston, Texas, November, 2007.

"An Important Treatment Option for Schizophrenia" for Janssen, Austin, Texas, November, 2007.

"An Important Treatment Option for Schizophrenia" for Janssen, Bastrop, Texas, October, 2007.

"An Important Treatment Option for Schizophrenia" for Janssen, Houston, Texas, September, 2007.

"Schizophrenia, Bipolar Disorders and Clinical Trials" for Texas Organization of Residential Homes, San Antonio, Texas, August, 2007.

"An Important Treatment Option for Schizophrenia" for Janssen, Dallas, Texas, August, 2007.

"An Important Treatment Option for Schizophrenia" for Janssen, Austin, Texas, August, 2007.

"Invega Clinical Experience Network Live Teleconference" for Janssen, Teleconference Leader, Austin, Texas, July 2007.

"Invega Clinical Experience Network Live Teleconference" for Janssen, Teleconference Leader, Austin, Texas, July 2007.

"A New Option for the Treatment of Schizophrenia" for Janssen, Round Rock, Texas, July 2007.

"A New Option for the Treatment of Schizophrenia" for Janssen, Temple, Texas, June 2007.

"A New Option for the Treatment of Schizophrenia" for Janssen, Bastrop, Texas, February 2007.

"A New Option for the Treatment of Schizophrenia" for Janssen, Austin, Texas, May 2007.

"A New Option for the Treatment of Schizophrenia" for Janssen, Irving, Texas, March 2007.

"A New Option for the Treatment of Schizophrenia" for Janssen, Austin, Texas, February 2007.

"Abilify in First Episode Schizophrenia and Bipolar Disorder" for Bristol-Myers Squibb at Bryan-College Station MHRM, Bryan College Station, Texas, January 2005.

"Use of Geodon in Mood Disorders" for Pfizer at Bluebonnet Trail MHRM, Round Rock, Texas, December 2004.

"Risperdal Consta: The First Long-Acting Atypical for the Treatment of Schizophrenia" for Janssen Pharmaceutica at the Austin State School, Austin, Texas, June 2004.

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"The Kindling Hypothesis and Bipolar Disorder" for the Depressive, Manic-Depressive Association, at St. David's Hospital, Austin, Texas, April 2004.

"Overview of Atypical Antipsychotics" for the Waco Area VA and MHMR Physicians and Nursing Staff, Waco, Texas, April 2004.

"Overview of Atypical Antipsychotics" for Nursing and Residency Staff at Austin State Hospital, Austin, Texas, November 2003.

"Clinical Update on Aripiprazole" for Bristol-Myers Squibb, Austin, Texas, November 2003.

"Aripiprazole in Patients with First Episode Schizophrenia" for the Bristol-Myers Squibb/Otsuka America VISION Conference, International Launch for Abilify, Boca Raton, Florida, September 2003.

"Aripiprazole - A New Dopamine Partial-Agonist Antipsychotic" for Austin Area Psychiatric Nurses at the Austin State Hospital, Austin, Texas, August 2003.

"An Overview of Schizophrenia and It's Treatment," at the Texas Organization Residential Care Homes (TORCH) Conference, San Antonio, Texas, August 2003.

"Aripiprazole in Patients with First Episode Schizophrenia" for the Bristol-Myers Squibb/Otsuka America program "National Network of Psychiatric Educators" Bonita Springs, Florida, June 2003.

"Aripiprazole - A New Dopamine Partial-Agonist Antipsychotic" teleconference for Bristol-Myers Squibb/Otsuka America, June 2003.

"Aripiprazole - A New Dopamine Partial-Agonist Antipsychotic" for the ADC Psychiatric Group, Austin, Texas, June 2003.

"Aripiprazole - A New Dopamine Partial-Agonist Antipsychotic" for the Austin State Hospital Medical Staff and residency program, Austin, Texas, March 2003.

"Aripiprazole in Patients with First Episode Schizophrenia" for the IXth International Congress on Schizophrenia Research; Colorado Springs, CO, March 2003.

"Aripiprazole - A New Dopamine Partial-Agonist Antipsychotic" for the Presidents of Texas NAMI and Mental Health Association state-wide legislative/lobbyist meeting, Austin, Texas, March 2003.

"Aripiprazole - A New Dopamine Partial-Agonist Antipsychotic" for Central Texas area psychiatrists, Austin, Texas, February 2003.

"Aripiprazole - A New Dopamine Partial-Agonist Antipsychotic" for the Austin State Hospital medical staff and residency program, Austin, Texas, February 2003.

"IM Geodon in Agitated, Psychotic Patients" for the San Antonio Emergency Physicians Quarterly Meeting, San Antonio, Texas, December 2002.

"IM Geodon in Agitated, Psychotic Patients" for Pfizer, San Antonio, Texas, November 2002.

"IM Geodon in Agitated, Psychotic Patients" for Seton and Brackenridge Hospitals Emergency Physicians, Austin, Texas, November 2002.

"IM Geodon in Agitated, Psychotic Patients" for the Audie Murphy VA Hospital Psychiatric Staff, San Antonio, Texas, November 2002.

"IM Geodon in Agitated, Psychotic Patients" for the Kerville State Hospital, Kerville, Texas, November 2002.

"IM Geodon in Agitated, Psychotic Patients" Grand Round, presentation for the Austin State Hospital, Austin, Texas, October 2002.

"Bipolar Disorder Treatment Update" for the Depressive and Manic Depressive Association, Austin, Texas, September 2002.

"Schizophrenia Treatment Update" for the National Alliance for Mental Illness, Austin, Texas, March 2002.

*David M. Stubb*

"Safety of Risperidone as Add-on Therapy to Mood Stabilizers in the Maintenance Treatment of Bipolar Disorder" and "Risperidone vs. Placebo as Combination Therapy to Mood Stabilizers In The Treatment of Manic Phase of Bipolar Disorder: Focus on Efficacy" for the American Psychiatric Association's Annual Scientific Poster Session in Chicago, May 2000.

"Update on the Treatment of Schizophrenia" for Austin Association of Psychiatric Nurses, CEU program, Austin, Texas, June 1998.

"Update on the Treatment of Depression" for Internal Medicine Grand Rounds, Brackenridge Hospital, Sponsored by Central Texas Medical Foundation and Eli Lilly and Company, Austin, Texas, March 1998.

"Advances in the Treatment of Bipolar Disorder" for Austin Manic Depressive Association, Austin, Texas, February 1998.

"Atypical Neuroleptics" for Austin Chapter of The National Alliance for Mental Illness, Austin, Texas, February 1998.

"New Treatments for Schizophrenia" for Primary Care Physicians, Fairfield, Texas, August 1997.

"New Treatment for Schizophrenia" for Primary Care Physicians, Waco, Texas, June 1997.

"New Treatments for Alzheimer's Disease" for National Alzheimer's Association -Austin Chapter, Austin, Texas, March 1997.

"Bipolar Disorder and Kindling" for Austin Manic Depressive Association, Austin, Texas, February 1997.

"Pharmacotherapy for Depression" for Austin Association of Physician Assistants, Austin, Texas, September 1995.

"New Treatments for Schizophrenia" for Medco Behavioral Health, Houston, Texas, 8/95; Dallas, Texas, September 1995.

"Successful Strategies for Patient Enrollment and Retainment" for Janssen Research Foundation, West Palm Beach, Florida, December 1995.

"Psychiatric Presentations of Epilepsy" for Seton Hospital Grand Rounds, Austin, Texas, November 1995.

"Advances in the Treatment of Bipolar Disorder" for the Depressive-Manic Depressive Association of Austin, Austin, Texas, October 1995.

"Pharmacology of Geriatric Depression" for the Waco Veterans Administration Medical Center/ telecast to the Temple Veterans Administration Medical Center, Waco, Texas, July 1995.

"Pharmacotherapy Update for Therapists" for Personal Performance Consultants, Austin, Texas, April 1995.

"Interview on Bipolar Disorder" for Good Morning, Austin, K-BVO Television Station, Austin, Texas, March 1995.

"Kindling and Bipolar Disorder" for St. David's Hospital Family Practice Department, Austin, Texas, October 1994.

"Biological Explanations for Mood Disorders" for the Texas Alliance for the Mentally Ill 1993 Convention, Austin, Texas, September 1993.

"Biology and Bipolar Disorder" for C.P.C. Capital Hospital Spring Lecture Series, Austin, Texas, March 1993.

"Kindling Hypothesis" for the University of Arkansas School for Medical Sciences (UAMS) Symposium, "Current Perspectives on Bipolar Disorder," Little Rock, Arkansas, March 1992.

"Pharmacological Treatment of Post-Traumatic Stress Disorder" for the UAMS Symposium, "Panic Disorder in Minorities and the Underserved," Little Rock, Arkansas, June 1992.

#### **Neuropsychiatric Rating Scales Training and Certifications**

- Positive and Negative Syndrome Scale (PANSS)
- Clinical Global Impressions (CGI)
- Montgomery-Asberg Depression Rating Scale (MADRS)
- Abnormal Involuntary Movement Scale (AIMS)
- Structured Clinical Interview for DSM-IV-TR (SCID)

*Meredith Ann Stutz*

- MINI International Neuropsychiatric Interview for Schizophrenia and Psychotic Disorders (MINI)
- Young Mania Rating Scale (YMRS)
- Columbia Suicide Severity Rating Scale (C-SSRS)
- Simpson Angus Scale (SAS)
- Barnes Akathisia Rating Scale (BARS)
- Hamilton Depression Rating Scale (HAM-D)
- Hamilton Anxiety Rating Scale (HAM-A)
- Personal and Social Performance Scale (PSP)
- Negative Symptoms Assessment Scale (NSA)
- Brief Psychiatric Rating Scale (BPRS)
- Calgary Depression Scale for Schizophrenia (CDSS)
- Global Assessment of Functioning (GAF)
- Inventory of Depressive Symptomatology-Clinician Rated (IDS-C30)
- Clinical Opiate Withdrawal Scale (COWS)
- CIWA-A/CIWA-B (Clinical Institute Withdrawal Assessment EtOH and Benzodiazepines)
- Movement Scales
- Mini-Mental State Examination (MMSE)
- Clinical Dementia Rating Scale (CDR)
- Alzheimer's Disease Assessment Scale Cognitive (ADAS-COG)

#### **Additional Training and Certifications of Site Staff**

- MCCB
- CogState
- CANTAB
- UCSD Performance-Based Skills Assessment (UPSA)
- UCSD Performance-Based Skills Assessment Brief (UPSA-B)
- Cognitive Assessment Interview (CAI)
- CNS Vital Signs
- WRAT III – Reading Test
- Paired Associates Learning (PAL)
- Tower of London
- Trailmaking Tests, A and B
- HVLT-B
- BVMT-B
- SCoRS

#### **Participation in Clinical Research**

RGH-MD-25: A Double-Blind, Placebo-Controlled, Randomized Withdrawal, Multicenter Clinical Trial Evaluating the Efficacy, Safety, and Tolerability of Cariprazine in a Dose-Reduction Paradigm in the Prevention of Relapse in Bipolar I Disorder Patients Whose Current Episode Is Manic or Depressive, With or Without Mixed Features; sponsored by Allergan, 2018-present.

TAK-831-2002: A Phase 2, 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel Study to Evaluate Efficacy, Safety, Tolerability, and Pharmacokinetics of 3 Dose levels of TAK-831 in Adjunctive Treatment of Adult Subjects With Negative Symptoms of Schizophrenia; sponsored by Takeda, 2018-present.

1289-0049: A phase II randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of orally administered BI 409306 during a 28-week treatment period as adjunctive therapy to antipsychotic treatment for the prevention of relapse in patients with schizophrenia; sponsored by Boehringer Ingelheim, 2018-present.

1289-0032: A phase II randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of orally administered BI 409306 during a 52-week treatment period as an early intervention in patients with attenuated psychosis syndrome; sponsored by Boehringer Ingelheim, 2018-present.

TOL3010B: A Pivotal, Multiple-Dose, Pharmacokinetic Bioequivalence Trial Comparing Generic to Reference Paliperidone Palmitate Extended-Release Injectable Suspension (156 mg/1.0 mL) in Patients with Schizophrenia or Schizoaffective Disorder; sponsored by Tolmar, 2018-present.

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6981-CL-0004: A Phase 1 Randomized, 2-way, Crossover Study to Assess the Safety, Tolerability, Pharmacodynamics and Pharmacokinetics of ASP6981 in Subjects with Schizophrenia; sponsored by Astellas, 2018.

ALK9072-A306: A Phase 3b, Multicenter, Randomized, Double-blind Study to Evaluate the Efficacy and Safety of Aripiprazole Lauroxil or Paliperidone Palmitate for the Treatment of Schizophrenia in Subjects Hospitalized for Acute Exacerbation; sponsored by Alkermes, 2017-present.

331-201-00083: Phase 3, A Multicenter, Open-label Trial to Evaluate the Safety and Tolerability of Brexpiprazole in the Treatment of Subjects with Bipolar I Disorder; sponsored by Otsuka, 2017-present.

331-201-00080: Phase 3, A Multicenter, Randomized, Double-blind Trial of Brexpiprazole versus Placebo for the Acute Treatment of Manic Episodes, With or Without Mixed Features, Associated With Bipolar I Disorder; sponsored by Otsuka, 2017-present.

