Donald J. Garcia, Jr., MD
7900 FM 1826
Health Plaza I, Suite 260
Austin, TX 78737

CONTACT INFORMATION:

Donald J. Garcia, Jr., MD
Cell: (512) 415-2401
Email: djgarciajr@gmail.com

AFFILIATIONS:

March 2016 to present
Seton Healthcare Network of Physicians Staff

EDUCATION:

August 1983-May 1987 Bachelor of Arts, Major: Biology
Rice University, Houston, Texas

August 1986-May 1990 Doctorate of Medicine
University of Texas Medical Branch, Galveston, Texas

INTERNSHIP AND RESIDENCIES:

July 1990-1991 Internship
University of Texas Southwestern Medical School, Parkland Memorial Hospital, Dallas, Texas

July 1991-June 1994 Residency, Area: Psychiatry
Parkland Memorial Hospital, University of Texas Southwestern Medical School, Dallas, Texas

July 1993-1994 Fellowship, Area: Geriatric Psychiatry
University of Texas Southwestern Medical School, Dallas, Texas

CERTIFICATION:

Diplomate, American Board of Psychiatry and Neurology, May 1997/March 2007

Fellowship, Royal Australian and New Zealand College of Psychiatrists, October 2002

LICENSURE:

Alabama State Medical License, License No. 18743 (1995)

Texas State Board of Medical Examiners, License No. H9939 (1991)

PROFESSIONAL EXPERIENCE:

Owner and Medical Director, March 2016 – Present
Donald J. Garcia, Jr., MD, PA, Austin, TX

President and Medical Director, May 2003 – Present
FutureSearch Clinical Trials, LP, Austin, TX

Investigator (Principal and Co-Investigator Roles), January 2001 – June 2003
Integrated Mental Health Service, Gold Coast Hospital, Southport, Queensland, Australia
Department of Research Clinical Trials Division

Staff Specialist and Consultant Psychiatrist, February 2002- June 2003
Clinical Director Mental Health Services for the Elderly, Gold Coast Hospital, Southport, Queensland, Australia

Site Coordinator and Instructor, MBBS Year 3 Medical Student Education, July 2002 – June 2003
University of Queensland, Brisbane, Queensland, Australia

Chairman, Committee for Electroconvulsive Therapy, January 2001 – June 2003

Locum Psychiatrist, January 2001 – January 2002
Global Medical Staffing assignment at Gold Coast Hospital, Southport, Queensland, Australia

Senior Lecturer in Psychiatry, May 2002- July 2003
University of Queensland, Brisbane, Queensland, Australia

Private Practice, February 1995 – January 2001
Outpatient & Inpatient care of Adult, Pediatric, and Geriatric Patients, Cullman, Alabama

Physician Advisor, August 2000 – January 2001
Blue Cross Blue Shield of Alabama

Staff Psychiatrist, July 1994 – January 1995
Terrell State Hospital, Terrell, TX

Associate Clinical Instructor, Department of Psychiatry, August 1994 – February 1995
University of Texas Southwestern Medical School, Dallas, TX

Private Practice, July 1994 – February 1995
Dallas, Texas General Psychiatry

PROFESSIONAL ORGANIZATIONS

American Medical Association

Travis County Medical Association

Texas Society of Psychiatric Physicians

President Cullman County Medical Society (Alabama) December 1998 – December 2000

Texas Medical Association

American Psychiatric Association

INVESTIGATOR EXPERIENCE:

Phase I • Attention Deficit Hyperactivity Disorder (ADHD) • Anxiety Disorders
Bipolar Disorder • Cognition • Depression • Fibromyalgia • Pediatric Psychiatry
Post Traumatic Stress Disorder • Sexual Dysfunction • Schizophrenia • Substance Abuse

ADDITIONAL TREATMENT EXPERIENCE:

Migraine • Obesity • Simple Hypertension • Smoking Cessation

CLINICAL TRIAL EXPERIENCE:

Phase I

Effect of XXX on Ambulatory Heart Rate and Blood Pressure in patients with Major Depressive Disorder who are being Treated with XXX

