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CONTACT INFORMATION:

Site Selection and Information:
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AFFILIATIONS:

Berlin Medical Associates
175 Cross Keys Rd, Suite 300A
Berlin, NJ 08009

Comprehensive Clinical Research
175 Cross Keys Road
Berlin, NJ 08009

EDUCATION:

1976 - 1980 Doctor of Osteopathic Medicine
Philadelphia College of Osteopathic Medicine, Philadelphia, PA

1975 - 1976 Additional Studies
Beaver College, Glenside, PA

1972 - 1974 M.A. Psychology
Temple University, Philadelphia, PA

1966 - 1971 A.B. cum laude
Temple University, Philadelphia, PA

INTERNSHIP AND RESIDENCY:

1981 - 1984 Residency in Psychiatry
Thomas Jefferson Medical College, Philadelphia, PA

1980 - 1981 Rotating Internship
Parkview Hospital, Philadelphia, PA

LICENSURE:

State of New Jersey - 25MB05320700
State of Pennsylvania - OS004863L

CERTIFICATION:

American Board of Psychiatry and Neurology - Certification in Added Qualifications in Geriatric Psychiatry #0867, 1994
Diplomate of the American Osteopathic Board of Neurology and Psychiatry #203, 1988
Diplomate of the American Board of Psychiatry and Neurology, Inc. #028231, 1986
Diplomate of the National Board of Examiners for Osteopathic Physicians and Surgeons #7223, 1981

MEMBERSHIP:

American College of Neuropsychiatrist, 1985 - Present
Board of Governors, 2001 - Present

American Osteopathic Board of Neurology and Psychiatry, 1995 - 2001
Secretary 1997

New Jersey Association of Osteopathic Physicians & Surgeons 1989-Present

New Jersey Psychiatric Association, 1989 - 1996
Residency Training Committee 1993-1996

South Jersey Psychiatric Association 1989-Present
Program Chair 1997-1998, President 1998

American Osteopathic College of Neurology and Psychiatry
Fellow of AOCNP Board of Governors, 2001-Present
President Elect and Program Chairman, 2006
President, 2007

Philadelphia Psychiatric Society 1985-1989
Councilor 1988-1989

Consultation/Liaison Association of Philadelphia 1984-1991

Pennsylvania Osteopathic Medical Association 1981-Present

American Psychiatric Association 1981-Present
Fellow of the AP, Distinguished Fellow of APA-2003

American Medical Association 1981-1989

MEMBERSHIP (*continued*):

Pennsylvania Psychiatric Society 1981-1989

American Osteopathic Association 1980-Present

Lambda Omicron Gamma 1980-1997
National Osteopathic Medical Fraternity
Treasurer 1989, Secretary 1990/91, Vice President 1992, President 1993

PROFESSIONAL EXPERIENCE:

Investigator, 2015 - present
Hassman Research Institute, LLC, Berlin, NJ

Investigator, 2010 - Present
Comprehensive Clinical Research, Berlin, NJ

Principal Investigator, Sub-Investigator, Rater, 2003 - Present
CRI Worldwide, LLC, Philadelphia, PA

Assistant Professor of Psychiatry, January 2008 - present
UMDNJ - School of Osteopathic Medicine, New Jersey Institute for Successful Aging, Cherry Hill, NJ

Director, Outpatient Services of the Department of Psychiatry, 2000-2003
UMDNJ-SOM, Department of Psychiatry Research Committee, Cherry Hill, NJ

Director, Outpatient Services 1996-2003
UMDNJ - SOM, Department of Psychiatry, Cherry Hill, NJ

Director, Outpatient Services of the Department of Psychiatry, 1996-2000
UMDNJ - School of Osteopathic Medicine, Cherry Hill, NJ

Attending and Supervising Psychiatrist, 1996-1999
UMDNJ - SOM Faculty Practice Plan Committee, Cherry Hill, NJ

Attending and Supervising, 1993 - 1996
NJ Psychiatric Association, Residency Training Committee, Cherry Hill, NJ

Committee Member, 1991-1994
UMDNJ - SOM Admissions Committee, Cherry Hill, NJ

Director of Residency Training, 1990-1996
UMDNJ - SOM, Department of Psychiatry, Cherry Hill, NJ

PROFESSIONAL EXPERIENCE (*continued*):

Residency Program Director of the Department of Psychiatry, 1990-1996
UMDNJ - School of Osteopathic Medicine, Cherry Hill, NJ

Psychiatry, 1989-2003
Our Lady of Lourdes Medical Center, Camden, NJ

Psychiatry, 1989-2003
Kennedy Memorial Hospitals/University Medical Center, Cherry Hill, NJ

Assistant Professor of Clinical Psychiatry, 1989-2003
UMDNJ - School of Osteopathic Medicine, Department of Psychiatry, Cherry Hill, NJ

Director of Consultation Liaison Services, 1989-1993
UMDNJ - SOM, Department of Psychiatry, Cherry Hill, NJ

Director of Consultation Liaison of the Department of Psychiatry, 1989-1992
UMDNJ - School of Osteopathic Medicine, Cherry Hill, NJ

Assistant Clinical Professor, 1984-1989
Jefferson Medical College, Department of Psychiatry and Human Behavior, Philadelphia, PA

Psychiatric Consultant to Thomas Jefferson Pain Treatment Center, 1984-1989
Department of Psychiatry and Human Behavior, Consultation Liaison Service
Thomas Jefferson University Hospital, Philadelphia, PA

Attending Physician (Psychiatry), 1984-1989
Consultation/Liaison Division, Thomas Jefferson Medical College, Philadelphia, PA

Medical Director of Pain Treatment Center, 1984-1989
Department of Psychiatry, Thomas Jefferson University Hospital, Philadelphia, PA

Instructor in Psychiatry, 1984-1986
Department of Psychiatry and Human Behavior, Jefferson Medical College, Philadelphia, PA

Contract Physician, 1982-1984
Fairmount Institute, Philadelphia, PA

INVESTIGATOR EXPERIENCE:

ADHD • Alzheimer's Disease • Anxiety • Bipolar Disorder • Chronic Pain
Depression • Fibromyalgia • Insomnia • Migraine • Neuropathic Pain • Osteoarthritis • Phase I
Post-Traumatic Stress Disorder • Schizophrenia/ Schizoaffective Disorder • Sexual Dysfunction
Sleep Disorder • Smoking Cessation

CLINICAL TRIAL EXPERIENCE:

Phase I Depression

A Phase I/II Two-Part Study of XXX as an Adjunctive Therapy in Subjects With Major Depressive Disorder

A Phase I, Two-Part, Double-Blind, Placebo-Controlled, Twice Daily Dose Study of XXX in Adult Participants with Major Depressive Disorder (Part B)

A Phase I Randomized, Open-Label, Pilot Parallel Study To Determine The Relative Pharmacokinetic Characteristics Between XXX Versus Injectable Paliperidone Palmitate Following Different Dosing Regimens In Schizophrenia Alone Or As Use In Schizoaffective Disorders As An Adjunctive Therapy To Antidepressants

A Phase I Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of Single Doses of XXX in Healthy Volunteers and Subjects with Treatment-Resistant Depression

A Phase I, Two-Part, Double-blind, Placebo-controlled, Single- and Multiple-Dose Study of XXX in Adult Participants with Major Depressive Disorder (Part A)

Phase I Healthy

A Phase I, Randomized, 3-Period, Crossover Study to Investigate the Effects of XXX on Measures of Drowsiness and Cognitive Function Compared to XXX and Placebo

A Phase I, Double-blind, Sponsor-open, Placebo-controlled, First-In-Human Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single Ascending Dose of XXX in Healthy Subjects

A Phase I, Randomized, Double-blind, Placebo-controlled, Single-Ascending-Dose Trial to Evaluate the Safety, Tolerability, Immunogenicity, and Pharmacokinetics of Intravenous XXX in Normal Healthy Volunteers

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Combined Single and Multiple Ascending Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX Oral Solution in Healthy Subjects (Part B MAD)

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Combined Single and Multiple Ascending Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX Oral Solution in Healthy Subjects (Part A SAD)

A Phase 0, Multi-Center Study in Schizophrenic Patients and Healthy Volunteers to Validate XXX Biomarkers for Use in Therapeutic Trials

CLINICAL TRIAL EXPERIENCE (*continued*):

A Double-blinded, Placebo-controlled, Sequential Cohort, Single-dose Escalation, Phase I Study to Evaluate the Safety and Single Dose Pharmacokinetics of XXX, a Reactive Species Decomposition Accelerant, in Healthy Volunteers - A First in Human Clinical Study

