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Chief Clinical Officer, Apex Innovative Sciences
CEO, Collaborative Neuroscience Research, LLC
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AFFILIATIONS:

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19401 S. Vermont Avenue, Suite F-100
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Collaborative Neuroscience Research, LLC
Collaborative Neuroscience Network, LLC
2600 Redondo Avenue, Suites 415 & 500
Long Beach, CA 90806

Ocean View Psychiatric Health Facility
2600 Redondo Avenue, Suite 500
Long Beach, CA 90806

Pacific Research Partners, LLC
901 Clay Street
Oakland, CA, 94607

EDUCATION:

1989-1993 Doctor of Philosophy in Counseling Psychology
University of Southern California, Los Angeles, California, APA Accredited

1987-1989 Master of Science in Counseling
California State University at Fullerton

1985-1986 Bachelor of Arts in Psychology
California State University at Long Beach, Long Beach, California

1983-1985 Associate of Arts in Social Science
Golden West College, Huntington Beach, California

INTERNSHIP:

1992-1993 Internship
University of Texas Medical Branch, Galveston, Texas, APA Accredited

CERTIFICATION:

Clinical Hypnotherapist, 1983
Cognitive-Behavior Therapy for the Chronic Depressions: The Unipolar Mood Disorders Institute of Virginia Commonwealth University, 1996

LICENSURE:

Licensed Psychologist, State of California, License No. PSY16657
Licensed Marriage, Family & Child Counselor, State of California, License No. MFC29326
Licensed Psychologist, State of Texas, License No. 25348 – License placed on inactive status October 2000

PROFESSIONAL EXPERIENCE:

Chief Clinical Officer, 2019 – Present
Apex Innovative Sciences

Chief Executive Officer and Principal Investigator, 2000-Present
Collaborative Neuroscience Research, LLC, Garden Grove, Long Beach & Torrance, CA
Collaborative Neuroscience Network, LLC, Garden Grove, Long Beach & Torrance, CA

Vice President of Clinical Services, 1997-2000
Psychiatric Management Resources & Stadt Solutions Pharmacy Corporation, San Diego, CA

Assistant Professor of Psychiatry and Behavioral Sciences, 1995-1997
Department of Psychiatry and Behavioral Sciences, University of Texas Medical Branch, Galveston, TX

Clinical Director, 1993-1997
The Gulf Coast Center Intensive Treatment Program, Galveston, TX

Research Scientist, 1993-1995
Dept. of Psychiatry and Behavioral Sciences, University of Texas Medical Branch, Galveston, TX

Crisis Response Clinician, 1992
College Hospital, Costa Mesa, CA

Primary Therapist, 1990-1992
Harbor View Adolescent Center, Long Beach, CA

Marriage, Family, & Child Counselor, 1991-1992
Huntington Psychotherapy, Huntington Beach, CA

Clinical Coordinator, 1989-1990
Bellflower Doctors Hospital, Bellflower, CA

PROFESSIONAL EXPERIENCE (*continued*):

Clinical Social Worker/Unit Therapist, 1988-1989
Western Medical Center, Anaheim, CA

Special Member of the Faculty, 1993-1996
Graduate School of Biomedical Sciences - University of Texas Medical Branch, Galveston, TX

Member Psychology Internship Program Committee, 1993-1997
University of Texas Medical Branch, Galveston, TX

Reviewer for Psychiatric Services (formerly Hospital and Community Psychiatry)

Reviewer for Psychiatry Research

Reviewer for American Journal of Clinical Hypnosis

Reviewer for Southwestern Psychological Association 1996 annual conference

Training in the conduction and administration of the Structured Clinical Interview for Diagnosis (SCID)

INVESTIGATOR EXPERIENCE :

Phase I-IV: ADHD • Alzheimer's Disease • Anxiety • Binge Eating Disorder • Bioequivalence
Bipolar Disorder • Cognitive Impairment • Dementia • Depression • Device • Digital
Ethno-Bridging • Friedrich's Ataxia • Healthy • Insomnia
Nausea Associated with Motion Sickness • Obsessive Compulsive Disorder
Opioid Use Disorder • Schizophrenia and Schizoaffective Disorders • Sexual Dysfunction
Smoking Cessation • Tardive Dyskinesia

CLINICAL TRIAL EXPERIENCE:

Phase I

Phase I Alzheimer's

A Phase I, Double-Blind, Randomized, Placebo-Controlled, Multiple, Escalating Dose Study to Evaluate the Safety, Tolerability and Pharmacokinetics of XXX in Elderly Volunteers and in Subjects With Mild Alzheimer's Disease

A Phase I, FIM, Randomized, Double-Blind, Placebo-Controlled, Combined Single Ascending Dose and Multiple Ascending Dose Study to Assess Safety, Tolerability, Immunogenicity, Pharmacodynamic Response, and Pharmacokinetics of Intravenous Infusions of XXX in Subjects With Mild to Moderate Alzheimer's disease

CLINICAL TRIAL EXPERIENCE (*continued*):

Phase I Depression

A Phase Ib, Randomized, Double-Blind, Placebo-Controlled Study to Assess Safety and Pharmacokinetics of Adjunctive XXX in Adult Subjects with Major Depressive Disorder

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, Twice Daily Dose Study of XXX in Adult Participants with Major Depressive Disorder (Part B)

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)

A Phase I, Randomized, Double-blind, Controlled, 6-week Pilot Trial to Assess the Impact of Novel Digital Interventions Designed to Improve Cognitive Dysfunction as Adjunct Therapy to Antidepressant Medication in Adults with Major Depressive Disorder (MDD)

A Phase I, Single-center, Randomized, Investigator/ Subject-blind, Placebo-controlled, Multiple--ascending Dose, Semi-sequential Adaptive Study to Investigate the Safety, Tolerability and Pharmacokinetics of XXX Following Oral Administration in Healthy Subjects and in Patients with Major Depressive Disorder

A Phase I, Single-center, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety, Tolerability, and Pharmacokinetics of Ascending Multiple Oral Doses of XXX as Adjunctive Therapy in the Treatment of Patients with Major Depressive Disorder

A Phase I, multi-center, randomized, double-blind placebo-controlled study to assess the safety, tolerability, and pharmacokinetics of ascending high doses of xxx as adjunctive therapy in the treatment of subjects with major depressive disorder

APhase I, Randomized, Double-Blind, Placebo-Controlled Study of Safety and Pharmacodynamic Effects of XXX in Major Depressive Disorder Subjects

Phase I Healthy Japanese

A Phase I, Randomized, Double-blind, Placebo-controlled Trial to Assess the Tolerability, Safety, and Pharmacokinetics of Ascending Multiple Oral Tablet Doses of XXX in Healthy Subjects of Japanese and Non-Japanese Origin

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Multiple-Ascending Dose and Single Dose Food Effect Study to Assess the Safety, Tolerability, and Pharmacokinetics of XXX in Healthy Subjects Part A and Part B.