A Study Investigating the Potential Interaction Between XXX and Antipsychotic Treatments in Subjects with Schizophrenia or Schizoaffective Disorder

A Placebo- and Positive-Controlled, Randomized Study, Evaluating Qt and Qtc Intervals Following Administration of Immediate-Release an Atypical Antipsychotic in Subjects with Schizophrenia or Schizoaffective Disorder

ADHD - Adult and Child

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

CLINICAL TRIAL EXPERIENCE (continued):

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 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 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, Multi-center Study of 3 Dosages of XXX in the Treatment of Adult Subjects with Attention-Deficit/Hyperactivity Disorder

A Phase IIa, Multi-center, Randomized, Double-blind, Placebo-controlled, Cross-Over Study to Assess the Efficacy, Safety and Pharmacokinetics of two Oral XXX a Dose Regimens and Placebo during 2 weeks of Treatment in Adult Users of Nicotine Containing Products and three Oral XXX Dose Regimes and Placebo during 2 weeks of Treatment in Adult Non-Users of Nicotine Containing Products in Patients with Attention-Deficit/Hyperactivity Disorder (ADHD)

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/Hyper-activity 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 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 Multi-center, Double-Blind, Placebo-Controlled, Randomized, Parallel-Group Study to Investigate the Safety and Efficacy of XXX in Adults with Attention-Deficit/Hyperactivity Disorder

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

A Prospective, Open-Label, Multi-center, Dose-Optimization Study Evaluating the Safety and Tolerability of XXX in Children Aged 6-12 Diagnosed with ADHD

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 Randomized, Double-Blind, Placebo-Controlled, Crossover Pilot Study of the Safety and Efficacy of Multiple Doses of XXX in Adults with Attention Deficit-Hyperactivity Disorder (ADHD)

A Phase IV, Multi-center, Open-Label Study of XXX to Characterize the Dermal Reactions in Pediatric Patients Aged 6-12 with Attention-Deficit/Hyperactivity Disorder (ADHD)

A Placebo-Controlled, Double-Blind, Parallel-Group, Dose-Titration Study to Evaluate the Efficacy and Safety of XXX Extended-Release Tablets in Adults with Attention Deficit Hyperactivity Disorder At Doses of 36 Mg, 54 Mg, 72 Mg, 90 Mg, or 108 Mg Per Day

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

A 24-Month, Open Label Study of XXX in Adults with Attention Deficit Hyperactivity Disorder

A Phase II, Randomized, Multi-center, Double-Blind, Parallel-Group, Placebo-Controlled, Safety and Efficacy Study of XXX in Adults Aged 18-55 with Attention Deficit Hyperactivity Disorder (ADHD)

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

A Phase IIIb, Open Label, Multi Center Study to Access Safety, Tolerability and Effectiveness Associated with the Use of XXX in Adults with Attention Deficit Hyperactivity Disorder and Evaluate an ADHD-Specific Novel Quality of Life Measure

Anxiety Disorders

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

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 Phase III, Randomized Double-Blind, Parallel-Group 10-week Placebo-Controlled Fixed Dose Study of XXX and XXX Evaluating the Efficacy and Safety of XXX for the Treatment of GAD

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, Placebo-Controlled, Phase II, Exploratory Study to Evaluate the Effect of XXX on Anxiety in Patients with Moderate to Severe Generalized Anxiety Disorder

A Multi-center, Randomized, Double-Blind, Placebo- and XXX-Controlled Trial of the Safety and Efficacy of XXX in the Treatment of Outpatients with GAD

An Eight-Week, Multi-center, Randomized, Double-Blind, Placebo-Controlled Study, with XXX as an Active Control, to Evaluate the Efficacy, Safety and Tolerability of a XXX Once Daily, in Patients with Generalized Anxiety Disorder

A Comparison of XXX Extended-Release vs. Placebo in the Treatment of Insomnia Associated with Generalized Anxiety Disorder (GAD) when Used Concomitantly with XXX.