RAP-MD-06: Phase 3, An Open-label, Long-term Safety Study of Rapastinel as Adjunctive Therapy in Patients with Major Depressive Disorder; sponsored by Naurex, Inc, an affiliate of Allergan, plc., 2017-present.

RAP-MD-04: Phase 3, A Randomized, Double-blind, Placebo-controlled, Multicenter Study of Rapastinel as Adjunctive Therapy in the Prevention of Relapse in Patients with Major Depressive Disorder; sponsored by Naurex, Inc, an affiliate of Allergan, plc., 2017-present.

RAP-MD-02: Phase 3, A Randomized, Double-blind, Placebo-controlled, Multicenter Study of Rapastinel as Adjunctive Therapy in Major Depressive Disorder; sponsored by Naurex, Inc, an affiliate of Allergan, plc., 2017-present.

ALK3831-A109: A Phase 1, Study to Evaluate the Effect of Multiple Doses of ALKS 3831 on QTc Interval in Subjects with Schizophrenia; sponsored by Alkermes, 2017-2018.

031-201-00104: A Phase 1, Open-label, Single Ascending Dose, Parallel Arm Trial to Determine the Pharmacokinetics, Safety, and Tolerability of Aripiprazole 2 Month Intramuscular Depot Administered Gluteally in Adult Subjects with Schizophrenia; sponsored by Otsuka, 2017-2018.

217-MDD-201: Phase 2, two-part (open-label followed by double-blind) study evaluating the safety, tolerability, pharmacokinetics, and efficacy of SAGE-217 in the treatment of adult subjects with moderate to severe Major Depressive Disorder; sponsored by Sage Therapeutics, 2017-2018 .

ROV-RISP-2016-01: Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Intramuscular Injections of Risperidone ISM® in Patients with Acute Exacerbation of Schizophrenia (PRISMA-3), Principal Investigator; sponsored by Laboratorios Farmacéuticos ROVI, S.A., 2017-present.

ALK3831-A308: A Phase 3 Study to Assess the Long Term Safety, Tolerability, and Durability of Treatment Effect of ALKS 3831 in Subjects with Schizophrenia, Schizophreniform Disorder, or Bipolar I Disorder; sponsored by Alkermes, 2017-present.

ALK3831-A307: Phase 3, A Study to Evaluate the Effect of ALKS 3831 Compared to Olanzapine on Body Weight in Young Adults with Schizophrenia, Schizophreniform, or Bipolar I Disorder Who are Early in Their Illness; sponsored by Alkermes, 2017-2018.

BP39207: A Phase IIb, Multicenter, Randomized, Double-blind, Parallel group, Placebo-controlled Study to Evaluate the Efficacy, Safety and Tolerability of BASMISANIL (RO5186582) as Adjunctive Treatment in Patients with Cognitive Impairment Associated with Schizophrenia Treated with Antipsychotics; sponsored by F. Hoffmann-La Roche, 2016-present.

ITI-007-303: Phase 3, An Open-Label, Multi-Center Trial to Assess the Safety and Effectiveness of ITI-007 in Patients with Schizophrenia; sponsored by Intracellular Therapies, 2016-2018.

TNX-CY-P303: Phase 3 A 12-week open-label extension study to evaluate TNX-102 SL taken daily at bedtime in patients with PTSD; sponsored by Tonix Pharmaceuticals, 2017-2018.

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TNX-CY-P301 A Phase 3, Double Blind, Randomized, Multicenter, Placebo-Controlled Study to Evaluate the Efficacy and Safety of TNX-102 SL Taken Daily at Bedtime in Patients with Military-Related PTSD; sponsored by Tonix Pharmaceuticals, 2017-2018.

16159B Phase 3, Interventional, Open-label, Flexible-Dose, Long-Term Safety Study of Lu AF35700 in Adult Patients with Schizophrenia; sponsored by Lundbeck, 2017-present.

16159A Phase 3, Interventional, randomised, double-blind, active-controlled, fixed-dose study of Lu AF35700 in patients with Treatment-resistant Schizophrenia, sponsored by Lundbeck, 2017-present.

HP-3070-GL-04: Phase 3, A Randomized, Double-Blind, Placebo-Controlled, Fixed-Dose, 6-Week, In-Patient Study to Assess Efficacy and Safety of HP-3070 in Subjects Diagnosed with Schizophrenia; sponsored by Noven Pharmaceuticals, 2016-2018.

ITI-007-201: A Phase 3, A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety of ITI-007 in the Treatment of Agitation in Patients with Dementia; sponsored by Intracellular Pharmaceuticals, 2016-2017.

ITI-007-402: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety of ITI-007 Adjunctive to Lithium or Valproate in the Treatment of Patients with Major Depressive Episodes Associated with Bipolar I or Bipolar II Disorder (Bipolar Depression); sponsored by Intracellular, 2015-present.

ITI-007-401: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety of ITI-007 Monotherapy in the Treatment of Patients with Major Depressive Episodes Associated with Bipolar I or Bipolar II Disorder (Bipolar Depression); sponsored by Intracellular, 2015-present.

ALK3831-A304: A Phase 3, Multicenter Study to Assess the Long Term Safety and Tolerability of ALKS 3831 in Subjects with Schizophrenia; sponsored by Alkermes, 2016-present.

ALK3831-A303: A Phase 3 Study to Evaluate Weight Gain of ALKS 3831 Compared to Olanzapine in Adults with Schizophrenia; sponsored by Alkermes, 2015-2018.

ALK9072-B102: A Phase 1 Study of an ALKS 9072N Initiation Regimen in Adults with Schizophrenia; sponsored by Alkermes, 2015-2016.

ALK6428-A301: A Phase 3 Study to Evaluate the Safety, Tolerability, and Efficacy of Naltrexone for Use in Conjunction with Buprenorphine in Adults with Opioid Use Disorder Prior to First Dose of VIVITROL®; sponsored by Alkermes, 2015-2016.

ITI-007-009: Phase 1, An open-label cross-over study to determine the tolerability, safety and pharmacokinetics of ITI-007 administered orally as an overencapsulated tablet in patients with schizophrenia and healthy geriatric volunteers; sponsored by IntraCellular, 2015-2016.

TAK-063-2002: A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel-group, 6-Week Study to Evaluate the Efficacy and Safety of TAK-063 in Subjects With an Acute Exacerbation of Schizophrenia; sponsored by Takeda, 2015-2016.

1289.27: Phase 1c, Randomized, Parallel-Group, Double-Blind Study of Systemic and Ocular Safety, Tolerability, Pharmacodynamics and Pharmacokinetics of 25 or 100 mg BI 409306 Film-Coated Tablets (Given Orally q.d. 14 Days) in Patients with Schizophrenia, Alzheimer's Disease, and Age-Matched Healthy Volunteers; sponsored by Boehringer-Ingelheim, 2015-2016.

ESKETINTRD3001: Phase 3, A Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Fixed Doses of Intranasal Esketamine Plus an Oral Antidepressant in Adult Subjects with Treatment-resistant Depression; sponsored by Janssen Pharmaceuticals, 2015-2017.

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ESKETINTRD3003: Phase 3, A Randomized, Double-blind, Multicenter, Active-Controlled Study of Intranasal Esketamine Plus an Oral Antidepressant for Relapse Prevention in Treatment-resistant Depression; sponsored by Janssen Pharmaceuticals, 2015-2017.

ITI-007-302: Phase 3, A Randomized, Double-Blind, Placebo- and Active-Controlled, Multi-Center Study to Assess the Antipsychotic Efficacy of ITI-007 After 6 Weeks of Treatment in Patients With Schizophrenia; sponsored by Intracellular, 2015-2016.

1289.6: A phase II randomised, double-blinded, placebo-controlled study to evaluate the efficacy, safety, and tolerability of four orally administered doses of BI 409306 during a 12-week treatment period in patients with schizophrenia on stable antipsychotic treatment; sponsored by Boehringer-Ingelheim 2014-2017.

ALK9072-A105: A Phase 1, Randomized, Open-label, Study Evaluating the Pharmacokinetics of Various Dosing Regimens of Aripiprazole Lauroxil in Subjects with Stable Schizophrenia; sponsored by Alkermes, 2014-2016.

ITI-007-301: A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Antipsychotic Efficacy of ITI-007 in Patients With Schizophrenia phase 3; sponsored by IntraCellular, 2014-2016.

ALK9072-B101: A Phase 1, Placebo-controlled, Single Ascending-dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of ALKS 9072N in Adults with Schizophrenia; sponsored by Alkermes, 2014-2015.

LY03004/CT-USA-104: A Randomized, Open-Label Pharmacokinetic Study of LY03004 Compared to Risperdal Consta Following a Single Intramuscular Injection at 25mg in Stable Patients with Schizophrenia and/or Schizoaffective Disorder, Phase 1; sponsored by Luye America Pharmaceuticals, LTD, 2014-2015.

ALK3831-401: A Phase 2, Randomized, Double-blind Study to Evaluate Efficacy, Safety, and Tolerability of ALKS 3831 in Subjects with Schizophrenia with Alcohol Use Disorder. Principal Investigator; sponsored by Alkermes, 2014-2017.

LY03004/CT-USA-102: Protocol Title: A Randomized, Open-Label, Parallel-Group Study to Assess the Relative Bioavailability of LY03004 and Risperdal® Consta® at 25 mg Following Multiple Intramuscular Injections in Stable Patients with Schizophrenia and/or Schizoaffective Disorder Phase 1, Principal Investigator; sponsored by Luye America Pharmaceuticals, Ltd., 2014-2015.

331-13-008 An Exploratory, Multicenter, Open-label, Flexible-dose Brexpiprazole (OPC-34712) Trial in Adults With Acute Schizophrenia, Phase 3, Principal Investigator; sponsored by Otsuka, 2014.

316-13-211 – A Randomized, Controlled, Parallel Group Study to Evaluate Adherence to Treatment with and Safety and Tolerability of the Medical Information Device #1 (MIND1) System in Subjects with Bipolar 1 Disorder or Schizophrenia who are currently Treated with Oral Aripiprazole, Phase 2, Principal Investigator; sponsored by Otsuka, 2014.

RB-US-13-0005: An Open-Label, Long-Term Safety and Tolerability Study of RBP-7000 in the Treatment of Subjects With Schizophrenia, Phase 3, Principal Investigator; sponsored by Reckitt Benckiser Pharmaceuticals Inc., 2014-2017.

RB-US-09-0010: A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of RBP-7000 (90 mg and 120 mg) as a Treatment in Subjects with Acute Schizophrenia Over 8 Weeks (2 Subcutaneous Doses), Phase 3, Principal Investigator; sponsored by Reckitt Benckiser Pharmaceuticals Inc., 2014-2015.

RGH-MD-06: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of Cariprazine (RGH-188) in the Prevention of Relapse in Patients with Schizophrenia, Phase 3, sponsored by Forest, 2013-2014.

MSI-CP.002: A Double-Blind, Placebo-Controlled, Randomized Add-On Study of MSI-195 (S-Adenosyl-L-Methionine, SAMe) For Patients With Major Depressive Disorder (MDD) Who Have Had An Inadequate Response to Current Antidepressant Therapy. Phase 2, Principal Investigator; sponsored by Methylation Sciences, Inc., 2013-2014.

A8241019- A 12-Week, randomized, phase 2, double-blind, parallel-group study of two dose levels of PF-02545920 compared to placebo in the adjunctive treatment of outpatients with sub-optimally controlled symptoms of schizophrenia. Phase 2, Principal Investigator; sponsored by Pfizer, 2013-2014.

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14644B Interventional, open-label, flexible-dose extension study of brexpiprazole in patients with schizophrenia. Phase 3, Principal Investigator; sponsored by Lundbeck, 2013-2016

14644A Interventional, randomized, double-blind, parallel-group, placebo-controlled, active-reference, flexible-dose study of brexpiprazole in patients with acute schizophrenia. Phase 3, Principal Investigator; sponsored by Lundbeck, 2013-2015.

31-12-298, An Open-label, Multiple Dose, Safety and Tolerability Study of Aripiprazole IM Depot Administered in the Deltoid Muscle in Adult Subjects with Schizophrenia. Principal Investigator; sponsored by Otsuka, 2013-2014.

1289.18: Safety, tolerability, pharmacokinetics and pharmacodynamics of BI 409306 film-coated tablets given orally q.d. for 14 days in patients with schizophrenia (randomized, parallel-group, double-blind, placebo-controlled study). Principal Investigator; sponsored by Boehringer-Ingelheim, 2013-2014.

ALK3831-302 A Phase 2, Randomized, Multicenter, Safety, Tolerability, and Dose-Ranging Study of Samidorphan, a component of ALKS 3831, in adults with Schizophrenia treated with Olanzapine. Principal Investigator; sponsored by Alkermes, 2013-2016.

LY03004/CT-1S01, An Open-Label, Single Ascending Dose Pharmacokinetic and Safety Study of LY03004 Following Escalating Single Intramuscular Injection in Stable Patients with Schizophrenia or Schizoaffective Disorder. Principal Investigator; sponsored by Shandong Luye Pharmaceutical Co., 2013-2014.

31-12-293, A Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Safety and Efficacy of Fixed-dose Once-daily Oral Aripiprazole in Children and Adolescents with Tourette's Disorder. Principal Investigator; sponsored by Otsuka, 2013.