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Multiple-Dose Study to Assess the Safety, Tolerability, and Pharmacokinetics of XXX in Healthy Japanese and Non-Japanese Participants

A Phase I, Randomized, Double-blind, Placebo-controlled Trial to Assess the Tolerability, Safety, and Pharmacokinetics of Ascending Single Oral Tablet Doses of XXX in Healthy Subjects and in Healthy Japanese Subjects and the Effect of a High-Fat Meal

A Phase Ib, Randomized, Controlled, Double-blind Trial to Evaluate the Safety and Immunogenicity of Multivalent Pneumococcal Conjugate Vaccines in Healthy Japanese Adults Aged 18 to 49 Years

A Phase I Investigator/Subject Blind, Randomized, Placebo-controlled Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single Doses of XXX in Healthy Japanese Subjects

A Phase I Rising Single and Multiple Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX in Healthy Adult Japanese Subjects

Phase I Healthy

A Phase I, Open-label, Randomized, Single Dose, Crossover Comparative Bioavailability and Food Effect Study of Two XXX Formulations in Healthy Adult Subjects

A Phase I, Double-Blind, Randomized, Single Dose, Sequential Dose-Escalation Study to Assess the Safety, Tolerability and Pharmacokinetics of XXX in Healthy Volunteers

A Phase I, Ascending, Single Oral Dose, Double-Blind, Randomized, Placebo-Controlled Study to Assess the Safety, Tolerability, and Pharmacokinetics of XXX in Fasted Healthy Adult Male Subjects

A Phase I, Open-label, 8-week Safety Study of Oral in Normal Healthy Subjects

A Phase I, Randomized, Cross-over, 2-Period, Drug-Drug Interaction Study Evaluating the Pharmacokinetics of XXX When Administered With or Without XXX

A Phase I Study to Evaluate the Effects of XXX on the Pharmacokinetics, Safety, and Tolerability of XXX

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Placebo controlled, Double-blind, Double-dummy Threeway Cross over Trial to Investigate the Effect of XXX and XXX on Ketamine-induced Cognitive Deficits in Healthy Male Subjects

A Noninterventional Study to Evaluate Positive Detection Accuracy of the Ingestible Sensor Using Reusable Wearable XXX and the Disposable Wearable in Healthy Volunteers

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

A Phase I, Relative Bioavailability Study of an Extended Release (ER)Tablet Formulation of XXX Compared to an Intermediate Release (IR) Capsule Formulation in Healthy Volunteers

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

A Placebo-Controlled, Double-Blind, Multiple Ascending Dose Study to Evaluate the Safety, Tolerability and Pharmacokinetic Profile of XXX in Healthy Volunteers

A Phase I, Placebo-Controlled, Double-Blind, Single Ascending Dose Study to Evaluate the Safety, Tolerability and Pharmacokinetic Profile of XXX in Healthy Volunteers

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 Pharmacokinetics of XXX Oral Solution in Healthy Adults

A Phase I, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, 5-Period, Crossover Study Assessing the Effects of XXX Compared to XXX, XXX and Placebo on Simulated Driving Performance in Normal Healthy Participants

A Phase I Open-label, Dose-escalating, Non-randomized, Single-Center Study to Determine the Safety and Pharmacokinetic Profiles of XXX in Healthy Volunteers

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase I, Double-blind, Placebo-controlled Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Single Doses of XXX in Healthy Adults and in Adults with ALS

A Phase I, Randomized, Open-label, Single-Dose, Two-Way Crossover Study to Assess the Relative Bioavailability of 5 mg of XXX vs. XXX in Healthy Subjects Followed by a Phase to Study Food Effect on the PK Profile of XXX

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose Study to Assess the Safety, Tolerability, and Pharmacokinetics of XXX in Healthy Subjects

A Phase I Single Dose Crossover Comparative Bioavailability and Food Effect Study of a New Formulations of XXX vs. the Original Fixed-Dose Combination Formulation of XXX and XXX in Healthy Male Volunteers

A Phase I, Double-Blind, Placebo-Controlled, Randomized, 2 Stage, 2 Way Crossover Study of a Single Oral Dose of XXX in Healthy Adult Subjects

A Phase I, Open-Label, Randomized, 2-Way Crossover, Pilot Trial to Assess the Bioequivalence of Oral Doses of XXX versus XXX Tablets in Healthy Subjects

A Phase I Study of the Safety, Tolerability and Pharmacokinetics of XXX in Healthy Normal Volunteers

A Phase I, combined single and multiple rising dose study of the safety and pharmacokinetics of XXX combination

A Phase I / II, randomized, double-blind, placebo-controlled study to assess the effect of 3 month multiple oral doses of XXX on safety, tolerability, pharmacokinetics and pharmacodynamics in healthy elderly subjects

A Phase I, Reliability and validity of an online neurocognitive test battery, the XXX Test, in normal healthy adults

A Phase I uncontrolled, sequential cohort study in healthy subjects to assess the safety and tolerability of multiple-dose administration of XXX , assess the pharmacokinetics (PK) of XXX following multiple-dose administration, and assess the effect of dose titration schedules on the tolerability of XXX in healthy male subjects

A Phase I, prospective, randomized, double-blind, placebo-controlled, sequential-cohort, escalating, single-dose study designed to determine the maximum tolerated oral dose of XXX in healthy, male volunteers

CLINICAL TRIAL EXPERIENCE (*continued*):

Phase I Schizophrenia and Schizoaffective Disorders

A Phase IIa, single-arm, single-blind, multiple dose study to evaluate safety and the effects of XXX on electroencephalograms and event-related potentials in subjects with schizophrenia

A Phase I, Open Label, One Sequence Study to Evaluate the Steady State Comparative Bioavailability of Intramuscular XXX and XXX

A Phase I, Open-Label Study in Stable Schizophrenia Patients to Evaluate the Safety, Tolerability, and Pharmacokinetics of Switching from Oral XXX to XXX Implant (6 month and 12 month)

A Phase I, Randomized, Multiple-Dose, Open-Label, Parallel-Group Study to Evaluate the Pharmacokinetic profile over the Entire Dosing Regimen and the Relative Bioavailability at Steady-State of XXX vs. XXX in Patients with Schizophrenia and/or Schizoaffective Disorders

A Phase I, Open-label, Adaptive, Repeat-dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX Long-acting Injection (LAI) in Patients with Schizophrenia

A Phase I/II, Open-label Study to Determine the Pharmacokinetics, Safety and Tolerability of Single Ascending Doses of a Subcutaneous Injection of XXX Long-Acting Injectable (LLAI) Formulation in Patients with Schizophrenia

A Phase I, Pilot, 4-Week, Randomized, Double-Blind, Placebo-Controlled, Inpatient, Multicenter Study of the Safety, Population Pharmacokinetics, and Exploratory Efficacy of XXX in Acutely Psychotic Adult Subjects With Schizophrenia

A Phase I/II, Multiple Dose Study to Assess the Safety, Tolerability and Pharmacokinetics of XXX Extended Release Capsules in Subjects with Schizophrenia, Schizoaffective Disorder

A Randomized, Single-dose, Crossover Study of the Effects of XXX on Electrocardiogram (ECG) Intervals in Subjects with Schizophrenia

A Phase I/II Study to Evaluate the Safety, Tolerability, Efficacy and effects on Neurophysiological Biomarkers of XXX Oral Treatment in Subjects with Schizophrenia and Normal Healthy Volunteers (Part 1 SAD and Part 2 MAD)

A Phase I, Open-label, Randomized, Single Ascending Dose Trial to Determine the Pharmacokinetics, Safety, and Tolerability of XXX Long Acting Injectable in Adult Subjects with Schizophrenia

A Phase I, Single Ascending Dose and Multiple Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX for Extended-Release Injectable Suspension for Subcutaneous Use, in Healthy Subjects and in Patients with Schizophrenia or Schizoaffective Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase Ib Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Multiple Ascending Doses of XXX in Subjects with Schizophrenia

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

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, 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 Multicentre, Randomized, Open label, Steady state, Balanced, Two treatment, Two Period, Two-way Crossover, Bioequivalence Study Comparing XXX 6 mg capsule to the reference listed drug XXX capsule in patients with Bipolar I Disorder or Schizophrenia who are tolerating a stable dosing regimen of XXX 6 mg capsule once daily