A Phase I, Randomized, Double-Blind, Placebo-Controlled Study of the Effects on Quantitative Electroencephalography and Event-Related Potential of Two Sequential Doses of XXX in Healthy Adult Males

A 2-Part, Phase I, Study of XXX Pharmacodynamics and Pharmacokinetics Alone and in the Presence of XXX or XXX

A Phase I, Randomized, Double-blind, Placebo-controlled Parallel Group Study of Multiple Doses of XXX Challenge, to Evaluate the Electrophysiology. Safety, Tolerability and Pharmacokinetics in Healthy Subjects

A Phase I Double-blind, Placebo-controlled Crossover Study of XXX Using Ketamine Challenge, to Evaluate Safety, Tolerability, Pharmacokinetics and Pharmacodynamic Response Using PET Imaging in Healthy Subjects

A Phase I, Double-blind, Placebo-controlled, Crossover Study of XXX Using a Ketamine Challenge to Evaluate the Electrophysiology, Safety, Tolerability, and Pharmacokinetics in Healthy Subjects

A Phase I Double-blind, Placebo-Controlled, Multiple Ascending Dose Study to Determine the Safety, Tolerability and Pharmacokinetices of XXX Oral Solution in Healthy Adults

A Phase I Open-Label, One-Sequence Study to Evaluate the Steady-State Comparative Bioavailability of Injectable and Oral INVESTIGATIVE DRUG

Phase I Schizophrenia and Schizoaffective Disorder

A Phase I Randomized, Open-Label, Parallel, Single-Dose Study to Evaluate the Pharmacokinetic Characteristics of XXX of Two Formulations versus INVEGA SUSTENNA® after Intramuscular Injection in Schizophrenia Patients

A Phase I, Randomized, Double-blind, Placebo-controlled, Ascending Dose study to Determine Efficacy, Pharmacokinetic and Safety of XXX in Agitation associated with Schizophrenia or Schizoaffective Disorder

A Phase Ib, Open-label, Multiple-dose, Randomized, Parallel-arm, Safety, Tolerability, and Pharmacokinetic Trial of XXX Intramuscular Depot Administered in the Gluteal Muscle in Adult Subjects With Schizophrenia or Bipolar I Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

An Open-label, Single- and Multiple-dose, Pharmacokinetic, Safety, and Tolerability Trial of XXX Administered in the Deltoid or Gluteal Muscle in Adult Subjects with Schizophrenia or Bipolar I Disorder

A Phase I, Open Label, Parallel-Design, Single Dose Study to Assess the Relative Bioavailability of XXX Extended-Release Suspension for Subcutaneous Administration XXX, in Vials compared to Prefilled Syringes, in Patients with Schizophrenia or Schizoaffective Disorder

A Phase I Randomized, Double-blind, Positive and Placebo-controlled, Four-Arm Crossover Study of the Effects of XXX at Therapeutic and Supra-therapeutic Doses, on the QTc Intervals in Schizophrenic Patients

A Phase Ib, Pivotal, Multiple-Dose, Pharmacokinetic Bioequivalence Trial Comparing Generic to Reference XXX Extended-Release Injectable Suspension (156 mg/1.0 mL) in Patients with Schizophrenia or Schizoaffective Disorder

A Phase I Investigational Study to Evaluate Adhesion of XXX in Adults with Schizophrenia

A Phase I, Randomized, Crossover, Open-Label, Multiple Dose, Pivotal Pharmacokinetic Bioequivalence Study Comparing XXX Extended-Release IM 156 mg/1 mL (100 mg eq) with XXX in Subjects with Schizophrenia or Schizoaffective Disorder

A Phase I Study to Evaluate the Effect of Multiple Doses of XXX on QTc Interval in Subjects with Schizophrenia

A Phase I, Single-Dose, Open-Label, Randomized, Parallel-Group Study to Assess the Pharmacokinetics, Safety, and Tolerability of a XXX 3-Month Formulation in Subjects With Schizophrenia

A Phase I, Open-Label, Long-Term, Multiple-Dose, Safety and Tolerability, Pharmacokinetic Study of 150 mg eq. XXX in the Treatment of Subjects with Schizophrenia

A Phase I, Open-Label, Parallel, Randomized Study to Explore the InVitro/InVivo Correlation of XXX and the Comparability of XXX and XXXX in Subjects with Schizophrenia

A Phase I, Local-Site Tolerability of Multiple-Dose Treatment with Deltoid Intramuscular Injection of XXX in Subjects With Chronic Schizophrenia

Phase I Other Indications

A Phase I Clinical Study to Determine the Safety and Tolerability of XXX at Three Increasing Dose Levels as Add On Administration in Chronic Back-Pain Patients During Opioid Treatment

CLINICAL TRIAL EXPERIENCE (*continued*):

An Open label, two-part study to evaluate the impact of an improved first-time user experience on engagement with reSET and reSET-O (reSET/O) in patients with substance use disorder

A Phase I, Open-Label Study to Evaluate the Pharmacokinetics and Safety of XXX in Subjects with Impaired Hepatic Function

A Phase Ia/Ib, Dose-Escalating, Two-Part Study to Evaluate the Safety and Pharmacokinetics of Single and Multiple Doses of XXX in Subjects with Type 2 Diabetes Mellitus

A Phase I, Study Comparing the Pharmacokinetics of Intranasal XXX in Subjects with Severe Renal Impairment and Subjects with Normal Renal Function

A Phase I, Randomized, Double-blind, Third-party Open, Placebo-controlled, Dose Escalating Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single and/or Multiple Intravenous and/or Subcutaneous Doses of XXX in Healthy Subjects who may be Mildly Atopic Subjects with Chronic Rhinosinusitis with Nasal Polyps, and Subjects with Moderate Severe Atopic Dermatitis

A Phase I, Systemic Pharmacokinetics of Intranasal XXX in Hepatic-impaired Individuals

A Phase I, Single and Multiple Dose Pharmacokinetic, Tolerability and Safety Study with XXX in Pediatric Patients with Attention Deficit/ Hyperactivity Disorder

A Phase I, Open Label, Parallel Group, Dose Comparison of Safety and Imaging Characteristics of 111 and 370 MBq (3 and 10 mCi) of XXX for Brain Imaging of Amyloid in Healthy Volunteers and Patients with Alzheimer's Disease (AD)

Phase II-IV

Addiction

Hair, Urine, and Saliva Procurement Protocol for the Development of Drugs of Abuse Tests

A Phase II, Multi-Center Trial of XXX in the treatment of Cocaine Use Disorder

ADHD

A Phase IV, Multicenter, 2-part Study Composed of a 1-Year Randomized, Double-blind, Parallel-group, Placebo-controlled, Active-comparator, Dose-optimization Evaluation followed by a 1-Year Open-label Evaluation to Assess the Safety and Efficacy of XXX in Children and Adolescents aged 6 to 17 Years with Attention-deficit/Hyperactivity Disorder

A Phase III Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of XXX in Adults with Attention Deficit/Hyperactivity Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel-Group Flexible-Dose Study of the Efficacy and Safety of XXX in Adults with Attention-Deficit/ Hyperactivity Disorder (ADHD)

A Phase III, Open-label, 52-Week, Multicenter Trial Evaluating the Long-term Safety and Tolerability of XXX Sustained-Release Tablets in Adults with Attention-Deficit/ Hyperactivity Disorder

A Phase III, Randomized, Double-blind, Multicenter, Placebo-controlled, Parallel-group Trial Evaluating the Efficacy, Safety and Tolerability of XXX Sustained-release Tablets in Adults with Attention-deficit/ Hyperactivity Disorder

An Open-label, 52-Week, Multicenter Trial Evaluating the Long-term Safety and Tolerability of XXX Sustained-Release Tablets in Adults with Attention-Deficit/ Hyperactivity Disorder

A Phase II Multicenter, Fixed-Dose, Double-Blind, Randomized Study to Evaluate the Efficacy and Safety of XXX in Adult Subjects (Ages 18-55) with Attention Deficit Hyperactivity Disorder (ADHD)

A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX Extended-Release Tablets for the Treatment of Impulsive Aggression in Pediatric Patients with Attention Deficit/Hyperactivity Disorder (ADHD) in Conjunction with Standard ADHD Treatment

A Phase III, Multicenter, Dose-Optimized, Open-Label Safety Study with XXX in Children with Attention-Deficit/Hyperactivity Disorder

A Phase III, Open-Label Extension Study to Evaluate the Safety of XXX Extended-Release Tablets for the Treatment of Impulsive Aggression in Pediatric Subjects with Attention Deficit/Hyperactivity Disorder (ADHD) in Conjunction with Standard ADHD Treatment