An Eight-Week, Multi-center, Double-Blind, Placebo- and XXX-Controlled Study Evaluating the Efficacy and Tolerability of Two Fixed Doses of XXX in Outpatients with General Anxiety Disorder

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

An Eight-Week, Double-Blind Placebo-Controlled, Multi-center Study with XXX as Positive Control, Evaluating the Efficacy, Safety and Tolerability of a Fixed Dose of XXX in Outpatients with General Anxiety Disorder (GAD)

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multi-center Study to Evaluate the Efficacy, Safety and Tolerability of XXX in Patients with Generalized Anxiety Disorder

A Comparison of XXX, XXX, and Placebo in Generalized Anxiety Disorder

The Efficacy of XXX as Adjunctive Therapy in Subjects with Insomnia Related to Generalized Anxiety Disorder (GAD)

A 10-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of XXX in the Treatment of Adults with Generalized Anxiety Disorder

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

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

A Four-Week Double-Blind, Placebo and Active Controlled, Dose-Ranging Study of 3 Doses of a Novel Anxiolytic and XXX in Outpatients with Generalized Anxiety Disorder

A Double-Blind, Flexible Dose, Comparison of XXX, and Placebo in the Treatment of Generalized Anxiety Disorder

A Double-Blind, Multi-center, Placebo-Controlled Study of XXX in Generalized Anxiety Disorder

Bipolar Disorder

A Phase III, Long-Term Open-Label Study of the Safety and Tolerability of XXX in Patients with Bipolar I Disorder

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

A Long-Term Open-Label Study of the Safety and Tolerability of XXX in Patients with Bipolar I Disorder

A 6-Month, Open-Label, Flexible-Dosage (150-200 mg/day) Extension Study of the Safety and Efficacy of XXX Treatment as Adjunctive Therapy in Adults With Major Depression Associated With Bipolar I Disorder

A Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dosage Study to Evaluate the Efficacy and Safety of XXX Treatment (150 and 200 mg/day) as Adjunctive Therapy in Adults with Major Depression Associated with Bipolar I Disorder

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

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

An Eight-Week, Multi-center, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled, Phase IV Study of the Efficacy and Safety of XXX Extended-Release as Mono-Therapy in Children and Adolescent Patients with Bipolar Depression

A Multi-center, Randomized Eight Week, Double-Blind, Placebo-Controlled, Flexible Dose Study to Assess the Safety, Tolerability and Efficacy of XXX in the Treatment of Bipolar I Depression.

A Dose-Escalating, Phase II Study to Assess the Safety and Tolerability of XXX in 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.

An International, Multi-center, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled, Phase III Study of the Efficacy and Safety of XXX and XXX as Monotherapy in Adult Patients with Bipolar Depression

A Multi-center, Randomized, Double-Blind, Placebo-Controlled, Study of XXX in the Treatment of Patients with Bipolar I Disorder with A Major Depressive Episode

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

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 Multi-center, Randomized, Double-Blind, Placebo-Controlled, Multi-Dose Efficacy and Safety Study of XXX for Inhalation in Patients with Bipolar I Disorder and Agitation

A Phase III, Randomized, Six-Month, Double-Blind Trial in Subjects with Bipolar I Disorder to Evaluate the Continued Safety and Maintenance of Effect of XXX Plus A Mood Stabilizer (vs. Placebo Plus A Mood Stabilizer) Following A Minimum of Two Months of Response to Open-Label Treatment with Both Agents

A Multi-center, 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 Mania

A Multi-center, Randomized, Double-Blind, Placebo-Controlled Clinical Research Study to Evaluate the Safety and Efficacy of XXX in Patients with Acute Mania in Bipolar Disorder .