A Phase I, 2-Part, Open-Label, Randomized, Crossover Pilot Trial to Assess the Relative Bioavailability of XXX versus XXX Oral Tablets in Subjects With Schizophrenia or Bipolar Disorder and 25-mg Oral Tablets in Healthy Subjects

A Phase I XXX Randomized, Double-blind, Crossover Study to Explore Dopamine Synthesis Capacity in the Whole Striatum after 2 weeks of Treatment with 150MG of XXX or Placebo in patients with Schizophrenia

A Pilot, Phase I, Randomized, Open Label, Parallel Group Study Assessing the Bioavailability of XXX vs. XXX in Adult Subjects with Schizophrenia and Schizoaffective Disorder

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose Study with Long-Acting Injectable (LAI) XXX Formulation to Evaluate Safety, Tolerability, and Pharmacokinetics of XXX in Subjects with Schizophrenia, Schizoaffective Disorder, or Schizophreniform Disorder

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, XXX Device Performance Study

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 Evaluation of the Effect of XXX on Cariprazine Exposure in Patients with Schizophrenia

A Phase I, Two-part, Open-label, Randomized, Exploratory and Single Ascending Dose, Parallel Arm Trial to Determine the Pharmacokinetics, Safety, and Tolerability of XXX Long-acting Injectable Administered Subcutaneously or Intramuscularly in Adult Subjects with Schizophrenia

A Phase I, Interventional, randomized, double-blind, parallel-group, active-control, multiple-dose study investigating the effect of XXX on cardiac repolarization in men and women with schizophrenia and schizoaffective disorder

A Phase I Randomized, Open-Label, Parallel Design, Multiple-Dose, Comparative Bioequivalence Study of XXX Extended-Release Injectable Suspension (156 mg/1.0 mL) Versus XXX Extended-Release Injectable Suspension (156 mg/1.0 mL) in Schizophrenia Patients Already Stabilized on XXX

A Phase I, Study to Evaluate the Effects of XXX on the Pharmacokinetic of XXX, in patients with Stable Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase I Study to Evaluate the Effects of XXX-Mediated Inhibition on the Pharmacokinetics, Safety, and Tolerability of XXX in Patients with Stable Schizophrenia

A Phase I, Multicenter, Randomized, Double-blind, Placebo-controlled, Crossover Trial to Evaluate the Effects of XXX in Patients with Negative Symptoms of Schizophrenia of Schizophrenia treated with Antipsychotics

A Phase I, Pilot, 20-Week, Open-Label, Randomized, Single-Dose, Two-Treatment, Crossover Study of XXX Long-Acting Injection, 25 mg and XXX, 25 mg in Male and Female Schizophrenic Subjects

A Phase I, Double-blind, Placebo-controlled, Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX in Subjects with Schizophrenia

A Phase I, Open-Label, Randomized, Multiple Dose, Safety and Pharmacokinetic Trial with Injectable XXX Compared to XXX in Patients with Chronic, Stable Schizophrenia or Schizoaffective Disorder

A Phase I, Open-Label, Single-Dose Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of Two Different Molecular Weights (Low, and High Molecular Weights as Test Treatments) of XXX Compared to Intermediate Molecular Weight (Reference Treatment) of XXX in Treatment-Seeking Subjects with Schizophrenia

A Phase I Study of XXX and XXX Co-administered with XXX in Adults with Schizophrenia

A Phase I, Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX Following Administration to the Deltoid or Gluteal Muscle in Adults with Schizophrenia or Schizoaffective Disorder

A Randomized, Double-blind, Placebo-controlled, Sponsor Open Parallel Group Phase Ib Study to Examine the Safety, Tolerability and Pharmacokinetics of Multiple Ascending Doses of XXX in Psychiatrically Stable Subjects with Schizophrenia

A Phase I, Randomized, Open-label, Study Evaluating the Pharmacokinetics, safety and tolerability of XXX when administered at 4-, 6-, and 8-week intervals to subjects with Stable Schizophrenia

A Phase I, Placebo-Controlled, Double-Blind, Ascending-Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX Alone and in Combination with XXX in Subjects with Chronic Stable Schizophrenia

A Phase I, Randomized, Open-Label, Parallel-Group Study to Assess the Relative Bioavailability of XXX and XXX at 25 mg Following Multiple Intramuscular Injections in Stable Patients With Schizophrenia or Schizoaffective Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase I, Double blind, randomized, multiple ascending dose safety, tolerability and pharmacokinetics study in patients with schizophrenia on a stable anti-psychotic regimen (other than XXX)

A Phase Ib, Open-Label Observational Pilot Study to Evaluate the Pharmacokinetics of XXX in Subjects with Bipolar 1 Disorder or Schizophrenia who have a History of Suboptimal Adherence and are Currently on Treatment with Oral XXX

A Phase I, Randomized, Single Blind, Placebo Controlled, Ascending Multiple Oral Dose Study Assessing the Safety, Tolerability, and Pharmacokinetics of XXX in Male and Female Subjects with Schizophrenia

A Phase I, Randomized Single-Blind, Placebo-Controlled, Ascending Single Oral Dose Study Assessing the Safety, Tolerability, and Pharmacokinetics of XXX in Male and Female Subjects with Schizophrenia

A Phase I, randomized, double-blind, placebo-controlled, sequential dose escalation cohort study to evaluate the safety, tolerability, and pharmacokinetics of XXX in psychiatrically stable schizophrenia subjects

A Phase I, open-label, randomized, two treatment, multiple dose, steady state, three-way crossover in vivo, pharmacokinetic study to determine the bioequivalence between XXX and XXX

A Phase I, Open-label, Multiple Dose, Safety and Tolerability Study of XXX IM Depot Administered in the Deltoid Muscle in Adult Subjects with Schizophrenia

A Phase I, Randomized, Double-blind, Placebo-controlled, Multiple-dose Study to Evaluate the Safety and Tolerability of XXX Following Deltoid Administration in Subjects with Chronic Stable Schizophrenia

A Phase I, Placebo-and Positive-controlled Study of the Electrophysiological Effects on the QT Interval after a Supratherapeutic Dose of XXX in Subjects with Schizophrenia

A Phase I, Open-label, Randomized, Parallel Arm, Bioavailability Study of XXX IM Depot Administered in the Deltoid or Gluteal Muscle in Adult Subjects with Schizophrenia

A Phase I, trial to evaluate the safety and tolerability of XXX IM depot treatment initiation in adult subjects with schizophrenia stabilized on atypical oral antipsychotics other than XXX

A Phase I, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety, Tolerability and Pharmacokinetics of Ascending, Multiple Oral Doses of XXX in Clinically Stable Adults with Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Placebo-controlled, Sponsor Open, Phase Ib Study to Examine the Safety, Tolerability and Pharmacokinetics of XXX in Psychiatrically Stable Subjects with Schizophrenia

A Phase I, Multi-center, Randomized, Double-Blind, Comparator-Controlled Study to Assess the Tolerability, Safety, Efficacy, and Pharmacokinetics of Ascending Multiple Oral Doses of XXX in Adult Subjects with a Diagnosis of Schizophrenia or Schizoaffective Disorder

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

A Phase I, Open-label parallel arm multiple dose tolerability, pharmacokinetics and safety study in adult patients with Schizophrenia following administration of XXX IM depot formulation once every four weeks

A Phase I, Parallel-group, Double-blind, Placebo and Positive Controlled Multiple Oral Dose Administration Trial to Evaluate the Effects of XXX on QT/QTc in Subjects with Schizophrenia or Schizoaffective Disorder

A Phase I, 2-part, open label, inpatient study to assess the safety and tolerability of multiple ascending doses of XXX in subjects with schizophrenia

