

CURRICULUM VITAE

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AFFILIATIONS:

Florida Clinical Research Center, LLC
Maitland, FL

Manatee Glens Mental Health Facility
Bradenton, FL

Lakeside Behavioral Healthcare
Orlando, FL

EDUCATION:

1983 Bachelor of Science in Biology
Haverford College, Philadelphia, Pennsylvania

1989 Doctor of Medicine
University of Virginia, School of Medicine, Charlottesville, Virginia

RESIDENCIES:

1989 - 1993 Residency in Internal Medicine
University of Virginia, Health Sciences Center, Charlottesville, Virginia

1990 - 1994 Residency in Psychiatry
University of Virginia, Health Sciences Center, Charlottesville, Virginia

CERTIFICATION:

Certified Position Investigator (CPI), Association of clinical Research Professionals (ACRP) 2005

American Board of Psychiatry and Neurology, October 1995

American Board of Internal Medicine, December 1993

LICENSURE:

Florida Medical License: July 1995, No. ME 0068720

Drug Enforcement Agency License: Number available on request

PROFESSIONAL EXPERIENCE:

Medical Director, President, and Principal Investigator, 1998 - Present
Florida Clinical Research Center LLC, Central Florida

Courtesy Assistant Professor, Department of Psychiatry, 2007 - Present
University of Florida, Gainesville, FL

*Clinical Assistant Professor,
Department of Psychiatry and Behavioral Medicine*, 1999 - Present
University of South Florida, Tampa, Florida

Instructor, Department of Psychology, 1999 - Present
University of Central Florida, Orlando, Florida

Medical Director/Director of Psychopharmacology Research, 1998 - 2002
Lakeside Alternatives Behavioral Healthcare Systems, Orlando, Florida

Co-Medical Director/Co-Director of Psychopharmacology Research, 1996 - 1998
Psychiatric Institute of Florida, Orlando, Florida

Director of Psychiatric Medicine and Psychiatry Grand Rounds, 1995 - 1996
Florida Hospital South, Orlando, Florida

Director of Consultation-Liaison Psychiatry, Department of Psychiatry, 1994 - 1995
University of Chicago, Biologic Sciences Division, Chicago, Illinois

Director of Adult Inpatient Services, Department of Psychiatry, 1994 - 1995
University of Chicago, Biologic Sciences Division, Chicago, Illinois

Director of Psychiatric Medicine, Department of Psychiatry, 1994 - 1995
University of Chicago, Biologic Sciences Division, Chicago, Illinois

Assistant Professor, Department of Psychiatry, 1994 - 1995
University of Chicago, Biologic Sciences Division, Chicago, Illinois

INVESTIGATOR EXPERIENCE:

Attention Deficit Hyperactivity Disorder (ADHD) • Alzheimer's Disease
Anxiety Disorders including Panic and OCD
Bipolar Disorder • Cognition • Depression • Fibromyalgia • Influenza
Schizophrenia • Sleep Disorders • Substance Abuse and Other Addictions

ADDITIONAL TREATMENT EXPERIENCE:

Obesity • Pain • Pediatric Disorders • Sexual Dysfunction • Smoking Cessation

CLINICAL TRIAL EXPERIENCE:

Addiction

A Phase II, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Forced-dose Titration Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in Adults Aged 18-55 Years with Binge Eating Disorder

A Phase II, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Adaptive Study of the Safety and Efficacy of XXX in Adults with Alcohol Dependence

ADHD

A Phase II, Double-blind, Randomized, Placebo-controlled, Multicenter, Fixed-dose Study to Assess Efficacy, Safety, and Tolerability of XXX in Adults with Inattentive-Predominant Attention Deficit/Hyperactivity Disorder (ADHD)

A Phase II, Multicenter, Randomized, Double-Blind, Parallel, Placebo-Controlled Proof-of-Concept Study of XXX in Adult Males with Attention-Deficit/Hyperactivity Disorder (ADHD)

A 40-week, Double blind, Placebo controlled, Multi-center, Randomized Withdrawal Study to Evaluate the Long Term Efficacy of XXX Extended Release in Children and Adolescents with ADHD

A Phase III, parallel, randomized, double-blind, multi-center, placebo-controlled, forced dose study to evaluate the safety and efficacy of XXX extended release capsules in the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric and adolescent patients aged 6 up to 18 years.