31-08-252, A 52-week, Multicenter, Open-label Study to Evaluate the Effectiveness of an Intramuscular Depot Formulation of Aripiprazole (OPC-14597) as Maintenance Treatment in Patients with Bipolar I Disorder. Principal Investigator; sponsored by Otsuka, 2013-2015.

ALK9072-003, A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study of the Efficacy and Safety of ALKS 9072 in Subjects with Acute Exacerbation of Schizophrenia. Principal Investigator; sponsored by Alkermes, 2012-2015.

ALK9072-003EXT, A Phase 3, Multicenter, Extension of Study ALK9072-003 to Assess the Long-term Safety and Durability of Effect of ALKS 9072 in Subjects with Stable Schizophrenia. Principal Investigator; sponsored by Alkermes, 2012-2015.

ALK9072-101, A Phase 1, Randomized, Open Label, Single-dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of ALKS 9072 Following Administration to the Deltoid or Gluteal Muscle in Subjects with Chronic Stable Schizophrenia. Principal Investigator; sponsored by Alkermes, 2012-2013.

31-12-291, A 12-week, Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Aripiprazole Intramuscular Depot (OPC-14597, Lu AF41155) in the Acute Treatment of Adults with Schizophrenia. Principal Investigator; sponsored by Otsuka, 2012-2013.

31-12-297, A 26-week, Multicenter, Open-label, Extension Study of Aripiprazole Intramuscular Depot (OPC-14597, Lu AF41155) in Patients with Schizophrenia. Principal Investigator; sponsored by Otsuka, 2012-2013.

D1050238, A Double-Blind, Placebo-Controlled, Randomized Withdrawal Study of Lurasidone for the Maintenance Treatment of Subjects with Schizophrenia. Principal Investigator; sponsored by Sunovion, 2012-2014.

D1050307, A 12-Week, Multicenter, Open-label Extension Study in Subjects with Schizophrenia. Principal Investigator; sponsored by Sunovion, 2012-2014.

331-10-231, A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Three Fixed Doses of OPC-34712 in the Treatment of Adults With Acute Schizophrenia. Principal Investigator; sponsored by Otsuka 2012-2014.

331-10-237, A Long-term, Phase 3, Multicenter, Open-label Trial to Evaluate the Safety and Tolerability of Oral OPC-34712 as Maintenance Treatment in Adults with Schizophrenia. Principal Investigator; sponsored by Otsuka, 2012-2014.

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331-10-242, A Parallel-arm, Double-blind, Placebo and Positive Controlled Multiple Oral Dose Administration Trial to Evaluate the Effects of OPC-34712 on QT/QTc in Subjects with Schizophrenia or Schizoaffective Disorder. Principal Investigator; sponsored by Otsuka, 2012.

RGH-MD-75 A Double-Blind, Placebo- Controlled, Study of Cariprazine (RGH-188) As Adjunctive Therapy In Major Depressive Disorder. Principal Investigator; sponsored by Forest, 2012.

H8Y-MC-HBBN A Phase 3, Multicenter, Double-Blind, Placebo-Controlled Safety and Efficacy Study of LY2140023 in Patients with DSM-IV-TR Schizophrenia. Principal Investigator; sponsored by Eli Lilly and Company, 2011-2013.

TAK-375SL\_201 A Randomized, Double-Blind, Placebo-Controlled, Proof-of-Concept, Phase 2 Study to Evaluate the Efficacy and Safety of Once a Day, TAK-375 (Ramelteon) Tablet for Sublingual Administration (TAK-375SL Tablet) 0.1 mg, 0.4 mg, and 0.8 mg in the Treatment of Acute Depressive Episodes Associated with Bipolar I Disorder in Adult Patients who are on Lithium and/or Valproate. Principal Investigator; sponsored by Takeda 2011-2014.

TAK-375SL\_203 A Randomized, Double-Blind, Placebo-Controlled, Proof-of-Concept, Phase 2 Study to Evaluate the Efficacy and Safety of once a day, TAK-375 SL 0.1 mg, 0.4 mg, and 0.8 mg As An Adjunctive Therapy To Treatment-As-Usual In The Maintenance Treatment of Bipolar I Disorder in Adult Patients. Principal Investigator; sponsored by Takeda 2011-2014.

P05691. A Phase 3b, Multicenter, Double-Blind, Fixed-Dose, Parallel-Group, Three Week Placebo Controlled Trial Evaluating the Safety and Efficacy of Asenapine in Subjects With Bipolar 1 Disorder Experiencing an Acute Manic or Mixed Episode (formerly 041044)). Principal Investigator; sponsored by SPRI-Merck, 2012-2015.

P05692 A Multicenter, Double-Blind, Fixed-Dose, Long-Term Extension Trial of the Safety of Asenapine in Subjects Diagnosed with Bipolar 1 Disorder who Completed Protocol P05691 (formerly 041044) (Phase 3B, formerly 041045)). Principal Investigator; sponsored by SPRI-Merck, 2012-2015.

ITI-007-005: A randomized, double-blind, placebo-controlled, multi-center study to assess the antipsychotic efficacy of ITI-007 in patients with schizophrenia Principal Investigator; sponsored by IntraCellular, 2012-2013.

ALK5461-202 A Phase 2, Randomized, Double-blind, Placebo-controlled Study to Evaluate ALKS 5461 in Subjects with Major Depressive Disorder and Inadequate Response to Antidepressant Therapy. Principal Investigator; sponsored by Alkermes 2012-2013.

31-11-289 An Open-label, Safety and Tolerability Trial of Aripiprazole IM Depot Initiation In Adult Subjects with Schizophrenia Stabilized on Atypical Oral Antipsychotics other than Aripiprazole. Phase 1, Principal Investigator; sponsored by Otsuka, 2012.

31-11-290 – An Open-label, Randomized, Parallel Arm, Bioavailability Trial of Aripiprazole IM Depot Administered in the Deltoid or Gluteal Muscle in Adult Subjects With Schizophrenia. Phase 1, sponsored by Otsuka, 2012

H8Y-MC-HBCG A Placebo- and Positive-Controlled Study of the Electrophysiological Effects on the QT Interval after a Supratherapeutic Dose of LY2140023 in Subjects with Schizophrenia. Principal Investigator; sponsored by Eli Lilly and Company, 2012-2014.

P05688 A Multicenter, Randomized, Double-Blind, Fixed Dose, 6-Week Trial of the Efficacy and Safety of Asenapine Compared with Placebo Using Olanzapine as an Active Control in Subjects With an Acute Exacerbation of Schizophrenia (Phase 3B, Protocol P05688 (formerly 041038)). Principal Investigator; sponsored by SPRI-Merck, 2012-2015.

P05689 A Multicenter, Double-Blind, Fixed Dose, Long-Term Extension Trial of the Safety of Asenapine using Olanzapine as an Active Control in Subjects Diagnosed with Schizophrenia who Completed Protocol P05688 (formerly 041038) (Phase 3B, Protocol P05689 (formerly 041039)). Principal Investigator; sponsored by SPRI-Merck, 2012-2015.

R092670-PSY-3012; Phase 3 A Randomized, Multicenter, Double-Blind, Relapse Prevention Study of Paliperidone Palmitate 3 Month Formulation for the Treatment of Subjects with Schizophrenia. Principal Investigator; sponsored by Johnson & Johnson Pharmaceutical Research & Development, L.L.C., 2012-2014.

CNS162-006 A Multicenter, Randomized, Double-blind, Active-Controlled Study of the Efficacy and Safety of Flexibly-Dosed BMS-820836 in Patients with Treatment Resistant Major Depression. Principal Investigator; sponsored by Bristol-Myers Squibb, 2011-2013.

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CN162-010: A Multicenter, Double-Blind, 58-week Rollover Study to assess the Safety and Tolerability of BMS-820836 in Patients with Treatment Resistant Major Depression. Principal Investigator; sponsored by Bristol-Myers Squibb, 2011-2013.

OND-003, A multi-center, randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of low-dose ondansetron for adjunctive therapy in adult patients with obsessive-compulsive disorder who have not adequately responded to treatment with a selective serotonin reuptake inhibitor. Principal Investigator; sponsored by Transcept 2011-2012.

H8Y-MC-HBDE, A Phase 3, Multicenter, Double-Blind Comparison of LY2140023 and Aripiprazole in Patients with DSM-IV-TR Schizophrenia Followed by Open- Label Treatment with LY2140023. Principal Investigator; sponsored by Eli Lilly and Company, 2011-2012.

H8Y-MC-HBBV, A Long-Term Open-Label Safety Study of Pomaglumetad Methionil in Patients with Schizophrenia. Principal Investigator; sponsored by Eli Lilly and Company, 2012.

31-10-270, An Open-Label, Multicenter, Rollover, Long-term Study of Aripiprazole Intramuscular Depot in Patients with Schizophrenia, sponsored by Otsuka, 2010-2013.

CX157-201, A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Assessment of the Efficacy, Safety and Tolerability of CX157 Modified Release Tablet, 125 mg Twice Per Day in Subjects with Treatment Resistant Depression, Principal Investigator; sponsored by CeNeRx, 2010-2013.

CIL0522DUS01 A 12-week, Randomized, Multi-center, Open-Label, iloperidone, (12-24mg/day), Flexible Dose Study Assessing Efficacy, Safety and Tolerability of Two Switch Approaches in Schizophrenia Patients Currently Receiving Risperidone, Olanzapine or Aripiprazole (i-FANS) (IND 36,827 - Phase IV study) .Principal Investigator; sponsored by Novartis, 2010-2012.

WN25305, A Phase III, multi-center, randomized, 12-week, double-blind, parallel-group, placebo-controlled study to evaluate the efficacy and safety of RO4917838 in patients with sub-optimally controlled symptoms of schizophrenia treated with antipsychotics followed by a 40-week double-blind, parallelgroup, placebo controlled treatment period. sponsored by Roche, 2010-2012.

WN25333, A phase II/III, multi-center, randomized, 4-week, double-blind, parallel group, placebo and active-controlled trial of the safety and efficacy of RO4917838 vs. placebo in patients with an acute exacerbation of schizophrenia. Principal Investigator; sponsored by Roche, 2010-2012

WN25308, A Phase III, multi-center, randomized, 24 week, double-blind, parallel-group, placebo-controlled study to evaluate efficacy and safety of RO4917838 in stable patients with persistent, predominant negative symptoms of schizophrenia treated with antipsychotics followed by a 28 week, double-blind treatment period. Principal Investigator; sponsored by Roche, 2010-2012.

RGH-MD-36, A Long-term open-label study of the safety and tolerability of cariprazine in patients with bipolar 1 disorder. Principal Investigator; sponsored by Forest, 2010-2011.

A8241012, A Phase 2a, multicenter, double-blind randomized, parallel group, 4-week inpatient treatment study to evaluate the safety, and efficacy of two fixed doses of PF-02545920 compared to placebo, using risperidone as an active control, in the treatment of acute exacerbation of schizophrenia. Principal Investigator; sponsored by Pfizer, 2010-2011.

096-050, Long-Term Eslicarbazepine Acetate Extension Study 093-046 Principal Investigator; sponsored by Sunovion, 2010-2012.

093-046 Double-Blind, Randomized, Historical Control Study of the Safety and Efficacy of Eslicarbazepine Acetate Monotherapy in Subjects with Partial Epilepsy Not Well Controlled By Current Antiepileptic Drugs. Principal Investigator; sponsored by Sunovion, 2010-2012.

PRO-05619-CLP-003 A 2-Part, Randomized, Double Blind, Sequential, Multiple Ascending Dose, Placebo Controlled, Parallel Group Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of TC-5619-238 in Elderly Subjects with and without Alzheimer's Disease, Principal Investigator; sponsored by Targacept, 2010-2011.

R092670-SCA-3004 Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of Paliperidone Palmitate Evaluating Time to Relapse in Subjects With Schizoaffective Disorder; Principal Investigator; sponsored by OMJSA, 2010.

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A9131005 A Randomized Phase 2, Double-Blind, Placebo-controlled, multi-center study of PF-03463275 as add-on therapy in outpatients with persistent negative symptoms of schizophrenia treated with a stable dose of a second generation antipsychotic. Principal Investigator; sponsored by Pfizer, 2010.

J&J R092670-SCH-3006, A 15 Month prospective, randomized active controlled, open-label, flexible dose study of the prevention of significant treatment events with Paliperidone Palimate compared with oral Antipsychotic Treatment in adults with schizophrenia recently discharged from jail. Principal Investigator; sponsored by OMJSA, 2010.

H8Y-MC-HBBO A Long-Term, Open-Label, Multicenter Study of LY2140023 Compared to Atypical Antipsychotic Standard of Care in Patients with DSM-IV-TR Schizophrenia. Principal Investigator; sponsored by Eli Lilly and Company, 2010-2012.

H8Y-MC-HBBM, A Phase 2, Multi Center, Double Blind Placebo Controlled Study of 2 doses of LY2140023 Vs Placebo in patients with DSM-IV-TR Schizophrenia. Principal Investigator; sponsored by Eli Lilly and Company, 2010-2012.