A Phase I, Evaluation of The Effects of Sequential Multiple-Dose Regimens of XXX on Cardiac Replolarization in Patients with Schizophrenia

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

A Phase I, Open-label, Parallel-arm, Two-period, Single-dose Pilot Study to Assess the Pharmacokinetics and the Effect of Food on the Pharmacokinetics of Five Once Weekly Oral Formulations of XXX on Adult Subjects with Schizophrenia

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

A Phase I, Double Blind, Randomized, Placebo- Controlled Study Evaluating QT/ QTc Intervals Following Administration of XXX and XXX in Subjects With Schizophrenia or Schizoaffective Disorder

A Phase I, Multi-center Double-Blind, Randomized, Parallel Group, Active-Controlled Tolerability and Safety Study of XXX in Clinically Stable Schizophrenic Outpatients

CLINICAL TRIAL EXPERIENCE (*continued*):

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

Phase I Other Indications

A Phase I, Randomized, Open-Label, Multicenter Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX (Test vs. Reference) Following Intramuscular Administration to the Gluteal Muscle in Healthy Female Subjects

A Phase I, Driving Simulation Cross-Over Study of Sedative Effects of XXX Compared to XXX and Placebo

AA Phase I Randomized, Multiple-Dose, Open-Label, 4-Week Study to Characterize the Pharmacokinetics, Cumulative Irritation, Safety, and Tolerability of XXX Transdermal System (d-ATS) in Adults Diagnosed With ADHD

A Phase I, Randomized, Double-blind, controlled study to assess the Safety, Tolerability, and Pharmacokinetics of XXX in Patients with Friedreich's Ataxia

A Phase I, Open-Label, Pharmacokinetic Study to Evaluate the Steady-State Venous and Capillary Plasma Concentrations of Five Antipsychotics: XXX, XXX, XXX, XXX, and XXX

A Phase I,Two-Period, Two Treatment, Two-Way Steady-State Crossover Bioequivalence Study of XXX Tablets under Fasting Conditions

Phase II-IV

ADHD

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Multicenter, Randomized, Double-blind, Active and Placebo-controlled Trial of the Safety and Efficacy of XXX in the Treatment of Adult 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 Phase III Randomized, Double-blind, Multicenter, Placebo-controlled, Parallel-group, Efficacy and Safety Study of 2 Doses of XXX in Adults with Attention Deficit Hyperactivity Disorder (ADHD)

A Interventional, Randomised, Double-blind, Placebo-controlled, Fixed-dose Study of XXX in adults with Attention Deficit Hyperactivity Disorder (ADHD)

A Phase III, 12-Month, Multicenter, Open-label, Safety Study of XXX in Adults with Attention Deficit Hyperactivity Disorder (ADHD)

A Phase II, Randomized, Double-blind, Parallel-group, Multicenter Efficacy and Safety Study of XXX versus Placebo in Adults with Attention Deficit Hyperactivity Disorder (ADHD)

Alzheimer's Disease

A Phase II, 24-month, Multi-centre, Randomized, Double-blind, Placebo-controlled, Parallel group Amyloid Imaging Positron Emissions Tomography (PET) and safety study of XXX and XXX Adjuvant in Subjects with Mild to Moderate Alzheimer's Disease

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

A 24 Week, Prospective, Randomized, Parallel-Group, Double-Blind, Multi-center Study Comparing the Effects of XXX vs. XXX on Activities of Daily Living and Cognition in Patients with Severe Dementia of the Alzheimer's Type

A Development of Treatment Satisfaction Measures for Alzheimer's XXX

A Multi-center, Randomized Double-Blind Placebo-Controlled Study of the Safety, Tolerability, Pharmacodynamic and Pharmacokinetic Effects of XXX in the Treatment of Patients with Mild to Moderate Alzheimer's Disease

A Phase II, Double Blind, Randomized, Placebo-Controlled, Multi-center, Dose-Ranging, Parallel-Group, Study to Evaluate the Safety and Efficacy of Oral XXX in Patients with Mild to Moderate Alzheimer's Disease

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IIb Nicotinic Agonist Alzheimer's Disease trial, Dose Ranging, Randomized, Double-Blind, Parallel-Group, Placebo-Controller, Multi-center Study of XXX Used as Add-On to XXX Treatment in Patients with Mild to Moderate Symptoms of Alzheimer's Disease

A Phase III Multi-center, Randomized, Placebo-Controlled, Double-Blind, Twelve-Month Safety and Efficacy Study Evaluating XXX in Patients with Mild-to-Moderate Alzheimer's Disease on XXX

A Phase III, Multi-center, Parallel-Group, Long Term Safety and Tolerability Treatment Trial of XXX in subjects with Alzheimer's Disease who Participated in Study XXX or in Study XXX

A Phase III, Multi-center, 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 E 4 Non-Carriers

A Randomized Controlled Trial to Assess the Efficacy of a Medical Food in Patients with Mild to Moderate Alzheimer's Disease using Alzheimer's Disease Medication

A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Safety and Efficacy Study of Oral XXX in Alzheimer's Disease

A Randomized, Open-Label, Three-Period Cross-Over Study in Healthy Subjects to Compare the Pharmacokinetic Profiles of a 7-Day Application of the XXX to Three Different Skin Sites

Tolerability, Pharmacodynamic and Pharmacokinetic Effects of XXX in the Treatment of Patients with Prodromal Alzheimer's Disease

A One-Year, Double-Blind, Randomized, Placebo-Controlled, Study of Medication Approved for the Treatment of Parkinson's Disease Added to a Medication Approved for Memory Impairment and Dementia Daily in Patients with Mild to Moderate Dementia of the Alzheimer's Type

A 24-Week, Multi-center, Randomized, Double-Blind, Placebo-Controlled, Efficacy and Safety Study of Three Dosage Levels of XXX in Outpatients with Mild to Moderate Alzheimer's Disease Treated with a Cholinesterase Inhibitor

A 52 Week, Two-Period, Multi-center, Randomized, Double-Blind, XXX-Referenced, Placebo-Controlled, Efficacy and Safety Study of 3 Dosage Levels of XXX in Outpatients with Mild to Moderate Alzheimer's Disease

Anxiety

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Efficacy and Safety of XXX in Patients with Social Anxiety Disorder (SAD)

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multicenter, Randomized, Double-Blind, Placebo Controlled Trial of XXX in Generalized Anxiety Disorder

A Randomized Double-Blind, Placebo Controlled, Flexible Dose, Parallel Group Study of Extended-Release XXX for the Treatment of Generalized Anxiety Disorder (GAD)

A Novel Anxiolytic vs. Placebo in Generalized Anxiety Disorder. A Randomized Double-Blind Placebo and XXX-Controlled Fixed Dose Parallel-Group Multi-center Study of 10 Weeks

Bipolar Disorder

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Assess the Efficacy and Safety of XXX Monotherapy in the Treatment of Patients with Major Depressive Episodes Associated with Bipolar I or Bipolar II Disorder (Bipolar Depression)

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of XXX for 4 weeks in the Treatment of Patients with Acute Manic Episodes Associated with Bipolar I 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 Double-blind, Randomized, Placebo-controlled, Parallel Group Study of the Efficacy, Safety, Tolerability, and Pharmacokinetics of XXX for the Treatment of Subjects with Bipolar Disorder I/II with a Current Major Depressive Episode

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of XXX for the Treatment of Major Depressive Episode Associated with Bipolar I Disorder (Bipolar I Depression)

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 Bipolar I Disorder Patients whose Current or Most Recent Episode is Manic, With or Without Mixed Features