A 6-month, Open-label Extension to a 40-week, Randomized, Double-blind, Placebo-controlled, Multicenter Efficacy and Safety Study of XXX in the treatment of Adult Patients with Childhood-onset ADHD

CLINICAL TRIAL EXPERIENCE (continued):

A Phase IIIb, Randomized, Double-blind, Multi-center, Placebo-controlled, Dose optimization, Crossover, Analog Classroom, Safety and Efficacy Study of XXX in Adolescent Subjects Aged 13-17 with Attention-Deficit/Hyperactivity Disorder (ADHD)

A 40-week, randomized, double-blind, placebo-controlled, multicenter efficacy and safety study of XXX in the treatment of adult patients with childhood-onset ADHD

A Phase I/IIa, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Safety, and Efficacy of a Single Dose of SPN-812V in Adults with Attention Deficit Hyperactivity Disorder (ADHD)

A Phase III, Double-Blind, Randomized, Multi-centre, Placebo-Controlled, Dose-optimization Study Evaluating the Safety, Efficacy, and Tolerability of Once-daily Dosing with Extended-Release XXX in Adolescents Aged 13-17 years Diagnosed With Attention Deficit/Hyperactivity Disorder (ADHD)

A Phase III, Double-blind, Placebo-Controlled, Multi-centre, Randomized-Withdrawal, Long-Term Maintenance of Efficacy and Safety Study of Extended-release XXX in Children and Adolescents Aged 6-17 With Attention-deficit/Hyperactivity Disorder

A Phase IV, Randomized, Double-Blind, Multi-center, Placebo-controlled, Parallel Group Study Evaluating the Safety and Efficacy of XXX on Executive Function (Self-Regulation) Behaviors in Adults with Attention-Deficit/Hyperactivity Disorder (ADHD) Reporting Clinically Significant Impairment of Real-World Executive Function Behavior

A Double-Blind, Randomized, Placebo-Controlled, Multi-center, Fixed Dose Titration Study to Assess Efficacy, Safety, and Tolerability of XXX in Adults with Attention Deficit/Hyperactivity Disease (ADHD)

A Phase II, Multi-center, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of XXX as Adjunctive Therapy in the Treatment of Adult Attention-deficit/Hyperactivity

A Phase III, Double-blind, Randomized, Multi-Center, Placebo controlled, Dose Optimization Study Evaluating the Tolerability and Efficacy of AM and PM Once Daily Dosing with Extended-release XXX in Children Aged 6-12 with a Diagnosis of Attention-Deficit/Hyperactivity Disorder

A Randomized, Double-Blind, Placebo- and Active-Controlled, Parallel-Group, Multicenter Study of 3 Dosages of XXX in the Treatment of Adult Subjects With Attention-Deficit/Hyperactivity Disorder

A Placebo-controlled, Double-Blind, Parallel-Group, Individualized Dosing Study Optimizing Treatment of Adults with Attention Deficit Hyperactivity Disorder to an Effective Response with XXX

CLINICAL TRIAL EXPERIENCE (continued):

A Phase IV, Double-Blind, Multi-Center, Placebo-Controlled, Randomized Withdrawal, Safety and Efficacy Study of XXX in Adults Aged 18-55 with Attention-Deficit/Hyperactivity Disorder (ADHD)

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) with Weekly Visits

A Follow-Up Extension, 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) with Weekly Visits for the First Month and Monthly Over Approximately One Year

A Randomized, Multi-Center, Double-Blind, Placebo-Controlled, 3x3 Cross-Over Study Demonstrating Superior Efficacy of XXX Versus XXX in children, Aged 6-12 Years, with Attention-Deficit/Hyperactivity Disorder (ADHD) in a Laboratory Classroom Setting

A Phase III, Double-Blind, Randomized, Placebo-Controlled, Multi-Center, Dose Optimization Study Evaluating the Efficacy and Safety of XXX in Combination with Psychostimulants in Children and Adolescents Aged 6-17 with a Diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD)

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

A Phase III, Multi-Center, 12-Month, Open Label Safety Study of XXX in Adults 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.