A Phase III, Randomized, Double Blind, Placebo Controlled Study to evaluate the Efficacy and Safety of XXX Extended-Release Tablets for the Treatment of Impulsive Aggression in Pediatric Patients with Attention Deficit/Hyperactivity Disorder (ADHD) in Conjunction with Standard ADHD Treatment

A Phase IV, Placebo Controlled Double-Blind, Parallel Group, Individualizing Dosing Study Optimizing Treatment of Adults with Attention Deficit Hyperactivity Disorder to an Effective Response With XXX

A Phase III, Randomized, Double-Blind, Multi-Center, Parallel-Group, Placebo-Controlled, Forced-dose Titration, Safety and Efficacy Study of XXX in Adolescents Aged 13-17 With Attention-Deficit/ Hyperactivity Disorder (ADHD)

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IIIb, Randomized, Double-Blind, Multi-Center, Parallel-Group, Placebo-Controlled, Dose Optimization Study, Designed to Evaluate the Efficacy and Safety of XXX in Adolescents Aged 13-17 Years with Attention-Deficit/Hyperactivity Disorder (ADHD)

A Phase IV, Multi-center, Open-label Study of XXX to Characterize the Dermal Reactions in Pediatric Patients Ages 6-12 with ADHD

A Phase III, Double-Blind, Randomized, Multi-Center, Flexible Dose Study Evaluating the Efficacy and Safety of XXX in Children Aged 6-12 With Symptoms of Oppositionality and a Diagnosis of Attention Deficit/Hyperactivity Disorder

A Randomized, Double-Blind, Placebo-Controlled, Phase II Dose-Ranging Study of the Safety and Efficacy of XXX in Adults with Attention-Deficit/Hyperactivity Disorder (ADHD)

A Phase III, 5-Week Treatment, Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Fixed-Dose Study of the Efficacy, Tolerability and Safety of XXX HCl Extended-Release Capsules Administered Once Daily in Pediatric Children with Attention-Deficit/Hyperactivity Disorder

A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Safety and Efficacy Study of XXX in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)

A Phase III, Multi-center, Open-label Study of XXX Transdermal System (MTS) in Pediatric Patients Aged 6-12 With Attention-Deficit/Hyperactivity Disorder (ADHD)

A Phase III, Randomized, Double-Blind, Multi-Center, Parallel-Group, Placebo-Controlled, Dose Optimization Study, Designed to Evaluate the Safety and Efficacy of XXX Transdermal System (MTS) vs. XXX ® in Pediatric Patients Aged 6-12 With Attention-Deficit/Hyperactivity Disorder (ADHD)

A Phase IV, Maintenance of Benefit After 8-Week and 52-Week Treatment with XXX in Adolescents With ADHD

A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Safety and Efficacy Study of XXX in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)

A Phase III, Randomized, Multi-Center, Double-Blind, Parallel-Group, Placebo-Controlled Study of XXX in Children Aged 6-12 Years with Attention Deficit Hyperactivity Disorder (ADHD) and its Open-Label Extension

A Phase III, Open-Label Study of XXX in Children and Adolescents Aged 6-17 with Attention-Deficit Hyperactivity Disorder (ADHD)

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Randomized, Double-Blind, Multi-Center, Parallel-Group, Placebo-Controlled Safety and Efficacy Study of XXX in Children and Adolescents Aged 6-17 with Attention Deficit Hyperactivity Disorder (ADHD)

A Phase IV, Double-Blind Study of Functional Outcomes with XXX and Placebo in Adult Outpatients with DSM-IV Attention Deficit/Hyperactivity Disorder

A 9-Week, Randomized, Double-Blind, Placebo-Controlled, Flexible-Dosage (up to 425mg/day), Parallel-Group Study to Evaluate the Efficacy and Safety of XXX (Film-Coated Tablet) in Children and Adolescents with Attention-Deficit/Hyperactivity Disorder

A 1-Year, Open-Label, Flexible-Dosage Study to Evaluate the Safety and Continued Efficacy of XXX (Film Coated Tablet Formulation) in Children and Adolescents with Attention-Deficit/Hyperactivity Disorder

A Phase III, Randomized, Multi-Center, Double-Blind, Parallel-Group, Placebo-Controlled Safety and Efficacy Study of XXX with an Open-label Extension, in the Treatment of Adolescents Aged 13-17 with Attention Deficit Hyperactivity Disorder (ADHD)

A Multi Center, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of the Efficacy and Safety of XXX (XXX) Extended Relief Capsules (at 5-30 mg a day) Administered once daily in Pediatric Patients 6-17 Years of age with Attention Deficit Hyperactivity Disorder

Alzheimer's Disease

A Phase II, Randomized, Double-blind, Placebo-controlled, 3-Arm Parallel Design Study to Evaluate the Effects of XXX in Patients with Early Stage Alzheimer's Disease

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Trial of XXX In Patients with Mild to Moderate Alzheimer's Disease Who Are Apolipoprotein E4 Non- Carriers

A Phase IIa, Multi-center, Randomized, Double Blind, Placebo-controlled Study to Investigate the Efficacy and Safety of XXX in Patients with Mild to Moderate Alzheimer's Disease

A Phase II, Randomized, Double-Blind, Placebo Controlled, Multi-Center Study of the Pharmacodynamics/ Efficacy, Safety, Tolerability, and Pharmacokinetics of 3 Fixed Dosages of XXX (5 mg, 15 mg, and 50 mg) in Patients with Mild to Moderate Alzheimer's Disease

A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Safety and Efficacy of XXX in Patients with Mild to Moderate Alzheimer's Disease

A Phase III, Study of the Efficacy and Safety of XXX in Patients with Mild to Moderate Alzheimer’s Disease

CLINICAL TRIAL EXPERIENCE (*continued*):

Anxiety

A Phase III, Double-Blind, Placebo-Controlled, Flexible-Dose Study of XXX in Patients with Generalized Anxiety Disorder

A Phase III, Double-blind, Placebo-Controlled Fixed-Dose Study of XXX in Patients with Generalized Anxiety Disorder

A Multi-Center, Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Phase II Study of 2 Oral Dose Groups of XXX, With a XXX Arm, in Subjects with Generalized Anxiety Disorder (GAD)

A Phase III, Multicenter, Randomized, Double-blind, Parallel-group, Placebocontrolled Study of the Efficacy and Safety of XXX Compared with Placebo as an Adjunct to Treatment in Patients with Generalized Anxiety Disorder who Demonstrate Partial or No Response to a Selective Serotonin Reuptake Inhibitor or Serotonin-Norepinephrine Reuptake Inhibitor Alone or in Combination with a Benzodiazepine

A Phase III, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Active-Controlled Study of the Efficacy and Safety of Sustained-Release XXX Compared with Placebo in the Treatment of Generalized Anxiety Disorder

A Phase III, Double-Blind, Placebo Controlled Trial of an Experimental Medication for the Treatment of Generalized Anxiety Disorder

A Phase III, Comparison of XXX, XXX Extended Release, and Placebo in the Treatment of Generalized Anxiety Disorder

A Phase III, 10-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of XXX at 4, 8, and 12 mg/day in the Treatment of Adults with Generalized Anxiety Disorder

A Phase III, 12-Month, Open-Label, Flexible-Dosage Study to Evaluate the Safety and Efficacy of XXX Treatment (up to 16 mg/Day) in Adults with Generalized Anxiety Disorder

Effectiveness of XXX in Treating Persistent Anxiety in Depressed Patients on Stable Doses of SSRI's

A 28-Day, Multicenter, Randomized, Placebo-controlled, Double-Blind, Efficacy and Safety Study of XXX (XXX Modified Release Tablets) in Patients with Generalized Anxiety Disorder

An 8-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dosage Study to Evaluate the Efficacy and Safety of XXX, at Dosages up to 16 mg/day, in the Treatment of Generalized Anxiety Disorder (GAD) in Adults

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, 12-Month, Open-Label, Flexible-Dosage Study to Evaluate the Safety of XXX at Dosages up to 16 mg/day in Adults with Generalized Anxiety Disorder

Bipolar Disorder

A Phase III Multicenter, Randomized, Double-blind, Placebo-controlled Study to determine Efficacy and Safety of Two Dose Levels of XXX in Bipolar I Disorder Patients with Acute Agitation

A Multicenter, Open-label Trial to Evaluate the Safety and Tolerability of XXX in the Treatment of Subjects with Bipolar I Disorder

A Multicenter, Randomized, Double-blind Trial of XXX versus Placebo for the Acute Treatment of Subjects Manic Episodes, With or Without Mixed Features, Associated With Bipolar I Disorder