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Randomized, Double-blind, Placebo-Controlled, Parallel Group, Multicenter, Fixed Dose Clinical Trial Evaluating the Efficacy, Safety and Tolerability of XXX in Patients with Bipolar I Depression

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety of XXX Monotherapy in the Treatment of Patients With Major Depressive Episodes Associated With Bipolar I or Bipolar II Disorder

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety of XXX Adjunctive to Lithium or Valproate in the Treatment of Patients With Major Depressive Episodes Associated With Bipolar I or Bipolar II Disorder

A Phase II Patients' Preferences for Treatment of Bipolar Depression: Patient Focus Group and Pilot Interview

A Phase IV, Formative Usability Study of the XXX Prototype by Subjects with Bipolar Disorder and Major Depressive Disorder

A Phase III, 52-week, Multicenter, Open-label Study to Evaluate the Effectiveness of an Intramuscular Depot Formulation of XXX as Maintenance Treatment in Patients with Bipolar I Disorder

A 52-week, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of an Intramuscular Depot Formulation of XXX as Maintenance Treatment in Patients with Bipolar I Disorder

A Prospective, Randomized, Double-Blind, Placebo-Controlled, Phase II Safety and Efficacy Study of XXX as an Adjunctive Maintenance Treatment in Patients with Bipolar I Disorder

A Multicenter, Double-Blind, Fixed-Dose, Long-Term Extension Trial of the Safety of XXX in Subjects Diagnosed with Bipolar 1 Disorder who Completed Protocol XXX

A Phase IIIb, Multicenter, Double-Blind, Fixed-Dose, Parallel-Group, Three Week Placebo Controlled Trial Evaluating the Safety and Efficacy of XXX in Subjects With Bipolar I Disorder Experiencing an Acute Manic or Mixed Episode

A Randomized, Double-Blind, Placebo-Controlled, Proof-of-Concept, Phase II Study to Evaluate the Efficacy and Safety of Once a Day XXX 0.1, 0.4, and 0.8 mg as an Adjunctive Therapy to Treatment-as-Usual in the Maintenance Treatment of Bipolar I Disorder in Adult Patients

A Randomized, Double-Blind, Placebo-Controlled, Proof-of-Concept, Phase II Study to Evaluate the Efficacy and Safety of Once a Day XXX Tablet for Sublingual Administration XXX 0.1 mg, 0.4 mg, and 0.8 mg In the Treatment of Acute Depressive Episodes Associated with Bipolar I Disorder in Adult Patients who are on Lithium and/or Valproate

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

A Randomized, 6-Week, Double-blind, Placebo-controlled, Flexible-dose, Parallel-group study of XXX or XXX for the treatment of Bipolar Depression.

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

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

A Multi-center, Double-Blind, Randomized, Placebo-Controlled Trial of the Use of a Novel Antipsychotic in the Treatment of Patients with Bipolar Depression

A Phase II 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 Multi-center, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled Phase III Study of the Efficacy and Safety of XXX Sustained-Release as Mono-Therapy in Adult Patients with Acute Bipolar Mania

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

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response, Multi-center Study to Evaluate the Efficacy and Safety of Three Fixed Doses of Extended-Release XXX in the Treatment of Subjects with Acute Manic and Mixed Episodes Associated with Bipolar I Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multi-center, Randomized, Parallel-Group, Double-Blind, Phase III Comparison of the Efficacy and Safety of an Atypical Antipsychotic to Placebo When Used as Adjunct to Mood Stabilizers in the Maintenance Treatment of Bipolar I Disorder in Adult Patients

A Placebo-Controlled, 21-Day Study of the Safety and Efficacy of XXX for the Treatment of Treatment-Resistant Bipolar I Disorder with an Optional Open Label Extension

A Phase III, Randomized, Placebo-Controlled Study Evaluating the Safety and Outcome of Treatment with a Novel Antipsychotic Subjects with Mania

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

Anti-Seizure Medication vs. Placebo as Add-On Treatment in Subjects with Bipolar Disorder in the Outpatient Setting

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 Six-Month, Open-Label, Multi-center Study of Extended Release XXX in Patients with Bipolar Disorder – an Extension of Protocols XXX and XXX

A Six-Month, Open Label, Multi-center Study of Extended Release XXX in Patients with Bipolar Disorder – an Extension

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of XXX Mono-Therapy in the Treatment of Acutely Manic Patients with Bipolar I Disorder

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

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response, Multi-center Study to Evaluate the Efficacy and Safety of Three Fixed Doses of Extended-Release XXX in the Treatment of Subjects with Acute Manic and Mixed Episodes Associated with Bipolar I Disorder

Depression

A Double-blind, Placebo-controlled, Randomized Dose-ranging Trial to Investigate Efficacy and Safety of Intravenous XXX Infusion in Addition to Comprehensive Standard of Care on the Rapid Reduction of Symptoms of Major Depressive Disorder in Subjects who have Suicidal Ideation with Intent

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II/III, Double-Blind, Placebo-Controlled Clinical Trial to Evaluate the Efficacy and Safety of XXX in Participants with Major Depressive Disorder

A Multi-center, Randomized, Controlled, 6-week, Parallel-group Trial to Evaluate the Effectiveness of a Digital Therapeutic XXX as Adjunctive Therapy in Adult Subjects Diagnosed with Major Depressive Disorder.

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX at 25 mg as Adjunctive Treatment of Major Depressive Disorder

A Phase III, Multicenter, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled, Study to Evaluate the Efficacy and Safety of XXX 20 mg as Adjunctive Therapy to Antidepressants in Adult and Elderly Patients with Major Depressive Disorder with Sleep Disturbance Who Have Responded Inadequately to Antidepressant Therapy and an Open labeled Long-term Safety Extension Treatment with XXX

A Phase IIa, Randomized, Placebo-Controlled Clinical Study to Evaluate the Efficacy and Safety of XXX Added to Stable Antidepressant Therapy in Participants With Treatment-Resistant Depression

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

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

A XXX Patch Acceptance Study in patients with Major Depressive Disorder

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 IIa, Randomized, Double-blind, Placebo-controlled Proof of Concept Study to Evaluate the Effects of Oral XXX Versus Placebo in Subjects 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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IIa, Double Blind, Placebo-Controlled, Multi-Centre Study Investigating the Efficacy, Safety, and Tolerability of XXX as Adjunctive Treatment in Adults with Major Depressive Disorder with Anxious Distress with Suboptimal Response to Standard Antidepressants

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 52-Week Open-Label Extension Study of XXX in Subjects With Major Depressive Disorder and Inadequate Response to Antidepressant Treatment

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Adjunctive XXX in Subjects With Major Depressive Disorder and Inadequate Response to Antidepressant Treatment

Evaluation and Documentation of the Content Validity of a Measure of Excessive Daytime Sleepiness in Patients 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 III, Final Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy, Safety, and Tolerability of XXX as Adjunctive Therapy in the Maintenance Treatment of Adults with Major Depressive Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

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, Phase 2 Trial to Test Efficacy and Safety of XXX as Adjunct to Current Antidepressant Therapy in Patients with Major Depressive Disorder (MDD) with an Inadequate Response to Current Antidepressants

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 II, Randomized, Double-blind, Placebo-controlled, Multicenter, Efficacy and Safety Study of XXX for Rapid Treatment of Symptoms of Depression and Suicidality in Adult Patients with Major Depressive Disorder

A Phase III, Double-blind, Randomized, Placebo Controlled Study to Evaluate the Efficacy and Safety of Intranasal XXX in Addition to Comprehensive Standard of Care for the Rapid Reduction of the Symptoms of Major Depressive Disorder, Including Suicidality, in Subjects Assessed to be at Imminent Risk for Suicide