A Randomized, Double-Blind, Active- and Placebo-Controlled, Parallel-Group, Multi-center 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

XXX vs. XXX and Placebo in the Treatment of Mild to Moderate Mania Associated with Bipolar I Disease

An Extension Trial of XXX in Combination with XXX or XXX for the Treatment of Bipolar Disorder-Manic or Mixed Episode

A Randomized, Double-Blind, Placebo-Controlled, Multi-center Study to Evaluate the Efficacy and Tolerability of XXX in the Treatment of Manic Episodes of Bipolar Disorder Over 3 Week, and 52 Week, Open Label Extension Study to Evaluate the Safety and Tolerability of XXX in the Treatment of Manic Episodes of Bipolar 1 Disorder

Efficacy of XXX in Combination with XXX or XXX in the Long Term Treatment of Mania in Patients with Bipolar I Disorder Partially Nonresponsive to XXX or XXX Monotherapy

A Phase III, Randomized, Placebo-Controlled, Double-Blinded Trial Evaluating the Safety and Efficacy of XXX in Subjects Continuing XXX or XXX for the Treatment of an Acute Manic or Mixed Episode

A Multi-center, Randomized, Parallel-Group, Double-Blind, Phase IV Comparison of the Efficacy and Safety of XXX (Oral Tablets Daily in Divided Doses) to Placebo as Adjunct Therapy to Mood Stabilizers (XXX or XXX) in the Treatment of Bipolar I Disorder and Alcohol Dependence in Adult Patient Receiving Treatment for 12 Weeks

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

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

A Phase III, Randomized, Placebo-Controlled, Double-Blind Trial Evaluating the Safety and Efficacy of Sublingual XXX vs. XXX and Placebo in 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 Multi-center, Randomized, Parallel-Group, Double-Blind, Phase III Comparison of the Efficacy and Safety of XXX (Oral Tablets 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

A 21-Day, Inpatient, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Efficacy and Safety of XXX in the Treatment of the Manic Phase of Bipolar Disorder

A Randomized, Inpatient, Double-Blind, Comparison of the Efficacy and Safety of XXX Intramuscular Formula XXX or Placebo in the Treatment of Acutely Agitated Patients with Bipolar I Disorders, Manic or Mixed

A Three-Week, Multi-center, Double-Blind, Parallel, Placebo-Controlled, Study of the Efficacy and Safety of XXX in the Treatment of Children and Adolescents with Bipolar I Mania

A Double-Blind, Multi-center, Placebo and Active Controlled Study of XXX in the Treatment of Acute Mania

Depression

A Randomized, Double-blind, Placebo-controlled, Parallel Group, Phase II Study of XXX in Subjects with Major Depressive Disorder

A Phase III Randomized, Placebo-controlled, Double-blind Study of XXX Fixed-dose 12 mg and 18 mg Once Daily as Adjunctive Treatment for Patients With Major Depressive Disorder Who Are Partial Responders to XXX Treatment

A Phase III, Long-Term, Open-Label, Flexible-Dose, Extension Study Evaluating the Safety and Tolerability of XXX in Subjects with Major Depressive Disorder

A Randomized, 6-week, Open-Label Study Evaluating the Safety, Tolerability, and Efficacy of XXX for the Treatment of Schizophrenia or Schizoaffective Disorder in Subjects SWITCHED From Other Antipsychotic Agents and A 24-Week, Flexible-Dose, Open-Label Extension Study of Subjects Switched to XXX for the Treatment of Schizophrenia or Schizoaffective Disorder

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 Phase IIA, Double Blind, Placebo-Controlled Study of the Efficacy and Safety of XXX Augmentation of Antidepressant Therapy in Major Depression

A Long-Term, Open-Label, Flexible-Dose, Extension Study Evaluating the Safety and Tolerability of XXXin Subjects with Major Depressive Disorder

A Multi-center, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study of the Safety and Efficacy of XXX as Adjunctive Therapy in the Treatment of Adults with Major Depressive Disorder

A IIIb, 12-Week, Double-Blind, Placebo-Controlled, Multi-center Study Evaluating the Safety and Efficacy of XXX 1MG Bid for Smoking Cessation in Subjects with Depression

A Randomized, Double-Blind Assessment Comparing Discontinuation Symptoms in Abrupt Discontinuation vs. a One Week Tapering Regimen in MDD Patients Treated for 6 Months Open Label with 50 mg XXX Sustained Release