31-09-265, An Open-label, Multi-center, Three Phase, Sequential Design, Single and Multiple Dose Study to Assess the Safety, Tolerability, and Pharmacokinetic Profile of an Enteric Coated Once-weekly Oral Formulation of Aripiprazole Administered to Children and Adolescents with Tourette's Disorder. Principal Investigator; sponsored by Otsuka 2010-2011.

Abbott M10-503, A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 2 Study of the Safety and Efficacy of ABT-288 in the Treatment of Cognitive Deficits in Schizophrenia. Principal Investigator; sponsored by Abbott, 2010-2012.

C10953/3074, A 6-Month, Open Label, Flexible-Dosage (150 and 200 mg/day) Extension Study to Evaluate the Efficacy and Safety of Armodafinil Treatment as Adjunctive Therapy in Adults With Major Depression Associated with Bipolar 1 Disorder. Principal Investigator; sponsored by Cephalon, 2010-2012.

C10953/3071, A Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dosage Study to Evaluate the Efficiency and Safety of Armodafinil Treatment (150 and 200 mg/day) as Adjunctive Therapy in Adults With Major Depression Associated with Bipolar 1 Disorder. sponsored by Cephalon, 2010-2012.

31-05-245, An Open-label, Parallel-arm, Two-period, Single-dose Pilot Study to Assess the Pharmacokinetics and the Effect of Food on the Pharmacokinetics of Five Once Weekly Oral Formulations of Aripiprazole in Adult Subjects with Schizophrenia, phase 1b. Principal Investigator; sponsored by Otsuka, 2009-2010.

CLOZ-0920, Comparative Steady-State Bioequivalence Study of Clozapine Orally Disintegrating Tablets (Mylan) and FazaClo® Orally Disintegrating Tablets (Azur) in Patients with Chronic or Subchronic Schizophrenia Already Taking Clozapine. Principal Investigator; sponsored by Mylan Pharmaceuticals Inc. 2009.

CSD0904, Post-Market Surveillance of Tobacco Products: A Multicenter Clinical Trial of Natural Adopters of Cigarettes, Moist Snuff, Camel SNUS, and Dual Use. Principal Investigator; sponsored by RJ Reynolds, 2009- 2010.

R092670-SCH-3004 A Prospective, Randomized, Active-controlled, Rater-blinded, International Study of the Prevention of Relapse Comparing Paliperidone Palmitate to Oral Risperidone in Adults with Recently-Diagnosed Schizophrenia Who Are at High Risk of Relapse Principal Investigator; sponsored by OMJSA, 2009-2010.

331-08-212 A Phase 2 Multicenter, Open-label Study to Assess the Safety and Tolerability of Oral OPC-34712 as Adjunctive Therapy in Adult Patients with Major Depressive Disorder. Principal Investigator; sponsored by Otsuka, 2009-2011.

331-08-211 A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of OPC-34712 as Adjunctive Therapy in the Treatment of Patients with Major Depressive Disorder with the protocol number 331-08-211 and investigational compound OPC-34712 to be conducted at Center. Principal Investigator; sponsored by Otsuka, 2009-2010.

SPD489-204 (Lisdexamfetamine dimesylate) (the "Study Drug"), according to Protocol SPD489-204 (the "Protocol"), entitled, "A Phase 2, Multicenter Study with Open-label and Randomized Double-blind Placebo-controlled Withdrawal Phases to Evaluate the Efficacy, Safety, and Tolerability of SPD489 in Adults with Schizophrenia and Predominant Negative Symptoms who are Clinically Stable and Taking Stable Doses of Atypical Antipsychotic Medication" Principal Investigator; sponsored by Shire, 2009-2011.

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PRO-05619-CRD-001, A double-blind, placebo-controlled, multicenter, parallel group study to assess efficiency, safety and tolerability of TC-5619 as augmentation therapy to improve cognition in outpatients with cognitive dysfunction in schizophrenia Principal Investigator; sponsored by Targacept, 2009-2011.

31-08-248, A 52-Week, Multicenter, Open-Label Study to Evaluate the Effectiveness of Aripiprazole Intramuscular Depot as Maintenance Treatment in Patients with Schizophrenia "ASPIRE OPEN-LABEL" (Aripiprazole Intramuscular Depot Program in Schizophrenia). Principal Investigator; sponsored by Otsuka, 2008-2014.

31-07-246, A 52-Week, Multicenter, Randomized, Double-Blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of an Intramuscular Depot Formulation of Aripiprazole (OPC-14597) as Maintenance Treatment in Patients with Schizophrenia. "ASPIRE US" (Aripiprazole Intramuscular Depot Program in Schizophrenia). Principal Investigator; sponsored by Otsuka, 2008-2011.

D144AC00001, A 8-Week, Multicenter, Double-Blind, Randomized, Parallel Group, Placebo-controlled, Study of Efficacy and Safety of Quetiapine Fumarate (Seroquel) Extended-release of Monotherapy in Children and Adolescent Patients with Bipolar Depression. Principal Investigator; Sponsored by AstraZeneca, 2008-2009.

D6702C00009, A Phase IIb, Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-controlled Efficacy and Safety Study of Adjunctive AZD6765 in Subjects with Severe Major Depressive Disorder (MDD) and a History of Poor Response to Antidepressants. Principal Investigator; Sponsored by AstraZeneca, 2008-2009.

11723A, A Randomized, Double-Blind, Parallel-Group, Flexible-Dose Study Exploring the Neurocognitive Effect of Sertindole versus Quetiapine in Patients with Schizophrenia Using the MATRICS Consensus Cognitive Battery (MCCB). Principal Investigator; sponsored by Lundbeck, 2008-2010.

H8R-MC-HJAQ, A Phase 2 Study of LY686017 Compared with Placebo for the Treatment of Alcohol Dependence. Principal Investigator; sponsored by Eli Lilly and Company, 2009.

C10953/2034/SZ/MN, A 24-Week, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dosage Study to Evaluate the Efficacy and Safety of Armodafinil (150, 200, and 250 mg/day) as Adjunctive Therapy in Adults with Schizophrenia. Principal Investigator; sponsored by Cephalon, 2008-2009.

C10953/1056/PK/US, An Open-Label Study to Evaluate the Effect of Repeated Administration of Armodafinil (250mg/day) on the Pharmacokinetics of Quetiapine Fumarate Following Administration of the Immediate-Release Formulation of Seroquel Tablets in Patients with Schizophrenia. Principal Investigator; sponsored by Cephalon, 2008-2009.

C10953/2032/DP/US, An 8-Week, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dosage Study to Evaluate the Efficacy and Safety of Armodafinil Treatment (150mg/day) as Adjunctive Therapy in Adults with Major Depression Associate with Bipolar I Disorder. Principal Investigator; sponsored by Cephalon, 2008.

D1050234, A Phase 3 Randomized, Double-Blind, Active Comparator-Controlled Clinical Trial to Study the Safety and Efficacy of Lurasidone in Subjects with Schizophrenia (Pearl 3 Extension Study). Principal Investigator; sponsored by Sumitomo, 2008-2009.

D1050233, A Phase 3 Randomized, Double-Blind, Placebo-and Active Comparator-Controlled Clinical Trial to Study the Efficacy and Safety of Two Doses of Lurasidone in Acutely Psychotic Subjects with Schizophrenia (Pearl 3). Principal Investigator; sponsored by Sumitomo, 2008-2009.

C-1073-14, A Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of CORLUX (Mifepristone) vs. Placebo in the Treatment of Psychotic Symptoms in Patients with Major Depressive Disorder with Psychotic Features. Principal Investigator; sponsored by Corcept, 2008-2009.

R076477-SCH-4013, A blinded-initiation study of medication satisfaction in subjects with schizophrenia treated with paliperidone ER after suboptimal response to oral risperidone. Principal Investigator; sponsored by Johnson & Johnson, 2007-2008.

QF 001, A Two-Period, Two-Treatment, Open-Label, Two-Way Steady-State Crossover Bioequivalence Study of Quetiapine Fumarate Extended Release 400-mg Tablets Under Fasting Conditions in Patients. Principal Investigator; sponsored by Anchen, 2008.

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NN20372, Randomized, double-blind, placebo controlled add-on trial of the safety and efficacy of R04917838 in outpatients on olanzapine,quetiapine, risperidone or paliperidone with prominent negative or disorganized thought symptoms. Principal Investigator; sponsored by Roche, 2008-2009.

153006, A multi-center cardiac safety study of subjects who participated in Organon sponsored Phase 1 and Phase 2 completed and discontinued trials with Org 2448 (Protocols; 22601; 22602; 22603; 153001; 153002; 153003; 153304, 29402,III.04.0311) Principal Investigator; sponsored by Organon, 2008-2009.

D1050237, Long-Term Safety, Tolerability, and Effectiveness of Lurasidone in Subjects with Schizophrenia or Schizoaffective Disorder: A Randomized, Active Comparator-Controlled Trial. Principal Investigator; sponsored by Sumitomo, 2008-2011.

D1050231, A Phase 3 Randomized, Placebo- and Active Comparator-Controlled Clinical Trial to Study the Safety and Efficacy of Two Doses of Lurasidone HCl in Acutely Psychotic Patients with Schizophrenia. Principal Investigator; sponsored by Sumitomo, 2008-2011.

3153A1-2203-WW, A Randomized, Double-Blind, Placebo-Controlled, Risperidone-Referenced, Parallel-Group, Adaptive-Design Study of the Efficacy, Safety and Tolerability of Vabicaserin (SCA-136) in Subjects with Acute Exacerbations of Schizophrenia. Principal Investigator; sponsored by Wyeth, 2008.

D3690C00011, A Multi-Center Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Phase IIb Proof of Concept Study with 3 Oral Dose Groups of AZD3480 during 12 Weeks Treatment of Cognitive Deficits in Patients with Schizophrenia. Principal Investigator; sponsored by AstraZeneca, 2007-2008.

A4251037, PD 0200390 Dose-Ranging Trial; A Randomized, Double-Blind, Parallel Group, Placebo Controlled, Multicenter Outpatient Trial of PD 0200390 in Adults with Primary Insomnia. Principal Investigator; sponsored by Pfizer, 2007-2009.

A1281158, A Six Week, Double-Blind, Multicenter, Placebo Controlled Study Evaluating the Efficacy and Safety of Flexible Doses of Oral Ziprasidone as Add On, Adjunctive Therapy with Lithium, Valproate or Lamotrigine in Bipolar I Depression. Principal Investigator; sponsored by Pfizer, 2007-2009.

ACP 104-003, A Six-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Phase II Study of the Efficacy and Safety of ACP 104 in Acutely Psychotic Subjects with Schizophrenia. Principal Investigator; sponsored by Acadia, 2007-2008.

MEM 3454-101, A Phase 2a, Multi-center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled study to evaluate the safety and efficacy of MEM 3454 as adjunctive treatment in combination with a preexisting antipsychotic in patients with cognitive impairment associated with Schizophrenia. Principal Investigator; sponsored by Memory Pharmaceuticals, 2007-2009.

R076477-SCA-3002, A Randomized, Double-Blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of Flexible Dose Paliperidone ER in the Treatment of Subjects with Schizoaffective Disorder. Principal Investigator; sponsored by Janssen, 2007-2008.

QUET-T300-PVSS-1, A Two-Period, Two Treatment, Two-Way Steady-State Crossover Bioequivalence Study of Quetiapine Fumarate 300 mg Tablets under Fasting Conditions. Principal Investigator; sponsored by Roxane Laboratories, Inc., 2007-2008.

F1D-US-HGMN, Predicting Response to Risperidone Treatment Through Identification of Early-onset of Antipsychotic Drug Action in Schizophrenia. Principal Investigator; sponsored by Eli Lilly and Company, 2007-2008.

M06-816, Double-blind, Randomized, Placebo-controlled Study to Evaluate the Safety and Efficacy of ABT-925 in Subjects with Acute Exacerbation of Schizophrenia. Principal Investigator; sponsored by Abbott, 2007-2008.

JDS04004, A Phase 3, Four-Week, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Multicenter, Efficacy and Safety Study of OAD Lithium in Bipolar I Disorder Subjects with Acute Symptoms of Mania. Principal Investigator; sponsored by JDS Pharmaceuticals, 2007-2008.

CAGO178A2301, An 8-week, randomized, fixed-dose, placebo-controlled, parallel-group, multicenter study of the efficacy, safety and tolerability of agomelatine 25 and 50 mg in the treatment of Major Depressive Disorder (MDD). Principal Investigator; sponsored by Novartis, 2007-2008.

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RGH-MD-03, A Double-Blind Placebo-Controlled Evaluation of the Safety and Efficacy of RGH-188 in the Acute Exacerbation of Schizophrenia. Principal Investigator; sponsored by Forest, 2007-2008.

D-21, Randomized Comparison of Outcomes in Patients with Treatment-Resistant Depression Who Receive VNS Therapy Administered at Different Amounts of Electrical Charge. Principal Investigator; sponsored by Cyberonics, 2006-2009.

056, A Study to Evaluate the Performance Characteristics and Potential Clinical Utility of Neuropsychological Tests for Use in Studies of Patients With Schizophrenia. Principal Investigator; sponsored by Merck, 2006-2008.

CN-138-402, Effects of Aripiprazole on the Steady-State Pharmacokinetics of Lamotrigine in Subjects with Bipolar I Disorder. Principal Investigator; sponsored by Bristol-Myers Squibb, 2006-2008.