A 12-Month Open Label Study of XXX in Children with Attention Deficit Hyperactivity Disorder

A Multi-Center, Double-Blind, Three Arm, Parallel-Group Study Comparing the Efficacy of Immediate Release XXX and Modified Release with Placebo in Children with Attention Deficit Hyperactivity Disorder

A Multi-Center, Open Label Trial of the Safety of XXX for 12 Months in Adults with Attention Deficit Hyperactivity Disorder

CLINICAL TRIAL EXPERIENCE (continued):

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of Four Weeks' Duration of the Efficacy and Safety of Three Doses of XXX Compared to Placebo in Adults with Attention Deficit Hyperactivity Disorder

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of XXX in Children with Attention Deficit Hyperactivity Disorder

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of XXX in Adults with Attention Deficit Hyperactivity Disorder

Anxiety

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Fixed-Dose Study Comparing the Efficacy and Safety of a Single Dose of XXX in Acute Treatment of Adults with Generalized Anxiety Disorder

A Double-Blind, Randomized, Placebo and Active-Controlled, Multi-Center Study Examining the Efficacy and Safety of XXX in Subjects with GAD

A Multi-Center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled 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 Selective Serotonin Reuptake Inhibitor or Serotonin-Norepinephrine Reuptake Inhibitor Alone or in Combination with Benzodiazepine

A Randomized, Double-Blind, Placebo and Active Comparator Controlled, Parallel-Group Safety and Efficacy Study of XXX in Adults with Generalized Anxiety Disorder

A Long-Term, Open Label Safety and Efficacy Study of XXX in Adults with Generalized Anxiety Disorder.

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy and Safety of Two Flexible Dosing Regimens of XXX in Subjects with DSM-IV Defined Generalized Anxiety Disorder.

An Eight-Week, Double-Blind, Placebo-Controlled, Multi-Center Study with XXX as Positive Control, Evaluating the Efficacy, Safety, Tolerability of a Fixed Dose of XXX in Outpatients with Generalized Anxiety Disorder.

A Double-Blind Placebo-Controlled Study of XXX in the Treatment of Adults with ADHD and Comorbid Social Anxiety Disorder.

A Four-Week, Double-Blind, Placebo and Active Controlled, Dose-Ranging Study of XXX, Three Doses and XXX in Outpatients with Generalized Anxiety Disorder

CLINICAL TRIAL EXPERIENCE (continued):

A Double-Blind, Placebo-Controlled Study of XXX in Children and Adolescents with Generalized Anxiety Disorder

A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Fixed Dose Study of the Efficacy, Safety and Tolerability of XXX Extended Release Compared to Placebo in Patients with Generalized Anxiety Disorder

A Flexible Dose Comparison of the Safety and Efficacy of XXX and Placebo in the Treatment of Generalized Anxiety Disorder

A Multi-Center, Double-Blind, Randomized, Placebo-Controlled Trial of the Safety and Efficacy of XXX as Add-On Therapy with XXX or XXX in the Treatment of Acute Mania

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of Flexible Doses of XXX in the Treatment of Hospitalized Patients with Acute Mania

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of Two Fixed Doses of XXX in the Treatment of Hospitalized Patients with Acute Mania

A Multi-Center, Randomized, Placebo-Controlled Trial of the Safety and Efficacy of XXX as Add-On Therapy with XXX or XXX in the Treatment of Acute Mania

A Phase III, Randomized, Placebo-Controlled Study Evaluating the Safety and Outcome of Treatment with Oral XXX in Subjects with Mania Who Are Receiving XXX

A Randomized, Double-Blind, XXX-and Placebo-Controlled Study of the Efficacy and Safety of XXX in Outpatients with Generalized Anxiety Disorder

A Study Evaluating the Safety and Outcome of Treatment with Oral XXX in Subjects with Mania Who Are Receiving XXX

An Open Label Extension Study of the Safety and Efficacy of XXX in Patients with Generalized Anxiety Disorder

An Open Label Study of the Safety, Tolerability and Efficacy of XXX in Patients with Generalized Anxiety Disorder

A Study of XXX in the Treatment of Signs and Symptoms of Mania in Elderly Patients with Dementia

The Efficacy and Safety of Single Dose Ranges of XXX vs. Placebo in the Treatment of Manic Episodes Associated with Bipolar Disorder I

A Double-Blind, Multi-Center, Placebo-Controlled Study of XXX vs. XXX in the Treatment of Outpatients with Generalized Anxiety Disorder

CLINICAL TRIAL EXPERIENCE (continued):

Bipolar Disorder

A Double-Blind, Placebo-Controlled Study of XXX in Bipolar Depression

A 24-Week, Flexible-Dose, Open-Label Extension Study of XXX for the Treatment of Bipolar I Depression

A Multi-Center Randomized, Double Blind, Placebo-Controlled, Parallel-Group Study of XXX in the Treatment of Depression in Outpatients with Bipolar Disorder.