A Randomized, 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

Hypo-Sexual Dysfunction in Patients with Depression

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

A Study of Augmentation with XXX for Patients with Major Depressive Disorder who are Partial Responders to Selective Serotonin Reuptake Inhibitor Treatment

A Double-Blind, Efficacy and Safety Study of XXX versus Placebo in the Treatment of Children and Adolescents with Major Depressive Disorder

A Multi-center, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate Functional Outcome in Outpatients with Major Depressive Disorder Treated with XXX

A Phase IIb, Multi-center, Randomized, Double-Controlled Efficacy and Safety Study of Adjunctive XXX in Patients with Severe Major Depressive Disorder (MDD) and a History of Poor Response or Tolerability to Antidepressants

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 Long-Term, Open-Label, Flexible-Dose, Extension Study Evaluating the Safety and Tolerability of XXX 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 12-Week Randomized Open-Label Trial of XXX vs. Generic SSRIs in the Treatment of a Severe Depressive Episode

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 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 Double-Blind, Randomized, Placebo-Controlled Study Examining, the Safety, Efficacy, and Tolerability of XXX in Subjects with Major Depressive Disorder (Including Atypical and Melancholic Features)

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

A Multi-center, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled Phase III Study of the Efficacy and Safety of XXX Sustained Release (XXX) as Mono-Therapy in the Treatment of Elderly Patients with Major Depressive Disorder

A Six-Week, Randomized, Double-Blind, Placebo-Controlled Study of XXX 80 in the Treatment of Adults with Major Depressive Disorder and Concomitant Anxiety

A 52-Week, Randomized, Double-Blind, Placebo-Controlled, Multi-center, Parallel-Group Study of the Long-Term Efficacy, Tolerability, and Safety of XXX in the Prevention of Relapse of Major Depressive Disorder (MDD) Following Open-Label Treatment of 16-24 Weeks

An 8-Week, Randomized, Fixed-Dosage, Placebo-Controlled, Parallel-Group, Multi-center Study of the Efficacy, Safety and Tolerability of XXX in the Treatment of Major Depressive Disorder (MDD)

A Comparison of XXX Extended-Release 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 Multi-center, Randomized, 24-52-Week, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of XXX Once Daily in the Prevention of Relapse of Depressive Symptoms in Outpatients with Major Depressive Disorder Who Achieved an Initial Response to 12 Weeks of Open-Label Treatment with XXX Once Daily

A Multi-center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Phase III Study of the Efficacy and Safety of Sustained-Release XXX and Sustained Release (XXX) as Monotherapy in the Treatment of Patients with Major Depressive Disorder

A Multi-center, Randomized, Double-Blind, Placebo and XXX Controlled Trail of the Safety and Efficacy of XXX in the Treatment of Outpatients with Major Depressive Disorder

An Eight-Week, Multi-center, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy, Safety and Tolerability of One Fixed Dose of XXX in Patients with Major Depressive Disorder

An Eight-Week, Double-Blind Placebo-Controlled, Multi-center Study with XXX as Positive Control, Evaluating the Efficacy, Safety and Tolerability of A Fixed Dose of XXX in Outpatients with Major Depressive Disorder (MDD)

A Multi-center, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of XXX as Adjunctive Therapy in the Treatment of Patients with Major Depressive Disorder

A Multi-center, Long-Term, Open-Label Study to Assess the Safety and Tolerability of XXX as Adjunctive Therapy in the Treatment of Outpatients with Major Depressive Disorder

A Multi-center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Flexible Dose Study to Evaluate the Efficacy, Safety and Tolerability of Extended-Release XXX in Elderly Subjects with Major Depressive Disorder

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

A 12-Week, Multi-center, Randomized, Double-Blind, Double-Dummy, Parallel-Group, Active-Controlled, Escalating Dose Study to Compare the Effects on Sexual Functioning of XXX and Extended Release XXX in Subjects with Major Depressive Disorder

A Multi-center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Study of a Flexible Dose of XXX in Adult Outpatients with Major Depressive Disorder.