A Phase III, Multicenter, Randomized, Double-blind, Double dummy, Placebo-controlled Study of the Efficacy and Safety of XXX in Subjects with Bipolar I Disorder Experiencing an Acute Manic Episode

A Phase III, 52-week, multicenter, open label study to evaluate the effectiveness of an Intramuscular Depot Formulation of XXX as a Maintenance Treatment in Patients with Bipolar I Disorder

A Phase IV, Multi-center, Double-blind, Double-dummy, Randomized, Parallel-group Study to Compare the Tolerability of XXX Immediate Release XXX With XXX Extended Release During Initial Dose Escalation in Patients with Bipolar Depression

A Phase II, Randomised, Double-Blind, Parallel-Group, Placebo-Controlled, XXX-Referenced, Fixed-Dose Study of XXX in the Treatment of Depression in Patients with Bipolar I or II Disorder

A Phase II, 8-Week, Double-Blind, Placebo-Controlled, Parallel Group, Fixed Dosage Study to Evaluate the Efficacy and Safety of XXX as Adjunctive Therapy in Adults with Major Depression Associated with Bipolar I Disorder

Controlled Trial of Safety and Efficacy of XXX Versus Placebo in Patients with Bipolar Depression

Controlled Trial of XXX versus Placebo in Patients with Bipolar Disorder in Manic or Mixed States

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Six-Week, Double-Blind, Multicenter, Placebo Controlled Study Evaluating The Efficacy And Safety Of Flexible Doses Of Oral XXX As Add-On, Adjunctive Therapy With XXX, XXX, or XXX In Bipolar I Depression

A Phase II, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXX in Patients with Acute Mania Associated With Bipolar I Disorder

A Phase IV, Double-Blind Placebo Controlled Trial of XXX and XXX in Bipolar I Disorder, Mixed Episode

A Phase III, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Multicenter, Efficacy and Safety Study of XXX in Bipolar I Disorder

A Phase III, Six-Week, Double-Blind, Multicenter, Placebo-Controlled Study Evaluating the Efficacy and Safety of Flexible Doses of Oral XXX in Outpatients with Bipolar I Depression

A Phase III, Multicenter, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled, Phase III Study of the Efficacy and Safety of XXX Sustained-Release as Monotherapy in Adult Patients with Acute Bipolar Depression

A Six–Week, Randomized, Double-Blind, Multicenter, Fixed-Flexible Dose, Placebo-Controlled Study Evaluating the Efficacy and Safety of Oral XXX in Outpatients with Bipolar I Depression

A Phase IV, Multicenter, Double-blind, Study of the Efficacy and Safety of XXX in Combination with XXX in the Long-term Maintenance Treatment of Patients with Bipolar I Disorder with a Recent Manic or Mixed Episode

A Phase III, Efficacy of XXX in Combination with XXX or XXX in the Treatment of Mania in Patients with Bipolar I Disorder Partially Nonresponsive to XXX or XXX Monotherapy

A Phase III, Randomized, Double-Blind, Active- and Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Extended-Release XXX as Maintenance Treatment After an Acute Manic or Mixed Episode Associated with Bipolar I Disorder

A Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of XXX Combined with XXX or XXX in the Treatment of Manic Episodes of Bipolar I Disorder Over Six Weeks with an Extension study

A Phase III, Three-Week, Double-Blind, Multicenter, Placebo-Controlled Study Evaluating the Efficacy and Safety of Add-On Oral XXX in Subjects with Acute Mania Treated With XXX or XXX

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Placebo-Controlled Study to Explore the Efficacy and Safety of XXX Long-Acting Intramuscular Injectable in the Prevention of Mood Episodes in Bipolar I Disorder, with Open-Label Extension

An Exploratory Study of Exposure to XXX and its Metabolite XXX in individuals Prescribed XXX and/or Subjects Enrolled in XXX Bipolar Study

A PK Study Study of Exposure to XXX and its Metabolite XXX in Individuals Prescribed XXX and/or Subjects Enrolled in XXX Bipolar Study XXX or XXX

A Phase IV, XXX/XXX Combination Versus XXX in the Treatment of Bipolar I Depression

A Phase III, Six-Week, Randomized, Double-Blind, Multicenter, Fixed-Flexible Dose, Placebo-Controlled Study Evaluating the Efficacy and Safety of Oral XXX in Outpatients with Bipolar I Depression

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-Group Study of XXX in the Treatment of Depression in Outpatients with Bipolar Disorder

A Confirmatory Multicenter, Double-Blind, Randomized, Placebo-Controlled Study of the Use of XXX (XXX) in the Treatment of Patients with Bipolar Depression

A Multicentre, Double-blind, Randomised, Parallel Group, Placebo Controlled, Phase III Study of the Efficacy & Safety of XXX & XXX as Monotherapy in Adult Patients with Bipolar Depression for 8 Weeks & XXX in Continuation Treatment for 26 up to 52 weeks

A Multicenter, Randomized, Parallel-group, Double-Blind, Phase III Comparison of the Efficacy and Safety of XXX (oral tablets 400 mg to 800 mg daily in divided doses) to Placebo when used as Adjunct to Mood Stabilizers (XXX or XXX) in the Maintenance Treatment of Bipolar I Disorder in Adult Patients

Depression

A Phase II, Randomized, Double-blind, Placebo-controlled Study of XXX for Relapse Prevention in Treatment Resistant Depression

A Phase II, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study of the Safety and Efficacy of XXX in the Treatment of Adults with Major Depressive Disorder

Phase IV Concept Elicitation and Cognitive Debriefing Interviews in Adults with Major Depressive Disorder and Sleep Disturbance

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, 6-week, multicenter, randomized, double-blind, double-dummy, placebo-controlled, parallel group study with a Quetiapine XR arm to evaluate the efficacy, tolerability and safety of XXX in patients with Major Depressive Disorder

A Phase III, Randomized, Double-blind, Placebo-controlled Study of the Efficacy and Safety of XXX with a Fixed, Repeated Treatment Regimen on Relapse Prevention in Adults with Major Depressive Disorder

A Phase III Open-Label Study to Assess the Long-term Safety and Efficacy of XXX in Subjects with Major Depressive Disorder

A Randomized, Double-Blind, Placebo-Controlled Trial of XXX Administered Orally to Subjects with Major Depressive Disorder

A Randomized, Double-blind, Placebo-controlled Study of the Safety, Tolerability, and Efficacy of XXX Compared to Placebo in Adult Subjects with Comorbid Major Depressive Disorder and Insomnia

A Phase II, Multi-center, Randomized, Subject and Investigator-blinded, Placebo-controlled, Active comparator, Parallel-group Proof of Concept Study to Evaluate the Efficacy, Safety, Tolerability, and Pharmacokinetics of XXX in Patient with Treatment-resistant Depression

A Phase III, Multicenter, Double-blind, Randomized, Placebo-controlled Study Evaluating the Efficacy of XXX in the Treatment of Adult Subjects with Major Depressive Disorder

A Phase III, Double-blind, Placebo-controlled Study of XXX as an Adjunct to Antidepressants in the Treatment of Patients with Major Depressive Disorder who have had an Inadequate Response to Antidepressants Alone

A Phase III Randomized, Double-blind, Placebo-controlled, Multicenter Study of XXX in the Prevention of Relapse in Patients with Major Depressive Disorder

A Phase IIa, Multicenter, Randomized, Double-Blind, Placebo-Controlled, 3-Arm Trial to Assess the Safety and Tolerability of a 7-Day Dosing with XXX 25 mg QD and 50 mg QD as Adjunctive Therapy in the Treatment of Patients Diagnosed with Major Depressive Disorder

A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter Study of XXX as Monotherapy in Patients with Major Depressive Disorder

A Double-Blind, Placebo-Controlled, Fixed-Dose Study of XXX in Patients with Major Depressive Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IIb, Randomized, Double-Blind, Parallel-Group, Placebo Controlled Study to Evaluate the Efficacy and Safety of 2 Fixed Doses (5.0 mg or 2.5 mg) of XXX in Adult Patients with Major Depressive Disorder

A Phase IIIb, Efficacy and Safety Study of Adjunctive XXX in Treatment Refractory Major Depressive Disorder

A Phase II, Two-Part (Open-Label Followed by Double-Blind) Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of XXX in the Treatment of Adult Subjects With Moderate to Severe Major Depressive Disorder

A Phase II Randomized, Double-Blind, Placebo-Controlled Study of Intermittent Doses of XXX in the Treatment of Subjects with Severe Depression despite Antidepressant Treatment