A Multi-Center, Double-Blind, Randomized Placebo-Controlled Double-Dummy Trial of the Use of XXX in the Treatment of Patients with Bipolar Depression

A Controlled Trial of Safety and Efficacy of XXX vs. Placebo in Patients with Bipolar Depression

A Controlled Trial of XXX vs. Placebo in Patients with bipolar Disorder in Manic or Mixed States

A 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 Three-Week Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Safety and Efficacy Study of Extended Release XXX in XXX Failure Patients with Bipolar Disorder

A Three-Week Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Safety and Efficacy Study of XXX in the Treatment of Bipolar Disorder

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

A Phase III, Randomized, Placebo-Controlled, Double-Blind Trial Evaluating the Safety and Efficacy of Sublingual XXX vs. XXX and Placebo In-Patients with an Acute Manic Episode

A Double-Blind, Nine-Week Extension Study Evaluating the Safety and Maintenance of Effect of XXX vs. XXX in the Treatment of Subjects with Acute Mania.

A Phase IIIb, Open Label Observational Safety Study of Extended-Release XXX Used in Combination with Other Psychotropic Medications for the Treatment of Bipolar I Disorder.

CLINICAL TRIAL EXPERIENCE (continued):

A Phase IIIb, Randomized, Double-Blind, Parallel-Group Study in Bipolar I Patients to Assess the Efficacy and Safety of XXX Administered Once-Daily vs. Twice-Daily in the Treatment of Manic Symptoms

An Extension Study to Evaluate the Long-Term Safety and Tolerability of XXX in the Treatment of Outpatients with Bipolar Disorder

A Six-Month, Open Label, Multi-Center Study of XXX in Patients with Bipolar Disorder

A Multi-Center, Randomized, Double-Blind Study of XXX vs. Placebo in the Treatment of Acutely Manic Patients with Bipolar Disorder

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of Flexible Doses of XXX in the Maintenance of Treatment of Patients with Bipolar Disorder

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of XXX in the Maintenance Treatment of Patients with Bipolar Disorder

A Multi-Center, Randomized, Double-Blind, Study of XXX vs. Placebo in the Treatment of Acutely Manic Patients with Bipolar Disorder

A Nine-Week, Open Label, Multi-Center Trial of Flexible Dose Ranges of XXX in the Treatment of Manic Episodes Associated with Bipolar I Disorder

A Phase III, Three-Week, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Safety and Efficacy Study of XXX in the Treatment of Bipolar I Disorder

A Three-Week Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Safety and Efficacy Study of Extended Release XXX in Patients with Bipolar Disorder

A Comparison of the Safety and Efficacy of XXX and XXX in the Treatment of Bipolar Disorder

An XXX vs. Placebo as Add-On Treatment in Subjects with Bipolar Disorder in the Outpatient Setting

An XXX vs. Placebo in the Prevention of Relapse in Bipolar Disorder

An XXX vs. XXX in the Treatment of Bipolar I Disorder, Manic or Mixed

An Evaluation of the Safety and Efficacy of XXX Compared to Placebo and XXX in the Treatment of an Acute Manic or Mixed Episode in Patients Who Have Bipolar Disorder

CLINICAL TRIAL EXPERIENCE (continued):

Depression

A Phase III, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of XXX in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant

A Randomized, 6-week, Double-Blind, Placebo-Controlled, Flexible-Dose, Parallel-Group Study of XXX For the Treatment of Major Depressive Disorder with Mixed Features

A Multicenter, Randomized, Double-Masked, Placebo-Controlled, Parallel Study to Investigate the Safety and Efficacy of 20 mg XXX versus Placebo in Adult Subjects with Major Depressive Disorder Followed by a 52-week Open-label Extension

A Phase III, Open-label, Multicenter, 12-month Extension Safety and Tolerability Study of XXX in Combination With an Antidepressant in the Treatment of Adults With Major Depressive Disorder With Residual Symptoms or Inadequate Response Following Treatment With an Antidepressant

A 12-week, Open-Label Extension Study For the Treatment of Major Depressive Disorder with Mixed Features