A Study of XXX Plus XXX in Treatment-Resistant Depression (TRD)

A Phase II, 6-Month, Multicenter, Double-Blind, Randomized, Flexible-Dose, Parallel-Group Study to Compare the Efficacy, Safety, and Tolerability of XXX versus XXX Extended-Release as Adjunctive Therapy to Antidepressants in Adult Subjects With Major Depressive Disorder Who Have Responded Inadequately to Antidepressant Therapy

A Phase II, Depression Diagnostic Aid Confirmatory Performance Study - An Abbreviated Investigational Device Exemption Study

A Phase II, Randomized, Double-blind, Placebo-Controlled, Parallel-groups Safety and Efficacy Study of XXX Administered Once Daily in Patients with Major Depressive Disorder with or without Anhedonia

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IIa, Multicenter, Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of XXX as an Adjunctive Treatment for Patients with Major Depressive Disorder with an Inadequate Response to Current Antidepressant Treatment

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, Multicenter Extension Study of XXX to Assess 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

A Phase III, Open-label, Long-term Safety Study of XXX as Adjunctive Therapy in Patients with Major Depressive Disorder

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

A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter Study of XXX as Adjunctive Therapy 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, Open-label Long-term Extension Safety Study of Intranasal XXX in Treatment-Resistant Depression

A Phase III, 8-Week Prospective Randomized, Controlled, Single-Blind Trial of the XXX vs. Treatment-as-Usual to Evaluate Efficacy of Assay-Guided Treatment in Adults with Major Depressive Disorder

A Phase II, Longitudinal Observational Cohort Study of XXX, a Neurogenic Compound among Out-Patients with Major Depressive Disorder

A Phase II, Double-Blind, Placebo-Controlled Study of XXX 40mg QD and 40mg BID among Outpatients with Major Depressive Disorder

A Phase III, Non-Interventional Study of Subjects who have participated in XXX, A Study of Adjunctive Treatment of Major Depressive Disorder

A Phase II, Multicenter Double-Blind Placebo-Controlled Dose Finding Study of XXX in Patients with Major Depressive Disorder (MDD)

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Fixed Doses of Intranasal XXX Plus an Oral Antidepressant in Adult Subjects with Treatment-resistant Depression

A Phase III, Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Fixed Doses of Intranasal XXX Plus an Oral Antidepressant in Adult Subjects with Treatment-resistant Depression - Trial of Rapid-acting Intranasal XXX for Treatment-resistant Major Depressive Disorder

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 assess the efficacy, safety, and tolerability of XXX as an adjunctive therapy in patients with major depressive disorder with an inadequate response to antidepressant treatment

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

A Phase III, Exploratory, Multicenter, Open-label, Flexible-dose Trial of XXX as an Adjunctive Treatment of Adults with Major Depressive Disorder Who Are in School or at Work

A Phase II, XXX as Treatment for Major Depressive Disorder in Adult Females

A Phase III, Long-Term, Open-Label Study of Safety and Tolerability of XXX as Adjunctive Therapy in Major Depressive Disorder

A Phase III, Double-blind, Placebo-controlled Study of XXX as Adjunctive Therapy in Major Depressive Disorder

A Randomized, Double-Blind, Multicenter, Active-Controlled Study of the Efficacy and Safety of XXX in Subjects with Treatment-Resistant Major Depression

A Phase IIIb, Multicenter, Open-label Exploratory Trial to Evaluate the Efficacy, Safety, and Subject Satisfaction of XXX as Adjunctive Therapy in the Treatment of Adults with Major Depressive Disorder and an Inadequate Response to Previous Adjunctive Therapy

An Exploratory, Multicenter, Open-label, Flexible-dose Trial of XXX as an Adjunctive Treatment of Adults With Major Depressive Disorder and Anxiety Symptoms

CLINICAL TRIAL EXPERIENCE (*continued*):

A Double-Blind, Placebo-Controlled, Randomized Add-On Study of XXX for Patients With Major Depressive Disorder (MDD) Who Have Had An Inadequate Response to Current Antidepressant Therapy

A Phase III, Open-Label Extension Study to Assess the Safety and Tolerability of Treatment With XXX in Patients Who Have Completed Study XXX

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Sequential Parallel Study of XXX in the Adjunctive Treatment of Subjects with Severe Depression and Recent Active Suicidal Ideation Despite Antidepressant Treatment

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

A Phase II, randomized, double-blind, parallel-group study of the safety and efficacy of XXX versus placebo, as adjunctive therapy in patients with major depressive disorder with inadequate response to ongoing antidepressant treatment

A Phase IIa, Multicenter, Randomized, Placebo-Controlled Clinical Trial to Evaluate the Safety and Efficacy of XXX for Treatment Augmentation in Patients with Major Depressive Disorder

A Phase IIb, Double-blind, Placebo-controlled Study of XXX as Adjunctive Therapy in Major Depressive Disorder

A Multicenter, Randomized, Double-blind, Parallel group, Placebo-controlled, Phase II Study of 2 Dose Groups of XXX Adjunct to Current Antidepressant Therapy in Patients with Major Depressive Disorder who exhibit an Inadequate Response to Antidepressants

A Phase III, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, XXX-Referenced, Fixed-Dose Study Comparing the Efficacy and Safety of 2 Doses (15 and 20 mg) of XXX in Acute Treatment of Adults With Major Depressive Disorder

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Multicenter, Double-blind, Parallel-group, Randomized, Placebo-controlled, Forced-dose Titration, Dose-ranging 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 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

A Multicenter, Double-Blind, 58 Week Rollover Study to Assess the Safety and Tolerability of XXX in Patients with Treatment Resistant Major Depression

A Phase II, Multicenter, Randomized, Double-blind, Active-Controlled Study of the Efficacy and Safety of Flexibly-Dosed XXX in Patients with Treatment Resistant Major Depression

A Phase III, Multicenter, Randomized, Double-blind Study to Evaluate the Efficacy, Safety and Tolerability of an Oral XXX Combination Therapy in Patients with Major Depressive Disorder

A Phase IIb, Randomized, Double-Blind, Placebo-Controlled, Active Controlled, Parallel Group, Multicenter Study to Assess the Safety and Efficacy of 2 Fixed Dose Groups of XXX as Monotherapy Treatment in Patients with Major Depressive Disorder with an Inadequate Response to Antidepressant Therapy

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 Phase III, Randomized Placebo-Controlled, Double-Blind Study of XXX Flexible-Dose 12 to 18 mg Once Daily as Adjunctive Treatment for Patients with Major Depressive Disorder Who Are Partial Responders to XXX

A Multi-center, Randomized, Double-Blind Study to Evaluate the Efficacy, Safety and Tolerability of an Oral XXX Combination Therapy in Patients 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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IIa, Multi-centre, Randomized, Double-Blind, Double-Dummy, Active and Placebo Controlled, Parallel Group Study to Assess the Efficacy and Safety of XXX after 6 weeks of treatment in Patients with Major Depressive Disorder

A Phase III, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Fixed-Dose Study Comparing the Efficacy and Safety of 2 Doses (10 and 20 mg) of XXX in Acute Treatment of Adults with Major Depressive 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 Multi-center, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Phase III, Long-Term Safety and Tolerability Study 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 Double-Blind, Randomized, Multi-center, Placebo-Controlled, Relapse Prevention Study with XXX in Out-Patient Adults with Major Depressive Disorder

A Phase 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 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 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 Double-Blind, Placebo-Controlled Project of XXX to XXX Antidepressant Therapy (ADT) among Outpatients with Major Depressive Disorder Who have Responded Inadequately to Prior ADT

A Multi-center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Two Fixed Doses of XXX in Adult Out subjects with Major Depressive Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

A Double-Blind, Placebo-Controlled Study of XXX as Adjunctive Therapy in Major Depressive Disorder

A Double-Blind, Placebo-Controlled Project of XXX Adjunctive to Antidepressant Therapy (ADT) among Outpatients with Major Depressive Disorder who have Responded Inadequately to Prior ADT

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

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

An Eight-Week, Double-Blind Study To Evaluate The Efficacy, Safety And Tolerability Of Two Fixed Doses Of XXX Once Daily In Combination With XXX Once Daily Compared To XXX Placebo In Combination With XXX Once Daily In Patients With Major Depressive Disorder

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

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

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

A Multi-center, Randomized, 24-52-Week, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of XXX 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

A Multi-center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study Evaluating Efficacy, Safety, and Tolerability of a Once Daily Novel Antidepressant vs. Placebo in Subjects with Major Depressive Disorder

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Fixed Dose Study Comparing the Efficacy and Safety of a New Anti-Depressant to Another Anti-Depressant to Placebo in Patients with Major Depressive Disorder.