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

A Multi-center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Flexible-Dose Study Evaluating Efficacy, Safety, and Tolerability of Once-Daily Oral XXX vs. Placebo in Subjects with Major Depressive Disorder Over an Eight-Week Treatment Period

An Eight-Week, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Multi-center, Fixed Dose Study Comparing the Efficacy and Safety of XXX or XXX to Placebo in Moderately to Severely Depressed Patients with Major Depressive Disorder

An Open-Label Extension Study of the Long-Term Safety of XXX in Patients with Major Depressive Disorder

An XXX vs. Placebo in the Treatment of Fibromyalgia Patients with or Without Major Depressive Disorder

A Study to Evaluate the Efficacy, Safety, and Maintenance Effect of an Atypical Antipsychotic Augmentation of XXX Monotherapy in Young and Older Adult Patients with Unipolar Treatment-Resistant Depression

A Double-Blind, Placebo-Controlled, Multi-center Study of the Long-Term Efficacy of a NK1-Receptor Antagonist in the Maintenance of Antidepressant Effect in Geriatric Outpatients with Major Depressive Disorder

A Double-Blind, Multi-center, Placebo- and Active-Controlled Acute and Extension Study of a Nk1-Receptor Antagonist in the Treatment of Patients with Major Depressive Disorder with Melancholic Features

A 10-Month, Open Label Evaluation of the Long Term Safety of XXX in Outpatients with Major Depressive Disorder

A Double-Blind, Flexible Dose, Comparison of XXX in the Treatment of Major Depressive Disorder

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Eight-Week, Safety and Efficacy Study of XXX Compared to Placebo in Subjects with Major Depressive Disease and Insomnia.

An XXX vs. XXX Extended Release in the Treatment of Major Depressive Disorder

A 12-Month Open Label, Evaluation of the Long Term Safety of XXX in Outpatients with Major Depressive Disorder

Fibromyalgia

A Dose Response Study of XXX vs. Placebo in the Treatment of Fibromyalgia Syndrome.

A Multi-center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Adaptive-Design, Efficacy, Safety and Tolerability Study of Four Fixed Oral Doses of XXX in Adult Outpatients with Fibromyalgia Syndrome.

An XXX vs. Placebo in the Treatment of Fibromyalgia Patients with or without Major Depressive Disorder.

Schizophrenia

A Phase III, Multicenter, Double-Blind, Placebo-Controlled Study of 3 Doses of XXX versus Placebo in Patients with DSM-IV-TR Schizophrenia

A Long-Term, Open-Label, Multicenter Study of XXX Compared to Atypical Antipsychotic Standard of Care in Patients with DSM-IV-TR Schizophrenia

A Phase 3 Open-Label, Multicenter, Rollover, Long-term Study of XXX in Patients with Schizophrenia

A 17-Week, Phase II, Multicenter, Randomized, Double-Blind Study of Treatment with XXX Combined with Standard of Care Compared to placebo Combined with Standard of Care in the Treatment of Patients with DSM-IV-TR Schizophrenia with Prominent Negative Symptoms

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of XXX Evaluating Time to Relapse in Subjects With Schizoaffective Disorder

A Phase IIa, Multi-center, Double-Blind, Randomized, Parallel Group, 4-Week Inpatient Treatment Study to Evaluate the Safety, Efficacy, and Pharmacokinetics of Two Fixed Doses of XXXCompared to Placebo, Using XXX as an Active Control, in the Treatment of Acute Exacerbation of Schizophrenia

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

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase II Study of the Safety and Efficacy of XXXin the Treatment of Cognitive Deficits in Schizophrenia (CDS)

A Phase IIa, Randomized, Double-Blind, Active-Controlled Pilot Polysomnography Study of the Effects of XXX on Sleep in Adult Subjects with Stable Schizophrenia

A Randomized, Double-Blind, Placebo-Controlled, Parallel, 12-Week, Phase II Study of Two Different Doses of an XXX or Placebo in Schizophrenia Subjects on Chronic Stable Atypical Anti-Psychotic Therapy

A Study Investigating the Potential Interaction Between XXX and Antipsychotic Treatments in Subjects with Schizophrenia or Schizoaffective Disorder