An 8-week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-center Study of the Efficacy and Safety of XXX Sublingual Tablets Administered Once Daily in Patients with Major Depressive Disorder (MDD)

A Multi-center, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Phase III, Efficacy and Safety Study of 3 Fixed Dose Groups of XXX as an Adjunct to an Antidepressant in Patients with Major Depressive Disorder Who Exhibit an Inadequate Response to Antidepressant Therapy

A Multi-center, Randomized, Double-Blind, Parallel Group, Active-controlled and Placebo-controlled Efficacy and Safety Study of XXX in Subjects with Major Depressive Disorder

A Phase II, Multi-center, Randomized, Double-Blind, Parallel-group, Placebo-controlled Exploratory Efficacy and Safety Study of XXX in Adults 18-55 years with Major Depressive Disorder (MDD) as Augmentation Therapy to an Antidepressant

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

CLINICAL TRIAL EXPERIENCE (continued):

A Phase II, Six-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Assessment of the Efficacy, Safety, Tolerability, and Steady-State Pharmacokinetics of XXX in Subjects with Major Depressive Disorder

A Randomized, Double-Blind, Placebo-Controlled Parallel-Group, Assessment of the Efficacy, Safety and Tolerability of XXX TID in Subjects with Major Depressive Disorder

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

A Long-Term, Open-Label Study of XXX in Adult Patients with Major Depressive Disorder

A One-Year Open Label Study Assessing the Safety of XXX in Patients with Major Depressive Disorder

A Double-Blind, Randomized, Placebo-Controlled, Double-Dummy, Multi-Center Study Examining the Safety, Efficacy and Tolerability of XXX in Subjects with SSRI Resistant Major Depressive Disorder

A Phase IIa Multi-Center, Randomized Double-Blind, Double-Dummy, and Placebo- and Active-Controlled Study to Investigate the Safety and Efficacy of XXX Administered to Subjects with Major Depressive Disorder

A 52-Week, Multi-Center, Open Label Study Evaluating the Long-Term Safety and Tolerability of XXX in Adult and Elderly Subjects with Major Depressive Disorder.

A Two-Week, Double-Blind, Placebo-Controlled Study of XXX in the Treatment of Severe Major Depressive Disorder

A Double-Blind Comparison of the Safety and Efficacy of XXX and XXX in the Treatment of XXX Non-Responders

A Double-Blind, Multi-Center, Placebo- and Active- Controlled, Acute and Extension Study of XXX in the Treatment of Major Depressive Disorder

A Double-Blind, Placebo- and XXX-Controlled, Multi-Center Study Evaluating the Efficacy of XXX in Patients with Major Depressive Disorder

A Double-Blind, Placebo-Controlled, Multi-Center Study of the Long-Term Efficacy of XXX in the Maintenance of Antidepressant Effect In-Patients with Major Depressive Disorder

CLINICAL TRIAL EXPERIENCE (continued):

A Flexible Dose Comparison of the Safety and Efficacy of XXX and Placebo in the Treatment of Major Depressive Disorder

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of XXX or XXX in the Treatment of Patients with Moderate Depression

A Phase IIb, Six-Week, Double-Blind, Placebo- and XXX-Controlled, Multi-Center Study to Evaluate the Safety and Efficacy of Oral XXX in Out-Patients with MDD

A Phase III Open Label Study of the Safety and Efficacy of XXX in Patients with Major Depressive Disorder with Psychotic Features Who Have Previously Demonstrated a Rapid Response to XXX or Placebo in Study XXX or XXX

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of XXX in Patients with Major Depressive Disorder with Psychotic Features

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of XXX in Patients with Major Depressive Disorder with Psychotic Features Who Are Not Receiving Antidepressants or Antipsychotics

A Six-Week, Double-Blind, Extension of a Phase II, Double-Blind, Placebo- and XXX-Controlled, Multi-Center Study to Evaluate the Safety and Efficacy of Oral XXX in Outpatients with Major Depressive Disorder

An Eight-Week, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Safety and Efficacy of Two Doses of XXX and XXX in Subjects with Major Depressive Disorder

A Double-Blind, Placebo- and XXX-Controlled, Multi-Center, Dose Ranging Study Evaluating the Efficacy and Safety of XXX in Outpatients with Severe Major Depressive Disorder

A Fixed Dose Study of Oral XXX and XXX in the Treatment of Outpatients with Moderate Depression