A Randomized, Double-Blind, Placebo-Controlled, Phase IV, Relapse Prevention Study Evaluating the Efficacy and Safety of XXX (5, 10 and 20 mg) in Adults With Major Depressive Disorder

A Phase II, Multicenter, Randomized, Double-blind, Placebo controlled, Study to Evaluate the Efficacy and Safety of Adjunctive XXX in Major Depressive Disorder

A Phase III, Randomized, Double-blind, Active-controlled Trial to Assess the Efficacy and Safety of XXX Administered Orally to Subjects with Treatment Resistant Major Depressive Disorder

A Phase III, Multicenter Study of the Long-Term Safety and Tolerability of XXX for the Adjunctive Treatment of Major Depressive Disorder in Adults Who Have an Inadequate Response to Antidepressant Therapy (the XXX Study)

A Phase III, Efficacy and Safety Study of XXX for Adjunctive Treatment of MDD

A Phase II, Double-Blind, Placebo-Controlled Study Of XXX As Adjunctive Therapy In Major Depressive Disorder

A Phase II, Randomized, Double-blind, Placebo-controlled Study to Evaluate XXX in Subjects With Major Depressive Disorder and Inadequate Response to Antidepressant Therapy

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of XXX in Subjects with Major Depressive Disorder

A Phase III, Double-Blind, Efficacy and Safety Study of XXX Versus Placebo in the Treatment of Children and Adolescents With Major Depressive Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Study of Augmentation With XXX for Patients With Major Depressive Disorder Who Are Partial Responders to Selective Serotonin Reuptake Inhibitor Treatment

A Phase IIb, Multicenter, Randomized, Double-blind, Parallel Group, Placebo-controlled Efficacy and Safety Study of Adjunctive XXX in Subjects with Severe Major Depressive Disorder (MDD) and a History of Poor Response to Antidepressants

A Phase III, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of XXX vs. Placebo in the Treatment of Psychotic Symptoms in Patients With Major Depressive Disorder With Psychotic Features

A Phase III, Randomised, Double-blind, Parallel-group, Placebo-controlled, XXX-referenced, Fixed Dose Study Comparing the Efficacy and Safety of XXX in Acute Treatment of Major Depressive Disorder in Elderly Patients

A Phase IV, Open-Label Study To Evaluate The Prevalence Of Phenotypic Poor Metabolizers At XXX Among XXX-Treated Outpatients With Depression

A Phase III, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Active-Referenced, Fixed-Dose Study Comparing the Efficacy and Safety of 2 Doses of XXX in Acute Treatment of Adults With Major Depressive Disorder

A Double-Blind, Placebo-Controlled Study of XXX in Combination with XXX in Patients With Major Depressive Disorder

A Phase IV, 12-Week, Randomized, Open-Label Trial of XXX Versus Generic SSRIs in the Treatment of a Severe Depressive Episode

A Phase II, Double-Blind, Placebo-Controlled Study Examining The Safety, Efficacy, and Tolerability of XXX in Subjects With Major Depressive Disorder (Including Atypical and Melancholic Features)

A Phase III, 52-week, Randomized, Double-blind, Placebo-controlled, Multi-center, Parallel-group Study of the Long-term Efficacy, Tolerability and Safety of XXX 25 and 50 mg in the Prevention of Relapse of Major Depressive Disorder (MDD) Following Open-label Treatment of 16-24 Weeks

A Phase IV, XXX Versus Placebo in the Long-Term Treatment of Patients With Late-Life Major Depression

A Multicenter, Double-Blind, Randomized, Parallel-Group, Placebo- Controlled Phase III Study of the Efficacy and Safety of XXX Sustained Release in Combination With an Antidepressant in the Treatment of Patients With Major Depressive Disorder With Inadequate Response to an Antidepressant Treatment

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, XXX-Referenced, Parallel-Group Study to Evaluate the Efficacy and Safety of 2 Fixed Doses (50mg, 100mg) of XXX Sustained-Release Tablets in Adult Outpatients With Major Depressive Disorder

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Two Fixed Doses (50 mg, 100 mg) of XXX Sustained-Release Tablets in Adult Outpatients With Major Depressive Disorder

A Multicenter, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled and Active-Controlled Phase III Study of the Efficacy and Safety of XXX Sustained-Release as Monotherapy in the Treatment of Patients With MDD

A Double-Blind Flexible Dose Comparison of the Safety and Efficacy of XXX and Placebo in the Treatment of Major Depressive Disorder in Diabetic Patients

A Phase III, Double-Blind Study of XXX in Adult Patients With Major Depressive Disorder

A Phase III, Fifty-two-week, Multicenter, Open-label Study Evaluating the Long-term Safety and Tolerability of XXX in Adult and Elderly Patients With Major Depressive Disorder

XXX as an Antidepressant Augmentation Agent in Treatment Refractory Unipolar Depression

A Phase IV, Comparison of XXX Dosing Strategies in The Treatment of Patients With Major Depression

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of Safety and Efficacy of XXX in the Treatment of Psychotic Symptoms in Patients with Major Depressive Disorder with Psychotic Features AND An Open-Label Extension Study of the Safety and Tolerability of XXX for Recurrent Psychotic Symptoms in Patients With Major Depressive Disorder With Psychotic Features

A Phase III, Multi-Centre, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Flexible Dose Study to Evaluate the Efficacy, Safety and Tolerability of Extended-release XXX (150mg-300mg once daily) in Elderly Subjects with MDD

A Phase III, Study of XXX plus XXX in Combination for Treatment Resistant Depression with and without Psychotic Features

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Fixed Dose Study Evaluating the Efficacy and Safety of XXX in Elderly Outpatients Diagnosed with Major Depressive Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

Fibromyalgia

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Study of XXX in Subjects With Fibromyalgia with an extension study

A Phase II/ III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Adaptive Design, Efficacy and Tolerability Study of 4 Fixed Doses of XXX in Adult Outpatients With Fibromyalgia Syndrome

Migraine

A Phase III, Randomized, Double blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of XXX in Migraine Prevention

A Phase III, Open-label Study of Safety and Tolerability of Chronic Intermittent Usage of XXX Nasal Spray Administered by the XXX device in Patients With Migraine Headache over 26/52 weeks

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Comparing the Efficacy, Safety and Tolerability of monthly Subcutaneous Administration of XXX Versus Placebo for the Preventive Treatment of Migraine in patients with inadequate response to 2 to 4 other preventive treatments

A Phase II/III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy, Safety, and Tolerability of Multiple Dosing Regimens of Oral XXX in Episodic Migraine Prevention

A Phase III, Double-Blind, Randomized, Placebo Controlled, Safety, Efficacy, Trial of XXX for the Acute Treatment of Migraine

A Phase III, Parallel Group, Double-Blind, Randomized, Placebo Controlled, Trial to Evaluate the Efficacy, and Safety, of XXX Administered Intravenously in Patients with Chronic Migraine

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Efficacy, Tolerability and Safety Study of XXX in Episodic Migraine With or Without Aura

A Phase II, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel group, Flexible-dose Evaluation of XXX 1200 mg/day, 1800 mg/day, 2400 mg/day and 3000 mg/day Compared with Placebo in the Prophylactic Treatment of Migraine Headache

A Phase III, Randomized, Multicenter, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of a Combination Product Containing XXX and XXX for the Acute Treatment of Migraine in Adolescents

CLINICAL TRIAL EXPERIENCE (*continued*):

Pain

A Phase II, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multiple-Dose Study to Assess the Efficacy and Safety of XXX in Subjects with Neuropathic Pain Associated with Diabetic Peripheral Neuropathy

A Phase IIa, Multicenter, Randomized, Double-blind, Placebo-controlled and Active-controlled, Parallel-group Study Evaluating the Analgesic Efficacy and Safety of XXX in Subjects with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee

A Phase IIa, Double-Blind, Randomised, Parallel-Group, Multi-Centre Study to Evaluate the Analgesic Efficacy of 28 Days Oral Administration of XXX Compared to Placebo in Peripheral Neuropathic Pain Patients With Mechanical Hypersensitivity

A Phase IIa, Double-Blind, Randomised, Parallel-Group, Multi-Centre Study to Evaluate the Analgesic Efficacy of 28 Days' Oral Administration of XXX Compared With Placebo in Patients With Painful Diabetic Neuropathy

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study Evaluating the Efficacy and Tolerability of Oral XXX 300 mg TID, a Glial Cell Modulating Agent, Versus Placebo in the Treatment of Post Herpetic Neuralgia

A Randomized, Double-Blind, Placebo-and active-controlled study of the safety and efficacy of XXX in patients with Diabetic Peripheral Neuropathic pain