A5401008, Phase 1, Investigator and Subject-Blind, Placebo-Controlled, Randomized, Sequential Group, Multiple Ascending Dose Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of CP-903,397 in Subjects with Schizophrenia. Principal Investigator; sponsored by Pfizer, 2006-2008.

3168A1-314-US, An Open-Label Extension Study To Evaluate The Long-Term Safety And Tolerability Of Bifeprunox In The Treatment Of Outpatients With Schizophrenia. Principal Investigator; sponsored by Wyeth, 2006-2008.

3168A1-313-US, A Multicenter, Randomized, Double-Blind, Parallel-group Fixed-Dose Study of the Effect on Weight of Bifeprunox versus Risperidone in the Treatment of Outpatients with Schizophrenia. Principal Investigator; sponsored by Wyeth, 2006-2008.

3168A1-312-US, An Open-Label Extension Study To Evaluate The Long-Term Safety And Tolerability Of Bifeprunox In The Treatment Of Outpatients With Schizophrenia. Principal Investigator; sponsored by Wyeth, 2006-2008.

3168A1-311, US A Multicenter, Randomized, Double-Blind, Parallel-Group Fixed-Dose Study of the Effect on Weight of Bifeprunox versus Olanzapine in the Treatment of Outpatients with Schizophrenia. Principal Investigator; sponsored by Wyeth, 2006-2008.

ACP-103-008, A randomized, double blind, multi-center study to assess the antipsychotic and motor effects of ACP-103 when administered in combination with haloperidol or risperidone to schizophrenic subjects. Principal Investigator; sponsored by Acadia, 2006-2007.

AMDC-004-201, A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Single Dose Efficacy and Safety Study of Staccato™ Loxapine for Inhalation in Schizophrenic Patients with Agitation. Principal Investigator; sponsored by Alexza, 2006-2007.

023, A Double-Blind, Double-Dummy, Active-Controlled, Randomized, 3-Arm, Parallel Study to Evaluate the Effects of Therapeutic and Supratherapeutic Doses of MK-3756 on QTc Interval in Male and Female Schizophrenic or Schizoaffective Patients. Principal Investigator; sponsored by Merck, 2006-2008.

021, A Multicenter, Double-Blind, Randomized, Parallel Group, Active-Controlled Tolerability and Safety Study of MK-3756 (SM-13496/Lurasidone) in Clinically Stable Schizophrenic Outpatients. Principal Investigator; sponsored by Merck, 2006-2007.

MEM-1003-101, A Multicenter, Double Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of MEM 1003 for the Treatment of Patients with Bipolar I Disorder Suffering Acute Manic or Mixed Episodes. Principal Investigator; sponsored by Memory, 2006-2007.

R076477-SCH-1014, A Double Blind, Randomized, Placebo-Controlled Study Evaluating QT/QTc Intervals Following Administration of Paliperidone ER and Quetiapine in Subjects with Schizophrenia or Schizoaffective Disorder. Principal Investigator; sponsored by Johnson & Johnson, 2006.

R076477-BIM-3003, A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Flexibly-Dosed Extended-Release Paliperidone as Adjunctive Therapy to Mood Stabilizers in the Treatment of Acute Manic and Mixed Episodes Associated with Bipolar I Disorder. Principal Investigator; sponsored by Johnson & Johnson, 2006-2007.

153003, A multicenter, randomized, double-blind, fixed-dose, efficacy and safety trial of farampator (Org 24448)(250 and 500 mg b.i.d.) vs. placebo as augmentation therapy in schizophrenic subjects currently receiving risperidone (2 or 3 mg b.i.d.). Principal Investigator; sponsored by Organon, 2006-2008.

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D14477C00134, A Multicenter, Randomized, Parallel-Group, Double-Blind, Phase III Comparison of the Efficacy and Safety of Quetiapine Fumarate (oral tablets 400 mg to 800 mg daily in divided doses) to Placebo When Used as Adjunct to Mood Stabilizers (Lithium or Divalproex) in the Maintenance Treatment of Bipolar I Disorder in Adult Patients. Principal Investigator; sponsored by AstraZeneca, 2006.

D1447C00144, Multicenter, Randomized, Parallel-group, Double-blind, Placebo-controlled Phase III Study of the Efficacy and Safety of Quetiapine Fumarate SEROQUEL® and Lithium as Monotherapy in for up to 104 weeks Maintenance Treatment of Bipolar I Disorder in Adult Patients. Principal Investigator; sponsored by AstraZeneca, 2006-2007.

3153A1-202-US, A Randomized, Double Blind, Placebo Controlled, Olanzapine Referenced, Parallel Group Safety, Efficacy and Tolerability Study of SCA-136 Versus Placebo in Subjects with Acute Exacerbations of Schizophrenia. Principal Investigator; sponsored by Wyeth Pharmaceuticals, 2006-2007.

SGS518-CL03, A Double-Blind, Placebo-Controlled, Dose-Ranging, Parallel-Group Study in Adults with Cognitive Impairment Associated with Schizophrenia (CIAS). Principal Investigator; sponsored by Saegis, 2005-2006.

VP-VYV-683-3101, A Randomized, Double-Blind, Placebo- and Ziprasidone-Controlled, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of a 24 mg/day Dose Iloperidone Given b.i.d. for 28 Days to Schizophrenic Patients in Acute Exacerbation Followed by a Long-Term Treatment Phase. Principal Investigator; sponsored by Vanda, 2005-2006.

3168A2-304-US, A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of Bifeprunox in the Treatment of Depression in Outpatients with Bipolar Disorder. Principal Investigator; sponsored by Wyeth, 2005-2006.

3168A2-307-WW, An Extension Study to Evaluate the Long-Term Safety and Tolerability of Bifeprunox in the Treatment of Outpatients with Bipolar Disorder. Principal Investigator; sponsored by Wyeth, 2005-2006.

EFC 5041, An Eight Week, Double-Blind, Placebo Controlled, Multicenter Study with Escitalopram (10 mg qd) as Positive Control, Evaluating the Efficacy, Safety, Tolerability of a Fixed Dose of SR58611A (350 mg q12) in Outpatients with Major Depressive Disorder (MDD). Principal Investigator; sponsored by Sanofi-Synthelabo, 2005-2007.

R092670-PSY-3003, A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (50 mg eq., 100 mg eq., and 150 mg eq.) of Paliperidone Palmitate in Subjects With Schizophrenia. Principal Investigator; sponsored by Johnson & Johnson, 2005-2007.

A7501024, A Randomized, Crossover Study Evaluating the Acceptability of Unflavored Asenapine and Raspberry Flavored Asenapine in Stable Subjects with a Psychotic Disorder. Principal Investigator; sponsored by Pfizer, 2005.

MN-305-CL-001, A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multi-center Study to Evaluate the Efficacy and Safety of Two Flexible Dose Regimens of MN-305 in Patients with DSM-IV Defined Generalized Anxiety Disorder (GAD). Principal Investigator; sponsored by Medicinova, 2005-2006.

CN138-134-113, Efficacy of Aripiprazole in Combination with Valproate or Lithium in the Treatment of Mania Patients with Bipolar I Disorder Partially Nonresponsive to Valproate or Lithium Monotherapy. Principal Investigator; sponsored by Bristol-Myers Squibb, 2005-2006.

CN138-165-020, A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Aripiprazole as Adjunctive Therapy in the Treatment of Patients With Major Depressive Disorder. Principal Investigator; sponsored by Bristol-Myers Squibb, 2005-2007.

D1444C00146, A 6-week, International, Multicenter, Double-blind, Randomized, Parallel-group, Phase III Study to Evaluate the Feasibility of Switching from Immediate-release Quetiapine Fumarate (SEROQUEL®) to Sustained-release Quetiapine Fumarate (400 to 800 mg/day) in Outpatients with Schizophrenia. Principal Investigator; sponsored by AstraZeneca, 2005-2007.

D1444C00147, A 12-week, International, Multicenter, Open Label, Non-comparative Study to Evaluate the Feasibility of Switching any Antipsychotic Treatment to Sustained-release Quetiapine Fumarate (SEROQUEL®) in Patients with Schizophrenia. Principal Investigator; sponsored by AstraZeneca, 2005-2006.

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R076477-SCH-1009, A Placebo- and Positive-Controlled, Randomized Study Evaluating QT and QTc Intervals Following Administration of Immediate-Release Paliperidone in Subjects with Schizophrenia or Schizoaffective Disorder. Principal Investigator; sponsored by Johnson & Johnson, 2005.

R092670-PSY-3001, A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Evaluating Paliperidone Palmitate in the Prevention of Recurrence in Subjects with Schizophrenia. Principal Investigator; sponsored by Johnson & Johnson, 2005-2006.

NKF100092, A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Fixed-Dose Study Evaluating the Efficacy and Safety of GW679769 in Subjects with Major Depressive Disorder. Principal Investigator; sponsored by GlaxoSmithKline, 2004-2006.

A7501007, A Double-Blind, 40-Week Continuation Study Evaluating the Safety of Asenapine and Olanzapine in the Treatment of Subjects With Acute Mania. Principal Investigator; sponsored by Pfizer, 2005-2007.

A7501006, A Double-Blind, 9-Week Extension Study Evaluating the Safety and Maintenance of Effect of Asenapine vs. Olanzapine in the Treatment of Subjects with Acute Mania. Principal Investigator; sponsored by Pfizer, 2005-2006.

A7501004, A Phase III, Randomized, Placebo-Controlled, Double-Blind Trial Evaluating the Safety and Efficacy of Sublingual Asenapine vs. Olanzapine and Placebo in In-Patients with an Acute Mania Episode. Principal Investigator; sponsored by Pfizer, 2004-2006.

A7501014, A Multicenter, Double-Blind, Flexible Dose, 6-Month Extension Trial Comparing the Safety and Efficacy of Asenapine with Olanzapine in Subjects who Completed Protocol A7501013. Principal Investigator; sponsored by Pfizer, 2004-2008.

A7501013, A Multicenter, Double-Blind, Flexible-Dose, 6-Month Trial Comparing the Efficacy and Safety of Asenapine with Olanzapine in Stable Subjects with Predominant, Persistent Negative Symptoms of Schizophrenia. Principal Investigator; sponsored by Pfizer, 2004-2009.

153-002, A multicenter, double-blind, placebo controlled, two-arm flexible-dose efficacy and safety trial with Org 24448 (250 - 750 mg b.i.d.) in subjects with acutely exacerbated schizophrenia. Principal Investigator; sponsored by Organon, 2004-2006.

CLIC477D 2301E1, A 52-week, open-label extension study to evaluate the safety and tolerability of licarbazepine 750-2500 mg/d in the treatment of manic episodes of bipolar I disorder. Principal Investigator; sponsored by Novartis Pharmaceuticals Corp., 2004-2007.

CLIC477D 2301, A randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and tolerability of licarbazepine 1000-2500 mg/d in the treatment of manic episodes of bipolar 1 disorder over 3 weeks. Principal Investigator; sponsored by Novartis Pharmaceuticals Corp., 2004-2006.

F1D-EW-LOBS, Pharmacokinetic Characterization of Intramuscular Olanzapine Depot as a Function of Particle Size Distribution. Principal Investigator; sponsored by Eli Lilly and Company, 2004.

041512, A multicenter, double-blind, flexible-dose, long-term extension trial of the safety and maintenance of effect of asenapine using Olanzapine positive control in subjects who complete protocols 041021/041022. Principal Investigator; sponsored by Organon, 2004-2007.

041022, A multicenter, randomized, double-blind, flexible-dose, 6-week trial of the efficacy and safety of asenapine compared with placebo using olanzapine positive control in subjects with an acute exacerbation of schizophrenia. Principal Investigator; sponsored by Organon, 2004-2006.

SB-223412/093, A Multicenter, Double-Blind, Double-Dummy, Placebo-Controlled, Randomized, Parallel Group Study of the Efficacy and Safety of Talnetant Versus Placebo and Risperidone in Subjects with Schizophrenia. Principal Investigator; sponsored by GlaxoSmithKline, 2004-2006.

28130, Prospective, Double-Blind, Randomized, Placebo-Controlled Dose finding Study of the Efficacy and Safety of Two Target Doses of Org 34517 used as Adjunctive Therapy in Subjects with Psychotic Major Depression (Major Depressive Episode, Severe, with Psychotic features). Principal Investigator; sponsored by Organon, 2004-2006.

D1444C00133, A 6-week, Multicenter, Double-blind, Double-dummy, Randomized Comparison of the Efficacy and Safety of Sustained-Release Formulation Quetiapine Fumarate (Seroquel) and Placebo in the Treatment of

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Acutely Ill Patients with Schizophrenia. Principal Investigator; sponsored by AstraZeneca, 2004-2006.

D1050199, An Open-Label, Multicenter, Twelve-Month Study of Safety and Tolerability of SM-13496 in the Treatment of Schizophrenia. Principal Investigator; sponsored by Sumitomo, 2004-2005.

Protocol D1050196, A Double-Blind Fixed Dose Study of SM-13496 and Placebo in the Treatment of Schizophrenia. Principal Investigator; sponsored by Sumitomo, 2004-2005.