The Maintenance of Antidepressant Effect of XXX in Geriatric Outpatients

An XXX vs. Placebo vs. XXX in the Acute Treatment of Major Depression

A Double Blind, Placebo-Controlled, Multi-Center Study of the Long-Term Efficacy of XXX in the Maintenance of Antidepressant Effect in Geriatric Outpatients with Major Depressive Disorder

A Phase III, Open Label Study of Safety, Tolerability, and Efficacy of the XXX in Elderly Subjects with Major Depressive Disorder

CLINICAL TRIAL EXPERIENCE (continued):

An Open Label Extension Study of the Safety and Efficacy of XXX in Patients with Major Depressive Disorder

Schizophrenia

Evaluation of the Long-Term Safety, Tolerability and Pharmacokinetics of XXX in Patients with Schizophrenia

A Double-Blind, Placebo and Active-Controlled Evaluation of the Safety and Efficacy of XXX in the Acute Exacerbation of Schizophrenia

A 52-week, Multicenter, Open-label Study to Evaluate the Effectiveness of as Maintenance Treatment in Patients with Schizophrenia

A Phase II, 6-week, Multi-center, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of XXX Once Daily and XXX Once Daily for Treatment of Hospitalized Adult Patients with Acute Schizophrenia AND Extension Study, A Phase II, Multi-center, Open-label Study to Assess the Safety and Tolerability of XXX Flexible-dosed as Monotherapy in Adult Patients with Schizophrenia

A Phase III, Randomized, Placebo- and Active Comparator-Controlled Clinical Trial to Study the Safety and Efficacy of Two Doses of XXX in Acutely Psychotic Subjects with Schizophrenia

A 38-week, Multicenter, Randomized, Double-Blind, Active-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of an Intramuscular Depot Formulation of XXX as Maintenance Treatment

A Multi-Center, Double-Blind, Randomized, Placebo-controlled, Study to Evaluate the Long-term Efficacy, Safety, and Tolerability of an Intramuscular Depot Formulation of XXX 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 Randomized, Double-Blind, Placebo- and XXX-Controlled, Multi-Center Study to Evaluate the Efficacy and Safety and Tolerability of XXX Given BID for 28 Days to Schizophrenic Patients in Acute Exacerbation Followed by a Long-Term Treatment Phase

A Six-Week, Multi-Center, Double-Blind, Double-Dummy, Randomized Comparison of the Efficacy and Safety of Sustained Release Formulation XXX and Placebo in the Treatment of Acutely Ill Patients with Schizophrenia

CLINICAL TRIAL EXPERIENCE (continued):

A Multi-center, Randomized, Double-Blind, Fixed-Dose, Six-Week Trial of the Efficacy and Safety of XXX Compared with Placebo Using XXX Positive Control in Subjects with Acute Exacerbation Schizophrenia

A Six-Week, Double-Blind, Randomized, Fixed Dose, Parallel-Group Study of Efficacy and Safety of Three Dose Levels of XXX Compared to Placebo and XXX in Patients with Schizophrenia Who Are Experiencing an Acute Exacerbation of Symptoms

A Controlled Trial of XXX vs. XXX in the Treatment of Schizophrenic and Schizoaffective Subjects with Prominent Negative Symptoms

A Controlled Trial of XXX vs. XXX in the Treatment of Schizophrenic and Schizoaffective Subjects with Comorbid Depression

A Double-Blind, Randomized, Fixed Dose, Placebo-Controlled, Parallel-Group, Six-Week, Efficacy, Safety and Tolerability Study of Two Dose Levels of XXX in Patients with Schizophrenia by DSM-IV Criteria Who Are Experiencing Acute Exacerbation of Symptoms

A Double-Blind, Placebo and XXX-Controlled, Multi-Center Study Evaluating the Safety and Efficacy of XXX in Schizophrenic Patients

A Double-Blind, Randomized, Fixed Dose, Placebo-Controlled, Parallel-Group, Six-Week Efficacy, Safety, and Tolerability Study of Two Dose Levels of XXX in Patients with Schizophrenia by DSM-IV Criteria Who Are Experiencing an Acute Exacerbation of Symptoms

A Double-Blind, Randomized, Multi-Center, Parallel-Group Design Study to Evaluate the Efficacy and Safety of Two Dose Ranges of XXX in Comparison with Placebo and XXX in the Treatment of Schizophrenia