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Study Evaluating Efficacy and Safety of XXX Controlled Release vs. Placebo in Patients with Major Depressive Disorder

A Prospective, Multi-center Study Comparing the Safety and Efficacy of XXX Hcl to Cognitive Behavioral Therapy - Chronic Depression (Cbt-Cd) and Combined XXX and Cbt-Cd for the Acute, Continuation and Maintenance Treatment of Chronic Forms of Depression.

An XXX and Cognitive Behavior Therapy for the Chronic Depressives: Pilot Study

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Eight-Week, Safety and Efficacy Study of a Sleep Medication Compared to Placebo in Subjects with Insomnia Related to Major Depressive Disorder

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

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

Insomnia

A Noninterventional, Observational Sleep Study to Develop a Sleep Algorithm to Support a Digital Medicine System

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

An Efficacy and Safety of XXX on Sleep Maintenance Insomnia with a Sub-Study of the Effect of XXX on Stable Type II Diabetes Mellitus: A One-Year, Multi-center, Randomized, Double-Blind, Placebo-Controlled Study

An Efficacy and Safety of a Hypnotic Sleep Maintenance Insomnia: A 12-Week Multi-center, Randomized, Double-Blind, Placebo-Controlled Study Followed by an Open-Treatment Phase Extension for 40 Weeks

An Evaluation of the Long-Term Efficacy and Safety of a Hypnotic 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, Eight-Week, Safety and Efficacy Study of a Novel Sleep Agent Compared to Placebo in Subjects with Major Depressive Disease and Insomnia

CLINICAL TRIAL EXPERIENCE (*continued*):

An Evaluation of the Long-Term Efficacy and Safety of a Sleep Medication 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)

Schizophrenia and Schizoaffective Disorders

A Phase III Randomized, Double-blind, Placebo-controlled, Parallel Group Trial to Examine the Efficacy and Safety of XXX Once Daily over 26 week Treatment Period in Patients with Schizophrenia and Ocular Sub-Study to Investigate the Ocular Safety of XXX in Patients with Schizophrenia Following oral administration of 10 mg Compared to Placebo in a Long-Term Study

A Phase III, Open-label Extension Study to Assess the Long-term Safety and Tolerability of XXX in Subjects with DSM-5 Schizophrenia

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Study Evaluating the Safety, Efficacy, and Pharmacokinetics, of XXX in Obese Adult Patients with Schizophrenia, Taking Antipsychotic Medications

A Phase III, Randomized, Double-blind, Parallel-group, Placebo-controlled, Multicenter Study to Evaluate the Efficacy and Safety of XXX in Acutely Psychotic Hospitalized Adults with DSM-5 Schizophrenia

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 II Randomized, Double-blinded, Placebo-controlled Parallel Group Trial to Examine the Efficacy and Safety of XXX Once Daily With Adjunctive Computerized Cognitive Training Over 12 Week Treatment Period in Patients With Schizophrenia

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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 IV, Open Label Study to Assess Long-Term Engagement with XXX in Patients 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 IV Post-XXX Study Interviews to obtain feedback on the digital therapeutic used in the XXX trial as well as new ideas for a future version

A Phase IV, Open-label Study to Assess the Safety, Tolerability, Pharmacokinetics, and Efficacy of 180 mg XXX Subcutaneous Injection Following a Switch From 6 mg Oral XXX in Patients With Clinically Stable 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 II Randomized, Sham-Controlled Study of XXX as an adjunct to standard-of-care treatment for 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

To create opportunities for the XXX Sponsor to interface with people with schizophrenia and to obtain their feedback on XXX prototypes

CLINICAL TRIAL EXPERIENCE (*continued*):

An open label, two-part study to evaluate the feasibility and engagement of using XXX in patients with 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, Multi-national, Double-blind (DB), Placebo-controlled, Randomized-Withdrawal Study Evaluating the Safety and Efficacy of XXX Compared with Placebo in the Prevention of Relapse in Patients with Schizophrenia

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 III Study to Evaluate the Effect of XXX Compared to XXX on Body Weight in Young Adults with Schizophrenia, Schizophreniform, or Bipolar I Disorder Who are Early in Their Illness

A Phase II, 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel Study to Evaluate Efficacy, Safety, Tolerability, and Pharmacokinetics of 3 Dose levels of XXX in Adjunctive Treatment of Adult Subjects with Negative Symptoms of Schizophrenia

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 Double-blind, Randomized, Active-controlled, Parallel-group Study of XXX 6-Month Formulation

A Phase II Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of XXX During a 28-week Treatment Period as Adjunctive Therapy to Antipsychotic Treatment for the Prevention of Relapse in Patients with Schizophrenia

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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 IIa, Randomized, Double-Blind, Placebo-Controlled Clinical Trial of the Efficacy and Safety of XXX using XXX as an Active Control in Subjects Experiencing an Acute Episode of Schizophrenia

A Phase II, 26-Week Open-label Safety and Tolerability Extension Study of XXX in Adult Subjects with Schizophrenia

An Adaptive Phase II/III, Double-Blind, Randomized, Placebo- controlled, Two-Part, Dose-Finding, Multi-center Study of the Safety and Efficacy of XXX, a D-Amino Acid Oxidase Inhibitor, as an Add-on Therapy with XXX, for Residual Symptoms of Refractory Schizophrenia in Adults

An Adaptive Phase IIb/III, Multi-center, Prospective, Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of XXX, a D-Amino Acid Oxidase Inhibitor, as an Add-on Treatment for Schizophrenia in Adults

A Phase II, 4-Week, Randomized, Double-blind, Parallel-group, Placebo controlled, Flexibly-dosed, Multicenter Study to Evaluate the Efficacy and Safety of XXX in Acutely Psychotic Adult Subjects with Schizophrenia

A Phase III, Open-Label, Multi-Center Trial to Assess the Safety and Effectiveness of XXX in 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

A Phase II Randomised, Double-blinded, Placebo-controlled Parallel Group Trial to Examine the Efficacy and Safety of 4 Once Daily Oral Doses of XXX over 12-week Treatment Period in Patients with Schizophrenia

An Interventional, open-label, flexible-dose, long-term safety study of XXX in adult patients with schizophrenia

Pilot study for Validation Test Plan XXX study

A Phase III, Multicenter Study to Assess the Long-Term Safety and Tolerability of XXX in Subjects with Schizophrenia

XXX for Cannabis Use Disorder in Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Fixed-Dose, 6-Week Study to Assess Safety and Efficacy of XXX Transdermal Patch for the Treatment of Schizophrenia AND A Phase II/ III, Randomized, Double-Blind, Placebo-Controlled, 52-week Study to Assess Efficacy and Safety and Tolerability of XXX Transdermal Patch as Maintenance treatment in Adults with Schizophrenia