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group with a Crossover Confirmation Period Study of XXX for the Treatment of Postherpetic Neuralgia

A Phase III, Double Blind, Active Controlled Crossover Study to Evaluate the Efficacy and Safety of XXX Tablets Versus Immediate Release XXX for the Management of Breakthrough Pain in Opioid Tolerant Patients With Chronic Pain Followed by a 12-Week Open-Extension to Evaluate the Impact of XXX on Patient Outcomes

A Randomized, Double-Blind, Placebo-Controlled, Crossover Study of XXX For the Treatment of Neuropathic Pain in Diabetic Peripheral Neuropathy

Post-Traumatic Stress Disorder

A Phase III, Multicenter, Randomized, Double-blind, Placebo- and Active-controlled Trial of XXX (2 - 3 mg/day) as Combination Therapy with Sertraline in the Treatment of Adults with Post-traumatic Stress Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Sequential Parallel Comparison, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Assess the Safety and Efficacy of Weekly and Daily Doses of XXX in Subjects with Post-Traumatic Stress Disorder

A Randomized, Double-blind, Placebo-controlled Phase II Study of XXX in Adults with Post-Traumatic Stress Disorder (PTSD)

A Phase III, 12-Week Open-Label Extension Study to Evaluate XXX Taken Daily at Bedtime in Patients with PTSD

A Phase II, Multicenter, Randomized, Double-blind, Placebo- and Active-controlled Trial of XXX (1-3 mg/day) as Monotherapy or as Combination Therapy in the Treatment of Adults with Post-traumatic Stress Disorder (PTSD)

A Phase III, Double-Blind, Randomized, Multicenter, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX Taken Daily at Bedtime in Patients with Military-Related Post-traumatic Stress Disorder (PTSD)

A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dosage Study to Evaluate the Efficacy and Safety of XXXat Dosages up to 16 mg/day, in the Treatment of Chronic Post-Traumatic Stress Disorder (PTSD) in Adults

A 12-Month, Open-Label, Flexible-Dosage Study to Evaluate the Safety of XXX at Dosages up to 16 mg/day in Adults with Post-traumatic Stress Disorder (PTSD)

Schizophrenia / Schizoaffective Disorder

A Phase II, multi-center, randomized, double-blind, parallel group, placebo-controlled trial of the efficacy and safety of XXX vs placebo in patients with an acute exacerbation of schizophrenia or schizoaffective disorder

A Randomized, Double-blind, Parallel-group Trial to Investigate the Safety and Efficacy of XXX Versus Placebo as Adjunctive Therapy in Participants with Schizophrenia Experiencing Inadequate Response to Ongoing Antipsychotic Treatment

A Phase III Multicenter, Randomized, Double-blind, Placebo-controlled Study to determine Efficacy and Safety of XXX in Agitation associated with Schizophrenia

A Phase III Extension study to Evaluate the Safety, Tolerability, and Effect of Risperidone Extended-Release Injectable Suspension XXX for Subcutaneous Use as Maintenance Treatment in Adult and Adolescent Patients with Schizophrenia

A 56-week Open Label Extension to Assess Safety and Tolerability of XXX in Adult Subjects with Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Randomized, Double-blind, Parallel-group, Placebo-controlled, Fixed-dose, Multicenter Study to Evaluate the Efficacy and Safety of XXX in Acutely Psychotic Adult Subjects with Schizophrenia

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XXX as an Adjunctive Treatment in Adult Patients with Schizophrenia

A Phase IIIb Multi-Center, Open-Label, Mirror-Image, Trial in Adult Subjects with Schizophrenia Treated Prospectively for 6-months with XXX

A Phase II/III, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-arm Study to Assess the Efficacy, Safety, and Tolerability of XXX for the Treatment of Negative Symptoms of Schizophrenia

A Phase II, Randomized, Double-blind, Multiple-dose, Placebo-controlled Study to Evaluate the Safety and Efficacy of XXX in Subjects with Cognitive Impairment Associated with Schizophrenia (CAIS)

A Phase IIIb Double-blind, Placebo-controlled, Randomized Withdrawal Multicenter Clinical Trial Evaluating the Efficacy, Safety, and Tolerability of XXX in a Dose Reduction Paradigm in the Prevention of Relapse in Patients with Schizophrenia

A Phase III, Interventional, Randomized, Double-blind, Active-controlled Study of the Efficacy of XXX in Patients With Early-in-disease or Late-in-disease Treatment-resistant Schizophrenia

A Phase II, Randomized, Double-blind, Placebo-controlled Study to Assess the Effects of XXX in Patients with Negative Symptoms of Schizophrenia

A Phase II Study to Assess the Safety, Tolerability, and Efficacy of XXX in Hospitalized Adults with DSM-5 Schizophrenia

A Phase IIa, Randomized, Double-Blind, Placebo-Controlled, Parallel-group Study to Assess the Safety and Efficacy of XXX as Add-on Treatment for Cognitive Impairment in Subjects with Schizophrenia on Stable Doses of Antipsychotic Medication

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Risperidone Extended-Release Injectable Suspension XXX for Subcutaneous Use as Maintenance Treatment in Adult Patients with Schizophrenia

A Phase IIb, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled Study, to Evaluate the Efficacy, Safety, and Tolerability of XXX as Adjunctive Treatment in Patients with Cognitive Impairment Associated with Schizophrenia Treated with Antipsychotics

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multicenter, Randomized, Double-blind, Parallel Group, Placebo-Controlled, Mono-Therapy, 12-Week Study to Evaluate the Efficacy and Safety of 2 Fixed Doses of XXX in Adult Patients with Negative Symptoms of Schizophrenia, Followed by 36-Week Open-Label Extension

A Phase IIIb, Multicenter, Randomized, Double-blind Study to Evaluate the Efficacy and Safety of XXX or XXX for the treatment of schizophrenia in subjects hospitalized for acute exacerbation

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Intramuscular Injections of XXX in Patients with Acute Exacerbation of Schizophrenia

A Phase III, 52-Week, Open-Label, Extension Study of XXX for the Adjunctive Treatment of Schizophrenia

A Phase III, Study to Assess the Long-Term Safety, Tolerability, and Durability of Treatment Effect of XXX in Subjects with Schizophrenia, Schizophreniform Disorder, or Bipolar I Disorder

A Phase III Study to Evaluate Weight Gain of ALKS 3831 Compared to Olanzapine in Adults with Schizophrenia

A Phase III Study to Evaluate Weight Gain of XXX Compared to XXX in Adults with Schizophrenia

An Multi-center, Prospective, Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of XXX as an Add-on Treatment for Schizophrenia in Adults

A 12-week, Phase IIa Randomized, Double-blind, Placebo controlled, Parallel Group Study to Evaluate the Safety, Efficacy and Pharmacokinetics of XXX in Subjects with Cognitive Impairment Associated with Schizophrenia (CIAS)

A Phase III, Interventional, Randomised, Double-blind, Active-controlled, Fixed-dose Study of XXX in Patients with Treatment-resistant Schizophrenia

A Phase IIa, prospective, randomized, double-blind, placebo-controlled, multiple-dose study designed to determine the safety, tolerability and preliminary efficacy of an oral dose range of XXX in patients with chronic schizophrenia not responding adequately to their current antipsychotic medication

A Phase II, 6-Week, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Oral XXX Once Daily and XXX Once Daily for Treatment of Hospitalized Adult Patients With Acute Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, 52-week, Multicenter, Open-label Study to Evaluate the Effectiveness of XXX Intramuscular Depot as Maintenance Treatment in Patients With Schizophrenia

A Phase II, Randomized, Double-blind, Placebo-controlled add-on Trial of the Safety and Efficacy of XXX in Outpatients on Select Atypical Antipsychotics With Prominent Negative or Disorganized Thought Symptoms

A Phase III, Randomised, Double-Blind, Parallel-Group, Flexible-Dose Study Exploring the Neurocognitive Effect of XXX Versus Comparator in Patients With Schizophrenia Using the MATRICS Consensus Cognitive Battery (MCCB)

A Phase IIa, Single-Blind, Placebo-Controlled, Trial to Evaluate the Pro-Cognitive Effects of XXX in Patients with Schizophrenia

A Phase IIa, Multi-Center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XXX as Adjunctive Treatment in Combination with a Preexisting Antipsychotic in Patients With Cognitive Impairment Associated With Schizophrenia

A Phase IIb, Two-Period, Two-Treatment, Open-Label Two-Way, Steady-State, Crossover Bioequivalence Study of XXX under Fasting Conditions in Schizophrenia Patients