CN138-020 Assessment of the In Vivo Release Characteristics and Safety of an Intramuscular Depot Formulation of Aripiprazole in Subjects with Schizophrenia or Schizoaffective Disorder. Principal Investigator; sponsored by Bristol-Myers Squibb, 2004-2005.

CN138-135 A Multicenter, Randomized, Double-Blind, Placebo Controlled Study of Aripiprazole Monotherapy in the Treatment of Acutely Manic Patients with Bipolar I Disorder. Principal Investigator; sponsored by Bristol-Myers Squibb, 2004-2007.

A7501001, A Double-Blind, Parallel, Multicenter Study to Assess the Effect of Asenapine, Quetiapine (Seroquel®), and Placebo on the QTC Interval in Patients with Schizophrenia. Principal Investigator; sponsored by Pfizer, 2004-2005.

H6U-MC-HGLM, Olanzapine Augmented with Atomoxetine in the Treatment of Schizophrenia: A Double-Blind, Placebo-Controlled Proof-of-Concept Study of Effects on Cognitive Function. Principal Investigator; sponsored by Eli Lilly & Company, 2004-2005.

ALK21-006-EXT, An Open Label, Multi-Center Study to Evaluate the Long-Term Safety of Medisorb® Naltrexone. Principal Investigator; sponsored by Alkerems, Inc., 2004-2007.

CN138-113, A Multicenter, Randomized, Double-Blind, Placebo Controlled Study of Three Fixed Doses of Aripiprazole in the Treatment of Patients with Acute Schizophrenia. Principal Investigator; sponsored by Bristol-Myers Squibb, 2004.

CN138-140, An Open-Label Study of the Pharmacokinetics and Safety of Single 60 to 150 mg Oral Doses of Aripiprazole in Adult Subjects with Schizophrenia or Schizoaffective Disorder Currently Maintained on 15 to 30 mg Oral Aripiprazole Daily. Principal Investigator; sponsored by Bristol-Myers Squibb, 2004-2005.

MT-210-A02, A Randomized, Double-Blind, Placebo-Controlled, In-Patient and Multi-Center Trial with Two Sequential Cohorts, Each Receiving Repeating Doses and Dose Escalation Within Each Patient, to Evaluate the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of MT-210 in Sustained Release Formulation for the Treatment of Schizophrenic Disease. Principal Investigator; sponsored by Mitsubishi Pharma Corporation, 2003-2005.

S1543001, A Randomized, Double-Blind, Placebo-Controlled and Risperidone-Referenced, Parallel-Group Efficacy and Safety Study of Two Fixed Doses of Bifeprunox in the Treatment of Schizophrenia. Principal Investigator; sponsored by Solvay Pharmaceuticals, Inc., 2003-2005.

S1543002, An Open-label, Flexible-dose, Long-term Safety and Efficacy Study of Bifeprunox in the Treatment of Schizophrenia (Extension of Protocol S1543001). Principal Investigator; sponsored by Solvay Pharmaceuticals, Inc. 2003-2008.

R076477-SCH-304/704, A Randomized, Double-Blind, Placebo and Active Controlled, Parallel-Group, Dose Response Study to Evaluate the Efficacy and Safety of Two Fixed Dosages of Extended Release OROS Paliperidone (6 and 12mg/day) and Olanzapine (10mg/day), with Open-Label Extension, in the Treatment of Subjects with Schizophrenia. Principal Investigator; sponsored by Johnson & Johnson, 2003-2005.

CN138-012, A Randomized, Double-Blind, Comparison of the Efficacy and Safety of Aripiprazole Intramuscular Formula, Haloperidol, or Placebo in the Treatment of Acutely Agitated Patients with a Diagnosis of Schizophrenia or Schizoaffective Disorder. Principal Investigator; sponsored by Bristol-Myers Squibb, 2003-2004.

CN138-013, A Randomized, Double-Blind, Comparison of the Efficacy and Safety of Aripiprazole Intramuscular Formula, Lorazepam, or Placebo in the Treatment of Acutely Agitated Patients Diagnosed with Bipolar I Disorder, Manic or Mixed. Principal Investigator; sponsored by Bristol-Myers Squibb, 2003-2004.

F1D-US-HGLF, Efficacy of High Dose Olanzapine in a Controlled Fixed Dose-Response Trial for the Treatment of Schizophrenia and Schizoaffective Disorder. Principal Investigator; sponsored by Eli Lilly and Company, 2003-2005.

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5077IL/0089, A multicenter, open-label, flexible-dose, parallel-group evaluation of the cataractogenic potential of quetiapine fumarate (Seroquel™) and risperidone (Risperdal™) in the long-term treatment of patients with schizophrenia or schizoaffective disorder. Principal Investigator; sponsored by AstraZeneca, 2003-2008.

DFI5413, A double-blind, eight-week, placebo- and risperidone-controlled, dose-finding study to evaluate the efficacy, safety, and tolerability of SR142801 in the treatment of patients with schizophrenia or schizoaffective disorder. Principal Investigator; sponsored by Sanofi-Synthelabo, 2004-2005.

R076477-SCH-102, Comparison of Steady-state Pharmacokinetics of Paliperidone after Extended-Release OROS Paliperidone 15mg and Immediate-Release Oral Risperidone 8 mg b.i.d. in Subjects with Schizophrenia or Schizoaffective Disorder. Principal Investigator; sponsored by Johnson & Johnson, 2003-2004.

R092670-USA-3, Pharmacokinetics, tolerability, and safety of Paliperidone after repeated intramuscular injection of Paliperidone Palmitate (R092670) in the arm of the buttock of subjects with schizophrenia. Principal Investigator; sponsored by Johnson & Johnson, 2003-2004.

A2501024, A 12 week multicenter, randomized, double-blind, placebo-controlled evaluation of Donepezil Hydrochloride as adjunctive therapy in the treatment of cognitive impairment in patients with schizophrenia or schizoaffective disorder. Principal Investigator; sponsored by Pfizer, Inc., 2003-2004.

SCA30926, A multicenter, double-blind, placebo-controlled, randomized, parallel group evaluation of the efficacy of a flexible dose of Lamotrigine versus placebo as add-on therapy in schizophrenia. Principal Investigator; sponsored about GlaxoSmithKline, 2003-2004.

ALK21-006, A randomized, open label, long term, multi-center study of the safety of Medisorb® Naltrexone. Principal Investigator; sponsored by Alkermes, Inc., 2003-2006.

M02-547, A randomized, double-blind study of the safety and efficacy of Depakote® ER plus an atypical antipsychotic vs. an atypical antipsychotic alone in the treatment of schizophrenia. Principal Investigator; sponsored by Abbott Laboratories, 2003-2004.

RIS-SCP-402, A randomized, double-blind study to evaluate the efficacy and safety of Risperidone vs. Quetiapine vs. placebo in subjects with an acute exacerbation of schizophrenia or schizoaffective disorder. Principal Investigator; sponsored by Janssen Pharmaceutical Products, L.P., 2003-2004.

R209130-SCH-202, A randomized double-blind, placebo-controlled, dose-response study of R209130 in subjects with schizophrenia who have predominantly negative symptoms. Principal Investigator; sponsored by Johnson & Johnson, 2003-2004.

CCR-02, A randomized, double-blind, placebo-controlled crossover study evaluating the efficacy, safety, and tolerability of Pramipexole in patients with Tourette's syndrome. Principal Investigator; sponsored by Community Clinical Research, Inc, 2003-2006.

F1J-MC-HMBV, Duloxetine versus placebo in the treatment of elderly patients with major depressive disorder. Principal Investigator; sponsored by Eli Lilly & Company, 2003.

AL7A-2896-006, PHA-543613, A single-dose, multiple-dose, safety, tolerability and pharmacodynamic study in patients with schizophrenia using P50 gating and cogtest as markers. Principal Investigator; sponsored by Pharmacia, 2003.

Merck 073, A Double-Blind, Multicenter, Placebo-Controlled Study of MK-0869 in the Treatment of Patients With Major Depressive Disorder. Principal Investigator; sponsored by Merck Research Laboratories, 2003-2004.

RIS-SCH-401, A 52-week, prospective, randomized, double-blind, multicenter study of relapse following transition from oral antipsychotic medication of two different doses (25 or 50 mg given every two weeks) of risperidone long-acting microspheres (Risperdal Consta™) in adults with schizophrenia or schizoaffective disorder. Principal Investigator; sponsored by Janssen Pharmaceutical Products, L.P., 2002-2004.

SCT-MD-15, A double-blind fixed dose comparison of the safety and efficacy of Escitalopram and placebo in the treatment of pediatric depression. Sub-Investigator; sponsored by Forest Laboratories, Inc, 2002-2003.

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C-1073-03, A phase III, randomized, double-blind, placebo-controlled study of safety and efficacy of C-1073 (Mifepristone) in patients with major depressive disorder with psychotic features who are not receiving antidepressants or antipsychotics. Principal Investigator; sponsored by Corcept Therapeutics, 2002-2003.

SB223412/078, A multicenter, double-blind, double-dummy, placebo-controlled, randomized, parallel group evaluation of the efficacy and safety of a fixed dose of Talnetant versus placebo versus Risperidone in subjects with schizophrenia. Principal Investigator; sponsored by GlaxoSmithKline, 2002-2003.

BOPP, Bipolar Outpatient Preference Project. Principal Investigator; sponsored by AstraZeneca, LP, 2002-2004.

A1281062, An international, multicenter large simple trial (LST) to compare the cardiovascular safety of Ziprasidone and Olanzapine. Principal Investigator; sponsored by Pfizer, Inc., 2002.

D1050174, A randomized, open-label, dose-blinded, multicenter, 6-month study of safety and tolerability of 3 dose levels of SM-13496 in patients with schizophrenia. Principal Investigator; sponsored by Sumitomo Pharmaceuticals America, Ltd., 2002 - 2003.

D1050049, A 6-week, double-blind, randomized, fixed-dose, parallel-group study of the efficacy and safety of three dose levels of SM-13496 compared to placebo and haloperidol in patients with schizophrenia who are experiencing an acute exacerbation of symptoms. Principal Investigator; sponsored by Sumitomo Pharmaceuticals America, Ltd., 2002-2003.

417.304, A phase III, three-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group safety and efficacy study of extended-release Carbamazepine in the treatment of bipolar I disorder. Principal Investigator; sponsored by Shire Pharmaceuticals Development, Inc., 2002-2003.

CN138-087, A prospective, multicenter, open-label study of Aripiprazole in the management of patients with schizophrenia and schizoaffective disorder in general psychiatric practices (Broad Effectiveness Trial with Aripiprazole – BETA). Principal Investigator; sponsored by Bristol-Myers Squibb, 2002-2003.

S1542010, A randomized, double-blind, placebo-controlled, Risperidone referenced, dose finding study of DU 127090 in the treatment of schizophrenia. Principal Investigator; sponsored by Solvay Pharmaceuticals, Inc., 2002-2003.

DERA-5334-038, Deramciclane 30 mg and 60 mg once daily versus placebo in 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. Principal Investigator; sponsored by Pharmacia Corporation, 2002-2003.

DERA-5334-025, Deramciclane 30 mg and 60 mg once daily versus placebo in generalized anxiety disorder. A randomized double-blind placebo- and Buspirone-controlled, fixed-dose, parallel-group, multicenter study of 10 weeks (including a 2-week single-blind placebo period). Principal Investigator; sponsored by Pharmacia Corporation, 2002-2003.

CIL0522A2328, A randomized, open-label, multicenter, 6-arm, parallel-group, safety study evaluating the effect of oral loperidone at doses of 8 mg b.i.d., 12 mg b.i.d., and 24 mg q.d. on QTc interval duration in the presence and absence of metabolic inhibition, relative to other antipsychotics (Ziprasidone 80 mg b.i.d. and Quetiapine 375 mg b.i.d. in the presence and absence of metabolic inhibition), in otherwise healthy patients diagnosed with schizophrenia or schizoaffective disorder. Principal Investigator; sponsored by Novartis Pharmaceuticals Corporation, 2002.

R167154-INT-4, A double-blind, placebo-controlled trial to estimate the maximum tolerated dose (MTD) of R167154 in patients with schizophrenia or schizoaffective disorder who are poor metabolizers for the CYP2D6 enzyme. Principal Investigator; sponsored by Johnson & Johnson Pharmaceutical Research and Development, L.L.C., 2002-2003.

NBI-34060-IR-0209, A randomized, placebo-controlled, double-blind, parallel-group study to assess the efficacy and safety of middle of the night administration of NBI-34060 in patients with primary insomnia. Principal Investigator; sponsored by Neurocrine Biosciences, Inc., 2002-2003.

A1281083, A phase III, randomized, placebo-controlled study evaluating the safety and outcome of treatment with oral Ziprasidone in subjects with mania. Principal Investigator; sponsored by Pfizer, 2002-2003.

CCR-01, A randomized, double-blind, placebo-controlled crossover study evaluating the safety, efficacy, and tolerability of Pramipexole in patients with Tourette's syndrome. Principal Investigator; sponsored by Community Clinical Research, Inc, 2002-2005.

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CN138-074, A multicenter, randomized, double-blind Study of Aripiprazole versus placebo in the treatment of acutely manic patients with bipolar disorder. Principal Investigator; sponsored by Bristol-Myers Squibb, 2002-2003.