A Multi-Center, Double-Blind, Randomized Comparison of the Efficacy and Safety of Sustained-Release Formulation XXX and Placebo in the Treatment of Patients with Schizophrenia

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of Three Fixed Doses of XXX in the Treatment of Patients with Acute Schizophrenia

A Phase II, Six-Week, Double-Blind, Placebo- and XXX-Controlled Study Evaluating the Safety and Efficacy of Oral XXX in Schizophrenia and Schizoaffective Disorder

An Open Label, Long-Term Follow-up Safety Study of XXX in Schizophrenic/Schizoaffective Patients

CLINICAL TRIAL EXPERIENCE (continued):

An Open Label, Treatment Switching Study from Orally Administered Antipsychotic Mono-Therapy to Orally Administered XXX Mono-Therapy in the Treatment of Chronic Schizophrenic and Schizoaffective Patients

A Randomized, Double-Blind, Placebo- and XXX-Controlled, Multi-Center Study to Evaluate the Efficacy and Safety of Two Non-Overlapping Dose Ranges of XXX Given BIP for 42 Days to Schizophrenic Patients Followed by a Long-Term Treatment Phase with XXX Given QD

A Randomized, Double-Blind, Placebo- and XXX-Controlled, Multi-Center Study to Evaluate the Efficacy and Safety of Two Non-Overlapping Dose Ranges of XXX Given BIP for 42 Days to Schizophrenic Patients Followed by a Long-Term Treatment Phase with XXX

A Randomized, Double-Blind, Placebo-Controlled, XXX-Referenced, Dose Finding Study of XXX in the Treatment of Schizophrenia

The Cost Effectiveness and Functional Outcomes XXX in the Treatment of Schizophrenia in Usual Clinical Practice: A Randomized Clinical Study

The Efficacy of XXX in the Treatment of Acutely Ill Non-Compliant Schizophrenic Patients

A Study of the Efficacy and Safety of XXX in Schizophrenic and Schizoaffective Patients

A Multi-Center, Double-Blind, Double-Dummy, Placebo-Controlled, Randomized Parallel- Group Evaluation of the Efficacy and Safety of a Fixed Dose of XXX vs. Placebo vs. XXX in Subjects with Schizophrenia

A Randomized, Open Label, Rater-Blinded, Assessment of Optimal Treatment Change Strategy to XXX for Patients Intolerant of XXX

Sleep Disorders

A Double-Blind, Randomized, Multi-Center, Placebo-Controlled, Parallel-Groups, Efficacy and Safety Extension Study of XXX in the Treatment of Adult Outpatients with Primary Insomnia.

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Safety and Efficacy Study of XXX in Elderly Subjects with Chronic Insomnia

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Efficacy and Safety of a Modified Release Formulation of XXX in Adult Primary Insomnia Patients with Sleep Maintenance Difficulties

CLINICAL TRIAL EXPERIENCE (continued):

A Phase III, Open Label, Fixed Dose Study to Determine the Safety of Long-Term Administration of XXX in Subjects with Chronic Insomnia

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Safety and Efficacy Study of XXX in Adults with Chronic Insomnia

A Phase III, Open Label, Outpatient Extension Study to Assess the Long-Term Safety of a Modified Release Formulation of XXX in Adult Primary Insomnia Patients with Sleep Maintenance Difficulties

Other Indications

A Phase IV, 26-Week Randomized, Double-Blinded, Active Controlled Study Comparing the Safety of XXX Fixed Dose Combination Versus XXX Monotherapy in Adolescents and Adults With Persistent Asthma

A Phase IV, Flexible Dosed XXX Versus Placebo in the Treatment of Fibromyalgia

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate XXX in Patients with Alzheimer's Disease of Mild to Moderate Severity

A Randomized, Open Label, Dose Blinded, Multi-Center, Six-Month Study of Safety and Tolerability of Three Dose Levels of XXX

A Comparison of Efficacy and Safety of XXX, XXX, and Placebo in the Treatment of Elderly Subjects Presenting with Alzheimer's Dementia and Psychoses or Other Selected Psychoses

An Open Extension Study Evaluating the Safety and Outcome of Oral XXX

An Open Label Extension Study of XXX in Treatment of Signs and Symptoms of Mania in Elderly Patients with Dementia

A Study of XXX (Also Known as XXX) Used in Elderly Subjects for the Prevention of Clinical Influenza During the Influenza Season