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

An Open-Label, Drug-Drug Interaction Study to Evaluate the Effect of XXX Extended-Release on the Steady-State Pharmacokinetics of XXX in Clinically Stable Subjects with Schizophrenia, Bipolar I Disorder or Schizoaffective Disorder

A 38-week, Multi-center, 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 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 Randomized Double-Blind, Placebo-Controlled Add-on Trial of the Safety and Efficacy of XXX in Outpatients on XXX, XXX, XXX, or XXX with Prominent Negative or Disorganized Thought Symptoms

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 Patients with Schizophrenia

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

A Two-Period, Two-Treatment, Open-Label, Two-Way Steady-State Crossover Bioequivalence Study of XXX Extended Release Tablets under Fasting Conditions in Patients

A Randomized, Double-Blind, Placebo-Controlled, XXX- Referenced, Parallel-Group Study of in Subjects with Acute Exacerbations of 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 Multi-center, Randomized, Double-Blind, Placebo-Controlled Multi-Dose Efficacy and Safety Study of Staccato XXX for Inhalation in Schizophrenia Patients with Agitation

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 Single Dose, Open-Label, Randomized, Two-Period, Parallel-Group Study to Assess the Pharmacokinetics, Safety, and Tolerability of a XXX Three-Month Formulation in Subjects with Schizophrenia

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Two Fixed Dosages of Extended Release XXX in the Treatment of Subjects with Schizophrenia.

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

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose Response Study to Evaluate the Efficacy and Safety of Three Fixed Doses of XXX in Subjects with Schizophrenia

A Multi-center, Randomized, Double-Blind, Placebo-Controlled, Single Dose Efficacy and Safety Study of Staccato XXX for Inhalation in Schizophrenic Patients with Agitation.

A Randomized Double-Blind Study of XXX vs. XXX in the Treatment of Schizophrenia

A Six-Week Multi-center, Randomized, Double-Blind, Placebo-Controlled, XXX-Referenced, Parallel-Group Study to Assess the Safety and Efficacy, of XXX in Subjects with Acute Exacerbations of Schizophrenia Requiring Hospitalization.

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

A Double-Blind, Placebo-Controlled, Dose-Ranging, Parallel-Group Study in Adults with Cognitive Impairment Associated with Schizophrenia (CIAS)

A Six-Week International, Multi-center, Double-Blind, Randomized, Parallel-Group, Phase III Study to Evaluate the Feasibility of Switching from Immediate-Release XXX to Sustained-Release XXX in Outpatients with Schizophrenia

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 an Acute Exacerbation of Schizophrenia

Efficacy of High-Dose XXX in A Controlled, Fixed-Dose-Response Trial for the Treatment of Schizophrenia and Schizoaffective Disorder

A Randomized, Double-Blind, Placebo-Controlled, Parallel- Group Study with an Open-Label Extension Evaluating Extended Release XXX in the Prevention of Recurrence in Subjects with Schizophrenia

A Randomized, Double-Blind, Placebo- and XXX-Controlled, Parallel-Group Safety and Efficacy Study of Two Fixed Doses of XXX in the Treatment of Schizophrenia with Optional Open-Label Extension Treatment

An Open-Label, Flexible-Dose, Long-Term Safety and Efficacy Study of XXX in the Treatment of Schizophrenia

A Multi-center, Open-Label, Flexible-Dose, Parallel-Group Evaluation of the Cataractogenic Potential of XXX and XXX in the Long-Term Treatment of Patients with Schizophrenia or Schizoaffective Disorder

A Double-Blind, Fixed Dose Comparison of XXX and Placebo in the Treatment of Schizophrenia

An Open Label, Multi-center 12-Month Study of Long-Term Safety and Tolerability of XXX in Patients with Schizophrenia

A 12-Week Multi-center Randomized, Double-Blind, Placebo-Controlled Evaluation of XXX as Adjunctive Therapy in the Treatment of Cognitive Impairment in Patients with Schizophrenia or Schizoaffective Disorder