F1D-MC-HGJX, A comparison of fasting triglyceride levels in cohorts with schizophrenia and related disorders treated chronically with Olanzapine, Risperidone, and typical antipsychotics. Principal Investigator; sponsored by Lilly Research Laboratories, 2001-2002.

SB-659746-A/014, A randomized, double-blind, parallel-group, placebo-controlled flexible-dose study evaluating efficacy and safety of SB-659746-A in patients with major depressive disorder. Principal Investigator; sponsored by GlaxoSmithKline, 2001-2002.

041502, An assessment of the long term efficacy and safety of Org 5222, Risperidone and placebo in subjects with schizophrenia. Principal Investigator; sponsored by Organon, Inc., 2001-2002.

041004, An assessment of the efficacy and safety of a sublingual dose of Org 5222 in subjects with schizophrenia (in an acutely exacerbated state) compared to Risperidone and placebo in a randomized double blind, fixed-dose 6-week trial. Principal Investigator; sponsored by Organon, Inc., 2001-2002.

061, A double-blind, multicenter, placebo- and active-controlled acute and extension study of 2 doses of MK-0869 in the treatment of patients with major depressive disorder. Principal Investigator; sponsored by Merck & Co., Inc., 2001-2003.

DRI3650, A double-blind, placebo- and paroxetine-controlled, multicenter, dose-ranging study evaluating the efficacy and safety of SR142801 in outpatients with major depressive disorder. Principal Investigator; sponsored by Sanofi Synthelabo Research, 2001-2002.

5077US/0043, A multicenter, double-blind, randomized comparison of the efficacy and safety of Quetiapine Fumarate (Seroquel) and Risperidone (Risperdal) and the treatment of patients with schizophrenia. Principal Investigator; sponsored by AstraZeneca Pharmaceuticals LP, 2001-2002.

SCT-MD-17, An open label extension study of the safety and efficacy of LU 26-054 in patients with generalized anxiety disorder. Principal Investigator; sponsored by Janssen Research Foundation, 2001-2002.

RIS-USA-265, An open label, long term safety trial of Risperidone long acting microspheres in the treatment of subjects diagnosed with schizophrenia. Principal Investigator; sponsored by Janssen Research Foundation, 2001-2003.

RIS-USA-259, Open label trial exploring a switching regimen from oral neuroleptics, other than Risperidone to Risperidone depot microspheres. Principal Investigator; sponsored by Janssen Research Foundation, 2001-2002.

F1D-EW-LOBE (b), A study to assess the safety, tolerability and pharmacokinetics of single and multiple doses of an intramuscular formulation of depot Olanzapine (Pamoate Salt) in stable schizophrenic subjects. Principal Investigator; sponsored by Lilly Research Laboratories, 2001-2002.

BR29060-785, A double-blind, placebo controlled, fixed-dosage study comparing the efficacy and tolerability of Paroxetine CR and Citalopram to placebo in the treatment of major depressive disorder with anxiety. Principal Investigator; sponsored by GlaxoSmithKline, 2001.

SCT-MD-06, Flexible dose comparison of the safety and efficacy of Escitalopram and placebo in the treatment of generalized anxiety disorder. Principal Investigator; sponsored by Forest Laboratories, Inc. 2001-2002.

5077IL/0099, A multicenter, double-blind, randomized, placebo-controlled trial of the safety and efficacy of Seroquel (Quetiapine Fumarate) as add-on therapy with lithium or Divalproex in the treatment of acute mania. Principal Investigator; sponsored by AstraZeneca, 2001.

5077IL/0041, A multicenter, double-blind, randomized comparison of the efficacy and safety of sustained-release formulation Quetiapine Fumarate (Seroquel) and placebo in the treatment of patients with schizophrenia. Principal Investigator; sponsored by AstraZeneca, 2001-2002.

RIS-USA-235, A randomized trial of oral Risperidone versus intramuscular Haloperidol in the emergency treatment of acute psychosis. Principal Investigator; sponsored by Janssen Research Foundation, 2001.

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F1D-US-HGJB, A controlled trial of Olanzapine versus Quetiapine in the treatment of schizophrenic and schizoaffective subjects with prominent negative symptoms. Principal Investigator; sponsored by Lilly Research Laboratories, 2000-2002.

CN138-047, A multicenter, randomized, double-blind, placebo controlled, 26 week study of a fixed dose of Aripiprazole in the treatment of stabilized patients with chronic schizophrenia. Principal Investigator; sponsored by Bristol-Myers Squibb Pharmaceutical Research Institute, 2000-2002

RIS-USA-239, The efficacy and safety of flexible dosage ranges of Risperidone vs placebo in the treatment of manic episodes associated with bipolar I disorder. Principal Investigator; sponsored by Janssen Research Foundation, 2000-2002.

RIS-INT-81, A nine-week, open-label, multi-center, safety study of flexible dosage ranges of Risperidone in the treatment of manic episodes associated with Bipolar I Disorder. Principal Investigator; sponsored by Janssen Research Foundation, 2000-2002.

A1601048, A multicenter, double-blind, randomized, placebo-controlled parallel group comparative study of the efficacy and safety of oral Eletriptan (40 MG) and Sumatriptan (100 MG) given for the acute treatment of migraine. Principal Investigator; sponsored by Pfizer Pharmaceuticals Group, 2000-2001.

387GCNS0069-012, Pharmacogenomics blood sampling protocol. Principal Investigator; sponsored by Pharmacia & Upjohn Company, 2000-2001.

387GCNS0069-011, PNU-101387G: Double-blind, randomized, placebo- and Olanzapine-controlled, dose-finding study in the treatment of psychotic disorders. Principal Investigator; sponsored by Pharmacia & Upjohn Company, 2000-2001.

950E-CNS-0005-087, Open-label Reboxetine continuation therapy. Principal Investigator; sponsored by Pharmacia & Upjohn Company, 2000-2001.

M2020/0046, Reboxetine, placebo, and Paroxetine comparison in patients with Major Depressive Disorder. Principal Investigator; sponsored by Pharmacia & Upjohn Company, 2000-2001.

M2020/0047, Reboxetine, placebo, and Paroxetine comparison in patients with Major Depressive Disorder. Principal Investigator; sponsored by Pharmacia & Upjohn Company, 2000.

950ECNS0323-001, Pharmacogenomics blood sampling protocol. Principal Investigator; sponsored by Pharmacia & Upjohn Company, 2000-2001.

041505, Long-term maintenance of subjects with schizophrenia with Org5222. Principal Investigator; sponsored by Organon Inc., 2000-2002.

041013, A double blind, three-armed, fixed-dose, placebo controlled dose-finding study with sublingual Org 5222 in subjects with acute phase schizophrenia. Principal Investigator; sponsored by Organon Inc., 2000-2002.

M99-082, A double-blind, placebo-controlled study of Depakote in the treatment of behavioral agitation in elderly patients with dementia. Principal Investigator; sponsored by Abbott Laboratories, 2000-2001.

CN138-010, A multicenter, randomized, double-blind, placebo controlled study of Aripiprazole in the maintenance of patients with bipolar disorder. Principal Investigator; sponsored by Bristol-Myers Squibb Pharmaceutical Research Institute, 2000-2003.

M99-010, Safety and efficacy of Depakote as combination therapy in the treatment of psychosis associated with schizophrenia. Principal Investigator; sponsored by Abbott Laboratories, 2000-2001.

CN138-007, A multicenter, randomized, double-blind, placebo controlled study of two fixed doses of Aripiprazole in the treatment of patients with acute mania. Principal Investigator; sponsored by Bristol-Myers Squibb Pharmaceutical Research Institute, 2000-2002.

CN138-001-031, A multicenter, randomized, double-blind, placebo controlled study of three fixed doses of Aripiprazole in the treatment of patients with acute schizophrenia. Principal Investigator; sponsored by Bristol-Myers Squibb Pharmaceutical Research Institute, 2000.

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RIS-USA-196, Risperidone depot (microspheres) in the treatment of subjects with schizophrenia or schizoaffective disorder. Principal Investigator; sponsored by Janssen Research Foundation, 1999-2003.

RIS-USA-121, Risperidone depot (microspheres) vs. placebo in the treatment of subjects with schizophrenia. Principal Investigator; sponsored by Janssen Research Foundation, 1999-2001.

H5Z-MC-LUAB, R-Fluoxetine versus placebo in the treatment of major depression. Principal Investigator; sponsored by Eli Lilly and Company, 1999-2001.

1008-84, Open-label safety study of Pregabalin (CI-1008) in patients with anxiety disorders. Principal Investigator; sponsored by Parke-Davis Pharmaceutical Research, 1999-2001.

1008-92, A placebo-controlled study of Pregabalin and Paroxetine in patients with panic disorder. Principal Investigator; sponsored by Parke-Davis Pharmaceutical Research, 1999-2001.

173-98-203, A phase II, randomized, double-blind, placebo-controlled, fixed dose study of oral OPC 14523 and Prozac in the treatment of outpatients with moderate depression. Principal Investigator; sponsored by Otsuka America Pharmaceuticals, Inc, 1999-2001.

128-116B, A 260- week (5-year), open extension study evaluating the safety and outcome of 40-200 mg daily of oral Ziprasidone or 1-8 mg BID of oral Risperidone daily in the treatment of subjects who have participated in previous Ziprasidone clinical trials. Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1999-2001.

2918, A comparison of the efficacy and safety of belfoxatone 2.5mg OD versus placebo in outpatients with moderate to severe major depressive disorders; a randomized, double-blind, 8-week multi-center phase II trial. Principal Investigator; sponsored by Synthelabo Research, 1999.

EMD 128 130-008, A double-blind, randomized, multicenter, parallel group design study to evaluate the efficacy and safety of two dose ranges of EMD 128 130 in comparison with placebo and Haloperidol in the treatment of schizophrenia. Principal Investigator; sponsored by Merck KGaA, 1999-2000.

RIS-INT-50, Risperidone versus Olanzapine in the treatment of schizophrenia in elderly subjects. Principal Investigator; sponsored by Janssen Research Foundation, 1999.

F1D-MC-HGGU, Olanzapine versus Risperidone and placebo in the treatment of psychosis and associated behavioral disturbances in patients with dementia. Principal Investigator; sponsored by Eli Lilly and Company, 1999.

041002, A double-blind, five-armed, fixed-dose, active- and placebo-controlled dose-finding study with sublingual Org 5222 in subjects with acute phase schizophrenia. Principal Investigator; sponsored by Organon Inc., 1999-2000.

041500, Extension to 041002. Principal Investigator; sponsored by Organon Inc., 1999-2000.

F1D-MC-HGGL(a), Allelic Variation in schizophrenia. Principal Investigator; sponsored by Eli Lilly and Company, 1999.

S1420015, A randomized, double-blind, placebo-controlled, parallel group study to measure the efficacy and safety of nicotine gum (2mg and 4mg for smoking cessation by gradual reduction. Principal Investigator; sponsored by Smith-Kline Beecham, 1999.

NKP608A-141, A randomized, double-blind, dose-range finding, multicenter, parallel-group, active and Placebo-controlled trial of the safety and efficacy of NKP608A in patients with moderate to severe major depressive disorder. Principal Investigator; sponsored by Novartis Pharmaceuticals, 1999.

NKP608A-107, A multicenter, randomized, double-blind, parallel-group, placebo-controlled, dose-range finding trial to evaluate the safety and efficacy of 4 doses of NKP608A in patients with social phobia. Principal Investigator; sponsored by Novartis Pharmaceuticals, 1999.

31-98-218, An open-label, follow-on study of the long-term safety of Aripiprazole in patients with chronic schizophrenia. Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1998-2003.

31-98-217, a multi-center, randomized, double-blind, active-controlled study to compare the long-term maintenance effects and safety of Aripiprazole and Haloperidol following acute relapse in schizophrenic patients. Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1998-1999.

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31-98-204, An open-label pilot study to determine tolerability of oral Aripiprazole in patients with first-episode schizophrenia or schizoaffective disorder. Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1998-2003.

31-98-222, An open-label follow-on study of the long-term safety of Aripiprazole administered orally in patients with psychotic disorders or psychotic behaviors of dementia. Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1998-2003.

F1D-US-HGHQ, A phase IIIb, multicenter, randomized, double-blind, parallel study of the efficacy of Olanzapine versus Divalproex in the treatment of acute mania. Principal Investigator; sponsored by Eli Lilly and Company, 1998-2000.

M97-696, Evaluation of the efficacy and safety of Depakote ER in the treatment of the manic phase of bipolar disorder: a placebo-controlled study. Principal Investigator; sponsored by Abbott Laboratories, 1999.

97-M-05, A six-month open-label safety trial of *d-threo*-methylphenidate hydrochloride (*d*-MPH) in children with symptoms of attention deficit hyperactivity disorder (ADHD). Principal Investigator; sponsored by Celgene Corporation, 1999.

DFI 3024, A double-blind and Haloperidol-controlled, multicenter study evaluating the safety and efficacy of SR 46349B in schizophrenic patients. Principal Investigator; sponsored by Sanofi Pharmaceuticals, 1998-2000.

DFI 3138, A double-blind, placebo and Haloperidol-controlled, multicenter study evaluating the safety and efficacy of SR 142801 in schizophrenic patients. Principal Investigator; sponsored by Sanofi Pharmaceuticals, 1998-2000.