A Phase III, Long-Term Safety, Tolerability, and Effectiveness of XXX in Subjects With Schizophrenia or Schizoaffective Disorder: A Randomized, Active Comparator-Controlled Trial

A Phase II, 24-Week, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dosage Study to Evaluate the Efficacy and Safety of XXX as Adjunctive Therapy in Adults With Schizophrenia

A Six-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Phase II Study of the Efficacy and Safety of XXX in Acutely Psychotic Subjects With Schizophrenia

A Multi-Center Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Phase IIb Proof of Concept Study With 3 Oral Groups of XXX During 12 Weeks Treatment of Cognitive Deficits in Patients With Schizophrenia

A Phase III, Randomized, Placebo-Controlled, Clinical Trial to Study the Safety and Efficacy of Three Doses of XXX in Acutely Psychotic Patients With Schizophrenia

A Phase IV, Blinded-initiation Study of Medication Satisfaction in Subjects With Schizophrenia Treated With XXX ER After Suboptimal Response to Oral XXX

A Phase IV, Single-arm Evaluation of the Safety of XXX Extended-Release (ER) in Subjects With Schizophrenia or Schizoaffective Disorder With Hepatic Disease

CLINICAL TRIAL EXPERIENCE (*continued*):

A Cross-Sectional, Randomized, Non-Intervention Methods Study in Clinically Stable Outpatient Subjects with Schizophrenia

A Phase III, Randomized, Multicenter, Double-Blind, Parallel Group Study To Compare the Effects of XXX and XXX on Weight Changes in Stable Schizophrenic Patients

A Phase III, Multicenter, Open-Label, Parallel-Group, Randomized, Flexible Dose Study To Evaluate the Safety and Tolerability of Switching From Existing Atypical Antipsychotics to XXX in Subjects With Schizophrenia or Schizoaffective Disorder

A Phase III, Multicenter, Randomized, Double-blind, Parallel-group Fixed-dose Study of the Effect on Weight of XXX versus XXX in the Treatment of Outpatients With Schizophrenia

A Phase IV, Multicenter, Randomized, Double-blind, Placebo-controlled, 16 Week Study of XXX Used as Dual Therapy in the Treatment of Patients With Chronic Stable Schizophrenia or Schizoaffective Disorder Demonstrating an Inadequate Response to XXX or XXX Monotherapy

A Phase III, Multicenter, Randomized, Double-Blind, Parallel-Group Fixed-Dose Study of the Effect on Weight of XXX versus XXX in the Treatment of Outpatients With Schizophrenia

A Phase II, Randomized, Double-Blind, Placebo-Controlled, XXX-Referenced, Parallel Group Safety, Efficacy, and Tolerability Study of XXX in Subjects With Acute Exacerbations of Schizophrenia

A Phase III, Randomized, Open-label Study Comparing the Effects of XXX Depot With Oral XXX on Treatment Outcomes in Outpatients With Schizophrenia

Sleep Disorders

A Phase IV, Double-Blind, Placebo-Controlled, Study to Evaluate the Efficacy and Safety of XXX for Adults With Excessive Sleepiness Associated With Obstructive Sleep Apnea/Hypopnea Syndrome With Major Depressive Disorder or Dysthymic Disorder

A Phase II, Randomized, Double-Blind, Placebo-Controlled Subjective Study to Assess the Efficacy of XXX in Patients With Primary Insomnia Characterized by Difficulty Maintaining Sleep

A Phase III, Two-Week, Double Blind, Placebo-Controlled, Randomized, Parallel Group, Efficacy and Safety Out-Patient Trial With XXX in Patients With Chronic Primary Insomnia

A Phase II, Double-Blind, Randomized, Placebo-Controlled Study of the Efficacy, Safety and Tolerability of 8 Week Treatment of XXX 8 mg (QHS) in Sleep Disturbed, Mild to Moderately Severe Alzheimer's Disease Subjects

CLINICAL TRIAL EXPERIENCE (*continued*):

A Comparison of XXX vs. Placebo in the Treatment of Insomnia Associated with Generalized Anxiety Disorder (GAD) when used concomitantly with XXX

A Comparison of XXX vs. Placebo in the Treatment of Insomnia Associated with Newly diagnosed Major Depressive Disorder (MDD) or Untreated MDD Relapse, When Used concomitantly with XXX

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Of The Efficacy And Tolerability Of XXX Therapy Initiated With XXX Versus XXX Monotherapy In Subjects With Insomnia And Co-Existing Major Depressive Disorder

A Phase III, Efficacy and Safety of XXX 5mg/Day on Sleep Maintenance Insomnia: a 12-week, Multicenter, Randomized, Double-blind, Placebo-controlled Study

A Phase III, Depression Response to XXX in Adults With Major Depressive Disorder (XXX): A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 8-Week, Safety and Efficacy Study of XXX 3 mg Compared to Placebo in Subjects with Insomnia Related to Major Depressive Disorder

Other Indications

A Phase III, Multicenter, Open-Label Trial to Evaluate the Safety and Tolerability of XXX in the Treatment of Adult Subjects with Borderline Personality Disorder

A Short-term, Multicenter, Randomized, Flexible-dose, Double-blind Trial of XXX Versus Placebo for the Treatment of Adults With Borderline Personality Disorder

A Phase IV, Randomized, Double-blind, Placebo-controlled, Clinical trial of Structured Opioid Discontinuation versus Continued Opioid Therapy in Suboptimal and Optimal Responders to High-dose Long-term Opioid Analgesic Therapy for Chronic Pain

A Phase IIa, Randomized, Open-label, Parallel, Study to Determine the Tolerability, Pharmacokinetics, and Efficacy of XXX in Subjects with Crohn's disease experiencing Abdominal Pain

A Phase IIa, Double-Blind, Randomized, Placebo-controlled, Exploratory Study to Evaluate the Safety, Biological Activity and Pharmacokinetics of XXX in Adult Patients With Moderate-to-Severe Atopic Dermatitis

A Phase III, Randomized, Double-blind, Placebo-controlled, Trial With an Open-label Extension Phase to Evaluate the Efficacy and Safety of Subcutaneously XXX in Premenopausal Women With Hypoactive Sexual Desire Disorder (HSDD)

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Double-Blind, Randomized, Placebo-Controlled, Multicenter, Dose-Ranging Study of 100 or 250 μg of XXX to Assess the Efficacy and Safety of the Vaccine as an Aid to Smoking Cessation

CONTINUING EDUCATION:

7/9/09	Human Participants Protection Education for Research Teams online course Sponsored by the National Institutes of Health
1/30/07	Human Participants Protection Education for Research Teams online course Sponsored by the National Institutes of Health
11/19/05	Medical Research Management GCP Continuing Education Course

PUBLICATIONS:

Steer, R.A., Ball, R, Ranieri, W.F. & Beck, A.T. (in press). Dimensions of the Beck Depression Inventory-II in clinically depressed outpatients. Journal of Clinical Psychology

Beck, A.T., Guth, D., Steer, R.A., Ball, R. (1997). Screening for Major Depressive Disorders in Medical Inpatients with the Beck Depression Inventory-PC, Behavior Research and Therapy, 35, 785-791

Beck, A.T., Steer, R.A., Ball, R., Ciervo, C.A. & Kabat, M. (1997). Use of the Beck Anxiety and Depression Inventories with Medical Outpatients, Assessments, 4, 211-219

Steer, R.A., Ball, R, Ranieri, W.F. & Beck, A.T. (1997). Further Evidence for the Construct Validity of the Beck Depression Inventory-II with Psychiatric Outpatients. Psychological Reports, 80, 443-446

CLINICAL ABSTRACTS/ POSTERS/ PRESENTATIONS:

Cohen, E. A., Hassman, H. H., Walling, D. P., Wyka, K., Horan, W. P., Keefe, R. S., Grindell, V. M., Glass, S. J., Ball, R. R., Styczynski, J., Lobb, J. M., & Ereshefsky, L. (May, 2020). The Placebo-Control Reminder Script in depression and psychosis trials: An antidote for the placebo and nocebo response. Poster presented at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting, Miami, FL.

Hassman, H. H., Cohen, E. A., Walling, D. P., Wyka, K., Grindell, V. M., Glass, S. J., Ball, R. R., Styczysnki, J., Lobb, J. M., Hazzard-Randolph, D., Joseph, A. V., and Ereshefsky, L. (2020, April). The Placebo conundrum: Mitigating the response at the site level. Poster presented at the Annual Meeting of the Schizophrenia International Research Society (SIRS), Florence, Italy.