A 52-Week, Prospective, Randomized, Double-Blind, Multi-center Study of Relapse Following Transition from Oral Antipsychotic Medication to Two Different Doses of XXX in Adults with Schizophrenia or Schizoaffective Disorder

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

A Multi-center, Randomized, Double-Blind, Study on the Effects of XXX on Overweight Patients Treated with XXX for Schizophrenia or Schizoaffective Disorder

A Multi-center, Randomized, Double-Blind, Parallel-Group, Study to Evaluate the Efficacy and Safety of a Flexible Dose of XXX, Compared to Placebo as an Adjunctive Therapy to an Atypical Antipsychotic Agent in Subjects with Schizophrenia

A Double-Blind, Inpatient, Long Term Extension Trial to Assess the Efficacy and Safety of Qd and Bid Dose Regimes of Up to 10 Mg/Day XXX in Subjects with Schizophrenia

An Open-Label Study of XXX Tablet vs. Wafer in the Treatment of Inpatients with Acute Schizophrenia

An Open-Label Study of XXX in the Treatment of Outpatients with Schizophrenia in the Australian Population

Sleep Disorders

An Evaluation of the Long-Term Efficacy and Safety of XXX Compared to Placebo, When Both Are Administered Over a Long-Term Period "as Needed" in Patients with Chronic Primary Insomnia. (A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-center, Phase IIIb Clinical Study)

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-center Study to Assess the Efficacy and Safety of XXX in Primary Insomnia Patients with Sleep Maintenance Difficulties

A North American, Four-Week, Multi-center, Phase IIb Double-Blind, Placebo-Controlled, Randomized, Multiple Dose, Parallel-Group Study of the Efficacy and Safety of XXX Tablets in the Treatment of Sleep Maintenance Insomnia

A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of XXX as Treatment for Adults with Residual Excessive Sleepiness Associated with Obstructive Sleep Apnea/Hypopnea Syndrome

A 12-Month, Open-Label, Flexible-Dosage Extension Study of the Safety and Efficacy of XXX in the Treatment of Patients with Excessive Sleepiness Associated with Narcolepsy, Obstructive Sleep Apnea/Hypopnea Syndrome, or Chronic Shift Work Sleep Disorder

A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of XXX as Treatment for Adults with Excessive Sleepiness Associated with Chronic Shift Work Sleep Disorder

A 12-Month, Open-Label Study to Evaluate the Safety and Efficacy of XXX in Adult Patients (18 to 85 Years of Age) with Primary Insomnia

A One-Year Open-Label, Flexible-Dosage Extension Study to Assess the Safety and Continued Effectiveness of XXX Treatment in Children and Adolescents with Excessive Sleepiness Associated with Narcolepsy or Obstructive Sleep Apnea/Hypopnea Syndrome

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

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

An Evaluation of the Long-Term Efficacy and Safety of XXX Compared to Placebo, When Both Are Administered Over A Long-Term Period "as Needed" in Patients with Chronic Primary Insomnia. (A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-center, Phase IIIb Clinical Study

A Six-Month, Chronic Efficacy and Safety Study of XXX in Adult Subjects with Primary Insomnia: A Randomized Double-Blind, Placebo-Controlled Study

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Eight-Week, Safety and Efficacy Study of XXX Compared to Placebo in Subjects with Major Depressive Disease and Insomnia

Other Indications

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed Dose Study Evaluating the Efficacy and Safety of the XXX in Posttraumatic Stress Disorder (PTSD)

A Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of XXX vs. Placebo for the Treatment of Relapse Prevention in Alcohol Dependence

A Multi-center Randomized, Double-Blind, Placebo-Controlled Study of A Combination of XXX and XXX in a Continuous Daily Regimen in Subjects with Premenstrual Dysphoric Disorder

A Randomized, Double-Blind, Placebo-Controlled, Multi-center Phase III Study to Evaluate the Efficacy and Safety of XXX for 12 Weeks for the Treatment of Opioid-Induced Bowel Dysfunction in Adults Taking Opioid Therapy for Persistent Non-Cancer Pain