31-98-220, An open-label follow-on study of the long-term safety of Aripiprazole administered orally in patients with Psychosis. Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1998-2003.

31-98-213, An open-label study of the neurocognitive effects of Aripiprazole compared to Olanzapine administered orally in patients with psychosis. Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1998-2000.

31-97-203, An open-label follow-on study of the long-term safety of Aripiprazole in patients with psychosis. Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc, 1998-2002.

31-97-202, A phase III double-blind placebo-controlled study of Aripiprazole in the treatment of psychosis, with Risperidone as active control. Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1998.

F1D-MC-HGHW, A double-blind randomized comparison of the efficacy and safety of short-acting intramuscular Olanzapine, short-acting intramuscular Lorazepam and intramuscular placebo in acutely agitated patients diagnosed with mania associated with bipolar disorder. Principal Investigator; sponsored by Eli Lilly and Company, 1998-2000.

F1D-MC-HGGN, The comparative efficacy of Olanzapine, Risperidone, and Haloperidol for cognition in schizophrenia. Principal Investigator; sponsored by Eli Lilly and Company, 1998-2000.

ILP-3000, A prospective, randomized, double-blind, placebo- and active-controlled, multicenter study to evaluate the efficacy and safety of three fixed doses of Iloperidone (4,8, and 12 mg/d) given BID for 42 days to schizophrenic patients with acute or subacute exacerbation, followed by a double-blind, active-controlled, flexible-dose, long-term, 20 week phase with Iloperidone (4, 8, 12, or 16 mg/d) given q.d. Principal Investigator; sponsored by Novartis Pharmaceuticals, 1998-1999.

ILP-3007, part 2, A prospective, randomized, double-blind, active-controlled, flexible-dose, parallel-group, multicenter study to evaluate the safety, tolerability and efficacy of Iloperidone compared with Risperidone (both 0.5 to 4.0 mg/d given b.i.d.) in treating psychotic and behavioral symptoms in institutionalized elderly patients with dementia. Principal Investigator; sponsored by Novartis Pharmaceuticals, 1998-2000.

128-108E-719, A 156 (3 year), double-blind extension study evaluating the safety and efficacy of two dose regimens of oral Ziprasidone (CP,88,059-1) (80-120 mg, QD, and 40-80 mg, BID) and Haloperidol (5-20 mg daily in the maintenance treatment of outpatients with schizophrenia or schizoaffective disorder who have successfully completed protocol 128-108. Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1996-1999.

160-108, UK-116, 044, A multi-center, randomized, open-label, comparative study of the safety, toleration, and efficacy of oral Eletriptan for long term treatment of subjects with acute migraine. Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1997-1999.

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128-108, Forty-week, double-blind study evaluating the safety and efficacy of two dose regimens of oral Ziprasidone (CP88, 059-1) (80-120 mg, QD, and 40-80 mg, BID) and Haloperidol (5-20 mg daily) in the maintenance treatment of outpatients with schizophrenia or schizoaffective disorder. Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1996.

31-94-202, A dose ranging study of the efficacy and tolerability of OPC – 14597 in acutely relapsing hospitalized schizophrenic patients. Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1995-1997.

E2020-A001-313, An open-label, multi-center clinical trial evaluating the safety and efficacy of Donepezil Hydrochloride in patients with Alzheimer's disease. Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1997.

31-95-201, An open-label study of the tolerability and safety of OPC-14597 in schizophrenic patients. Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1995-1996.

BRL-029060/648, A 12 week, double-blind, placebo controlled, parallel group study to assess the efficacy and tolerability of Paroxetine in patients suffering from posttraumatic stress disorder (PTSD). Principal Investigator; sponsored by Smith-Kline Beecham, 1999.

BRL 029060/641, A randomized, double-blind, placebo-controlled, fixed dosage trial to evaluate the efficacy and tolerability of 20 and 40 mg/day Paroxetine in patients with generalized anxiety disorder. Principal Investigator; sponsored by Smith-Kline Beecham, 1999.

EMD 68 843-009, A double-blind, randomized, multicenter, parallel designed study to evaluate the efficacy and safety of individual maximum tolerated doses of EMD 68 843 in comparison with placebo and fluoxetine in outpatients with major depressive disorder. Principal Investigator; sponsored by Merck KGaA, 1998-1999.

EMD 68 843-010, A double-blind, randomized, multicenter, parallel designed study to evaluate the efficacy and safety of individual maximum tolerated doses of EMD 68 843 in comparison with placebo and fluoxetine in outpatients with major depressive disorder. Principal Investigator; sponsored by Merck KGaA, 1998-1999.

M97-817, An open-label extension study of Depakote in the treatment of signs and symptoms of mania in elderly patients with dementia. Principal Investigator; sponsored by Abbott Laboratories, 1998-1999.

M97-738, A double-blind, placebo-controlled study of Depakote in the treatment of signs and symptoms of mania in elderly patients with dementia. Principal Investigator; sponsored by Abbott Laboratories, 1998-1999.

B1Y-US-HCIR, Fluoxetine versus placebo in geriatric nursing home and assisted living patients with major depression. Principal Investigator; sponsored by Eli Lilly and Company, 1998-1999.

128-602, A phase III, randomized, placebo-controlled study evaluating the safety and outcome of treatment with oral Ziprasidone in subjects with mania who are receiving Lithium. Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1998-1999.

128-602E-0243, An open extension study evaluating the safety and outcome of 40-160 mg daily of oral Ziprasidone in the Treatment of subjects who have participated in protocol 602. Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1998-1999.

RIS-USA-102, The safety and efficacy of Risperdal (Risperidone) vs. placebo vs. Haloperidol as add-on therapy to mood stabilizers in the treatment of the manic phase of bipolar disorder. Principal Investigator; sponsored by Janssen Research Foundation, 1998-1999.

M100907/3005, A multicenter, open-label, long-term follow-up safety study of M100907 tablets in schizophrenic and schizoaffective subjects who participated in protocol M100907/3001 or protocol M100907/3002. Principal Investigator; sponsored by Hoechst Marion Roussel, 1998-1999.

M100907/3001, A multicenter, placebo and active control, double-blind, randomized study of the efficacy, safety and pharmacokinetics of M100907 (10 and 20 mg per day) in schizophrenic and schizoaffective patients (3001). Principal Investigator; sponsored by Hoechst Marion Roussel, 1998-1999.

B1Y-MC-HCIZ, Weekly enteric-coated Fluoxetine Hydrochloride versus daily Fluoxetine or placebo in the continuation treatment of major depressive disorder. Principal Investigator; sponsored by Eli Lilly and Company, 1998-1999.

*Wendy M. Smith*

160-103, A multicenter, double-blind, randomized, placebo-controlled, paralleled group study of the efficacy and safety of escalating the dose of oral Eletriptan in subjects with acute migraines. Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1997-1999.

RIS-USA-113, Risperidone versus Olanzapine in the treatment of schizophrenia. Principal Investigator; sponsored by Janssen Research Foundation, 1997-1999.

RIS-USA-112, Risperidone versus Olanzapine in the treatment of schizophrenia. Principal Investigator; sponsored by Janssen Research Foundation 1997-1998.

F1D-MC-HGFT, Fluoxetine augmentation in schizophrenic or schizoaffective patients with depressive or negative symptoms who are partial or non-responders to Olanzapine. Principal Investigator; sponsored by Eli Lilly and Company, 1997-1998.

311CIL/0073, A multicenter, double-blind, randomized placebo-controlled evaluation of Zolmitriptan (311C90, Zomig) efficacy at early time points in the acute treatment of migraine headaches, efficacy in recurrence, and efficacy as late dosing for prevention of recurrence of migraine headaches. Principal Investigator; sponsored by Zeneca Pharmaceuticals, 1997-1998.

F1D-MC-HGEU, Olanzapine versus placebo in the treatment of psychosis and behavioral disturbances associated with Alzheimer's disease. Principal Investigator; sponsored by Eli Lilly and Company, 1996-1998.

128-127E, An open extension study evaluating the safety and outcome of 40-200 mg daily of oral Ziprasidone in the treatment of subjects who have participated in previous Ziprasidone clinical trials. Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1997-1998.

128-125, A phase III, randomized study comparing two doses of intra-muscular Ziprasidone (2 mg and 10 mg) in subjects with psychosis and acute agitation. Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1997.

128-121, A phase III, randomized, multicenter, open-label study evaluating the toleration and safety of three days of treatment with intra-muscular Ziprasidone (CP-88, 059-27) (20 to 80 mg daily) or Haloperidol (up to 40 mg daily) followed by four days of treatment with oral Ziprasidone (CP-88,059-1) (40 to 200 mg daily ) or Haloperidol in subjects with a diagnosis of psychotic disorder. Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1997.

29060/497, A double-blind, placebo-controlled, flexible dosing trial to evaluate the efficacy of modified release Paroxetine in the treatment of panic disorder. Principal Investigator; sponsored by SmithKline Beecham, 1997.

RIS-USA-69, A bio-equivalence study comparing one 6mg Risperdal tablet with two 3 mg Risperdal tablets in chronic schizophrenic patients. An open-label, randomized, cross-over study. Principal Investigator; sponsored by Janssen Research Foundation, 1997.

Aricept for the treatment of Alzheimer's Disease. Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1996-1997.

RIS-USA-79, A comparison of Risperidone and Haloperidol for prevention of relapse in subjects with schizophrenia and schizoaffective disorder. Principal Investigator; sponsored by Janssen Research Foundation, 1996.

RIS-USA-64, An open multicenter study to evaluate the tolerability and safety of Risperdal tablets in elderly subjects with psychotic disorders. Principal Investigator; sponsored by Janssen Research Foundation, 1996.

RIS-USA-72, A double-blind, parallel group, phase III multicenter study, safety and efficacy of Risperidone 8mg qd and 4mg qd compared to placebo in the treatment of schizophrenia. Principal Investigator; sponsored by Janssen Research Foundation, 1995-1996.

Pramipexole (Mirapex) in the treatment of depression, Supported by the Upjohn Company. Principal Investigator at Pharmaco LSR, Austin, TX, Phase II study; 1995.

Zaleplon in the treatment of insomnia; Supported by Wyeth-Ayerst; at Pharmaco LSR, Austin, TX, Phase II study; 1994.

Bropheramine in the treatment of post-traumatic stress disorder; Supported by the Upjohn Company; University of Arkansas for Medical Sciences, Little Rock, Arkansas; 1991-1992.

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Abecarnil in panic disorder; Supported by Sandoz Pharmaceuticals; Institute for Behavior and Health; Rockville, Maryland; 1990-1991.

Fluoxetine (Prozac) in geriatric depression; Supported by Eli Lilly and Company; Institute for Behavior and Health; Rockville, Maryland; 1990-1991.

Xanax SR in panic disorder; Supported by the Upjohn Company; Institute for Behavior and Health; Rockville, Maryland; 1990-1991.

Evaluation of nimodipine in bipolar disorder; National Institutes of Mental Health, Biological Psychiatry Branch; Bethesda, Maryland; 1990-1991.

Lithium augmentation of nortriptyline in major depression with psychosis, University of Texas Medical School at Houston; 1989-1990.

Multicenter evaluation of Depakote in bipolar disorder; Supported by Abbott Laboratories; University of Texas Medical School at Houston, Houston, Texas; 1989-1990.

Evaluation of Remoxipride in schizophrenia; Supported by Merck and Company; University of Texas Health Science Center at Houston, Houston, Texas; 1989-1990.

#### **Other Relevant Experience**

Principal Investigator for Community Clinical Research, Inc; 1994 - present

Private Practice in Psychiatry, 8334 Cross Park Drive, Austin, TX 78754; November 2006 - present

Associate Professor, UT Department of Psychology, Austin, Texas; 2009 – present

Medical Director, Cross Creek Hospital and Inpatient Treatment Center, Austin, Texas; February 2015 – November 2015

Adult Services Medical Director, Georgetown Behavioral Health, Georgetown, TX; August 2014 – November 2014

Private Practice in Psychiatry, 4411 Medical Parkway, Austin, TX 78756; July 1993 - November 2006

Medical Director, Seton Community Living Program, Austin, Texas; January 2013 – November 2013

Vice-President, Medical Staff, Shoal Creek Hospital, Austin, Texas; January 1998 - January 2000

Volunteer Psychiatric Consultant, Seton East Community Clinic, Austin, Texas; January 1997 - 2013

Visiting Lecturer, Psychiatry Residency Program, Austin State Hospital/Seton Hospital, Austin, Texas; August 1993-2000

Assistant Professor of Psychiatry, UAMS, 4301 West Markham, Little Rock, Arkansas; July 1991 - August 1992

Consultant, Institute of Behavior and Health, Rockville, Maryland; September 1990 - June 1991

TroopMaster, Troop 310, Bee Cave District; 2015 – present

Cubmaster, Pack 310, Bee Cave District; 2011 – 2015

St. Andrew's School, Austin, Texas; Pack 23, Assistant Cubmaster; 2008 – 2009

St. Andrew's School, Austin, Texas; Pack 23, Den 5 Den Leader; 2006 – 2008

Childrens' Sunday School Teacher, Westlake Presbyterian Church, 2012- 2013

Childrens' Sunday School Teacher, All Saints Episcopal Church, 2005- 2009

Bilingual in English and Spanish

#### **References**

Available upon request

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