CLINICAL ABSTRACTS/ POSTERS/ PRESENTATIONS (*continued*):

Cohen, E. A., Hassman, H. H., Walling, D. P., Wyka, K., Ball, R. R., Joseph, A. V., Lobb, J. M., Hazzard-Randolph, D., Ereshefsky, L., Grindell, V., Glass, S. J., Styczynski, J. (2019, November). Broadening the Empirical Exploration of the Placebo-Control Reminder Script to Reduce Placebo and Nocebo Effects: A Preliminary Data Analysis of Subjects with Schizophrenia and Schizoaffective Disorders. Poster presented at the Annual Meeting of the CNS Summit Conference, Boca Raton, FL.

Cohen, E. A., Hassman, H. H., Walling, D. P., Hoover, S., Wyka, K., Ball, R. R., Joseph, A. V., Lobb, J. M., Hazzard-Randolph, D., Ereshefsky, L. (2018, November). A first-time investigation of a subject intervention to reduce the placebo and nocebo effects: A multicenter, randomized, single-blind, all placebo study of a Placebo-Control Reminder Script for subjects with Major Depression. Poster presented at the Annual Meeting of the CNS Summit Conference, Boca Raton, FL.

Hassman, H., Cohen, E.A., Ball, R.R., Joseph, A.V., Wyka K., Lobb, J.M., & Ereshefsky, L., (2018, February). Can subjects with Major Depression learn about key placebo response factors? The effect of an educational placebo response video. Poster presented at the Annual Meeting of the International Society for CNS Clinical Trials and Methodology Conference, Washington, DC.

Beck, A.T., Steer, R.A., Ball, R. & Ranieri, W.F. (1996). Comparison of the Beck Depression Inventories-IA and II in Psychiatric Outpatients. Journal of Personality Assessment, 67, 588-597

Ball, R. (1994) Chronic Pain. The Jefferson Journal of Psychiatry. Vol. II, 11-24

Submitted to Center for the Aging to investigate the chronic pain experience in the elderly population.

A Fresh Look at Chronic Pain. American Osteopathic Association Annual Convention and Scientific Seminar, New Orleans, LA, October 25, 1983.

Current Therapeutic Trends in Psychiatry. Allentown State Hospital, May 20, 1985.

Depression in the Chronic Pain Patient. Thomas Jefferson University Eighth Annual Conference on Psychosomatic Disorders, October 25, 1986.

Stress Management. Thomas Jefferson University Hospital OR Nurses, April 17, 1986.

Psychiatric Assessment and Treatment of Chronic Pain. Thomas Jefferson University Hospital, Department of Rehabilitation Medicine, May 28, 1986.

Psychiatric Aspects and Treatment of Patients with Spinal Cord Injury. Thomas Jefferson University Hospital Neurology Grand Rounds, September 5, 1986.

CLINICAL ABSTRACTS/ POSTERS/ PRESENTATIONS (*continued*):

Chronic Pain — A Multi-disciplinary Approach. Crozer-Chester Medical Center, September 10, 1986.

Management of Chronic Pain. Plymouth Psychological Associates, September 12, 1986.

Chronic Pain — Current Concepts Diagnoses and Treatment. Course Director, Thomas Jefferson University Hospital Ninth Annual Psychosomatic Conference, October 25, 1986.

Multi-disciplinary Evaluation and Treatment of Chronic Pain. American College of Neuropsychiatrist, Lansing, MI, March 28, 1987.

Chronic Pain from GP to the Pain Clinic. 4th Annual Philadelphia College of Osteopathic Medicine Post Founders' Day, St. Thomas U.S. Virgin Islands, January 25, 1988.

The Place for Psychiatry in Heart Disease. 4th Annual Philadelphia College of Osteopathic Medicine Post Founders' Day, St. Thomas U.S. Virgin Islands, January 28, 1988.

The Place for Psychiatry in G.I. Disease. 4t^{h} Annual Philadelphia College of Osteopathic Medicine Post Founders' Day, St. Thomas U.S. Virgin Islands, January 29, 1988.

Evaluation and Management of Chronic Pain. Beebe Hospital, Lewes, DE, March 4, 1988.

Psychiatric Aspects of AIDS. LAMBDA OMICRON GAMMA National Osteopathic Medical Fraternity Annual Meeting, Baltimore, MD, April 22, 1988.

What's New in Dementia. Pennsylvania Osteopathic Medical Association, Valley Forge, PA, April 29, 1988.

Evaluation and Management of Chronic Pain. Prince George Women's Medical Association, New Carrolton, MD, May 25, 1988.

Evaluation and Management of Chronic Pain. Frankford Hospital-Torresdale, Philadelphia, PA, September 20, 1988.

Stress and Illness. Course Director, Thomas Jefferson University Hospital Eleventh Annual Psychosomatic Conference, October 29, 1988.

Management of Chronic Pain in the Elderly. University of Medicine and Dentistry of New Jersey, Cherry Hill, NJ, 3' Annual Geriatric Conference, November 10, 1988.

Mood States, Cognitive Dysfunction and Structural Brain Lesions in Patients with Multiple Sclerosis. American Psychosomatic Society 46th Annual Meeting, San Francisco, CA, March 10, 1989.

CLINICAL ABSTRACTS/ POSTERS/ PRESENTATIONS (*continued*):

Women's Healthcare in the 90's-Depression. LAMBDA OMICRON GAMMA Osteopathic Medical Fraternity Annual Meeting, Washington D.C., April 1, 1989.

Stigma in the General Hospital. American Psychiatric Association, 142' Annual Meeting, San Francisco, CA, May 8, 1989.

Psychiatric Disorders — Recognition and Management in the General Hospital. Kessler Memorial Hospital, Hammonton, NJ December 6, 1989.

Depression and Anxiety Recognition with Management in Primary Care. 6th Annual Philadelphia College of Osteopathic Medicine Alumni Conference, St. Thomas U.S. Virgin Islands, January 26, 1990.

A Multi-disciplinary Approach to Chronic Pain. 20th European Congress on Behavior Therapy, the Faculte de Medicine, Paris, France, September 14, 1990.

Evaluation and Treatment of Depression, Department of Internal Medicine, UMDNJ-SOM, Stratford, NJ, December 22, 1990.

Evaluation and Treatment of Depression, Seventh Annual Alumni Conference Philadelphia College Osteopathic Medicine, St. Thomas, VI, February 2, 1991.

Depression Update. 8th Annual Alumni Conference Philadelphia College of Osteopathic Medicine St. Thomas, VI, January 28, 1992.

Demoralization of the American Physician. American Psychiatric Association 146th Annual Meeting San Francisco, CA, May 26, 1993.

Depression Update. Psychiatry in Primary Care Conference, UMDNJ-SOM, Stratford, NJ, September 18, 1993.

Consultation to Primary Care: Can We Do It Better? American Psychiatric Association, 147th Annual Meeting, Philadelphia, PA, May 25, 1994.

Management of the Depressed/Anxious Geriatric Patient. American College of Osteopathic Family Practitioners, East Brunswick, NJ, February 5, 1995.

Psychiatric Aspects of Menopause. American Osteopathic College of Neuropsychiatry Mid-Year Meeting, Phoenix, AZ, April 6, 1995.

Psychiatry-An Overview for Lawyers. Temple University Academy of Advocacy, Philadelphia, PA, July 12, 1995.

CLINICAL ABSTRACTS/ POSTERS/ PRESENTATIONS (*continued*):

Assessment & Treatment of Anxiety and Depression in Primary Care. Twelfth Annual Alumni Conference, Philadelphia College of Osteopathic Medicine, St. Thomas U.S. Virgin Islands, January 30, 1996.

Consultation to Primary Care: Can We Do It Better? American Psychiatric Association, 149th Annual Meeting, New York, NY, May 6, 1996.

Treatment of Psychiatric Disorders During Pregnancy. South Jersey Perinatal Cooperative, Stratford, NJ, September 30, 1996.

Chronic Pain-From Primary Care to Psychiatry. American Osteopathic College of Neuropsychiatry Mid-Year Meeting, San Diego, CA, April 3, 1997.

Psychiatric Disorders in the Elderly. Fourteenth Annual Alumni Conference, Philadelphia College of Osteopathic Medicine, St. Thomas U.S. Virgin Islands, February 28, 1998.

Preserving Quality of Outpatient Care. American Psychiatric Association, 151st Annual Meeting, Toronto, Ontario, Canada, June 4, 1998.

Manuscript for The Journal of Clinical Psychiatry — "Effects of Tiagabine plus Fluoxetine or Escitalopram in Patients with Disturbed Sleep Associated with Mild to Moderate Depression, an Open-Label Pilot.