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

A Phase III, One Year, Randomized, Double-blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of XXX as a Maintenance Treatment in Patients with Schizophrenia

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

A Phase IV, Safety and Tolerability of Initiating XXX in Subjects with Schizophrenia who are Inadequately Treated with XXX

A Phase III, Multicenter Study to Assess the Long Term Safety and Tolerability of XXX in Subjects with Schizophrenia

A Phase III, Study to Determine the Antipsychotic Efficacy and Safety of XXX in Adult Subjects with Acute Exacerbation of 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 III, Exploratory, Multicenter, Randomized, Double-Blind, fMRI Study of Fixed-dose XXX (2 and 4 mg/Day Tablets) in Adults With Schizophrenia With Impulsivity

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Parallel-group, 6-week Study to Evaluate the Efficacy and Safety of XXX in Subjects with an Acute Exacerbation of Schizophrenia

A Phase II, multicenter, randomized, double blind, placebo-controlled study to assess the efficacy, safety and tolerability of XXX for the treatment of negative symptoms of schizophrenia

A Phase III, Prospective, Matched-Control, Randomized, Open-Label, Flexible-Dose, Study in Subjects with Recent-Onset Schizophrenia or Schizophreniform Disorder to Compare Disease Progression and Disease Modification Following Treatment with XXX Long-Acting Injection or Oral Antipsychotics

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Protocol for Psychometric Testing and Validation of a Novel PRO Measure for Assessing Subjective Experience of Cognitive Impairment of (PRECIS) Schizophrenia

A Phase III, randomized, double-blind, placebo- and active-controlled, multi-center study to assess the antipsychotic efficacy of XXX in patients with schizophrenia

A randomized, double-blind, placebo- and active-controlled, multi-center study to assess the antipsychotic efficacy of XXX in patients with schizophrenia

A Phase II randomised, double-blinded, placebo-controlled study to evaluate the efficacy, safety, and tolerability of 10 mg, 25 mg, 50 mg, and 100 mg once daily oral administration of XXX during a 12-week treatment period in patients with schizophrenia on stable antipsychotic treatment

A Multicenter, 8-week, Open-label Study to Assess Usability of the Medical Information Device System in Adult Subjects with Schizophrenia Who Are Treated with Oral XXX

An Open-Label, Long-Term Safety and Tolerability Study of XXX in the Treatment of Subjects with Schizophrenia

A Phase II, Randomized, Double-blind Study to Evaluate Efficacy, Safety, and Tolerability of XXX in Subjects with Schizophrenia with Alcohol Use

A Phase III Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of XXX (90-mg and 120 mg) as a Treatment in Subjects with Acute Schizophrenia Over 8 Weeks (2 Subcutaneous Doses) and Long term safety, and tolerability of XXX in stable schizophrenia subjects

A Phase III, An Exploratory, Multicenter, Open-label, Flexible-dose XXX Trial in Adults with Acute Schizophrenia Associated Cognitive Impairment

A Phase III, 104-Week, Flexible-dose, Open-label, Multicenter, Extension Study to Evaluate the Long-Term Safety and Effectiveness of XXX in Pediatric Subjects with Schizophrenia and Subjects with Irritability Associated With Autistic Disorder

A 6-Week Randomized, Parallel, Double-blind, Placebo-Controlled, Fixed-Dose, Multicenter Study To Evaluate The Efficacy And Safety Of XXX In Adolescent Subjects With Schizophrenia

An Exploratory, Multicenter, Open-label, Flexible-dose XXX Trial in the Treatment of Adults with Early-Episode Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Controlled, Parallel Group Study to Evaluate Adherence to Treatment with and Safety and Tolerability of the Medical Information Device XXX System in Subjects with Bipolar 1 Disorder or Schizophrenia who are Currently Treated with Oral XXX

A Phase III, Interventional, open-label, flexible-dose extension study of XXX once-monthly in patients with schizophrenia

A 12-Week, Randomized, Phase II, Double-blind, Parallel-group, Study of Two Dose Levels of XXX Compared to Placebo in the Adjunctive Treatment of Outpatients with Sub-Optimally Controlled Symptoms of Schizophrenia

A Phase III, Interventional, open-label, flexible-dose extension study of XXX in patients with schizophrenia

A Phase III, Interventional, randomized, double-blind, parallel-group, placebo-controlled, active-reference, flexible-dose study of XXX in patients with acute schizophrenia

A Phase II, Randomized, Multicenter Study to Evaluate the Efficacy and Safety of XXX for the Treatment of Schizophrenia to Mitigate or Prevent XXX -Induced Weight Gain

A Phase III, Open Label, Multicenter, Extension of Study XXX to Assess the Long-term Safety and Durability of Effect of XXX in Subjects with Stable Schizophrenia

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

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Fixed-dose XXX (4, 2, and 1 mg/day) in the Treatment of Adults with Acute Schizophrenia

A Phase III, 28-week, randomized, open-label study evaluating the effectiveness of XXX once-monthly versus XXX in adult patients with schizophrenia

A Phase II, partial-blind, multi-center extension study to evaluate the long-term safety and health outcomes of XXX in subjects who completed Study XXX

A 12-week, Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of XXX in the Acute Treatment of Adults With Schizophrenia

A Phase II, Randomized, Double-blind, Placebo-controlled, Parallel-group, Phase 2 Study of the Safety and Efficacy of XXX in the Treatment of Cognitive Deficits in Schizophrenia (CDS) in Smokers

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III Multicenter, Double-Blind, Fixed-Dose, Long-Term Extension Trial of the Safety of XXX using XXX as an Active Control in Subjects Diagnosed with Schizophrenia who completed Protocol XXX

A Phase IIIb Multicenter, Randomized, Double-Blind, Fixed-Dose, 6-Week Trial of the Efficacy and Safety of XXX Compared With Placebo Using XXX

A 12-week, Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of XXX in the Acute Treatment of Adults With Schizophrenia

A Randomized, Double-blind, Placebo-controlled, Parallel, 12‑Week, Phase III Study of 2 Doses of XXX or Placebo as an Adjunctive Pro-cognitive Treatment in Schizophrenia Subjects on Chronic Stable Atypical Antipsychotic Therapy

A Phase III Multicenter 40-Week Extension Study to Evaluate the Safety and Clinical Effects of Prolonged Exposure to 1 and 2 mg Doses of XXX as an Adjunctive Pro cognitive Treatment in Subjects with Schizophrenia on Chronic Stable Atypical Antipsychotic Therapy

A Phase IIb, 12 week randomized, double-blind, placebo-controlled, parallel group, multiple dose, proof-of-concept study to evaluate the effects of XXX on cognition in stable schizophrenia patients

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy, Safety, and Tolerability of XXX as Maintenance Treatment in Adults with Schizophrenia

A Phase III, multi-center, randomized, 12 week, double-blind, parallel group, placebo-controlled study to evaluate efficacy and safety of XXX in patients with sub-optimally controlled symptoms of schizophrenia treated with antipsychotics followed by a 40-week double-blind, parallel-group, placebo-controlled treatment period

A Phase IIa, Open-Label, Multiple Ascending Dose Study of the Safety, Tolerability, Pharmacokinetics, and Primary Pharmacodynamic Markers of Efficacy of 60mg, 90mg, and 120mg XXX Subcutaneous (SC) Injections in Subjects with Clinically-Stable Schizophrenia

A Randomized, Double-blind, Placebo-controlled, Dose-ranging, Parallel-group, Phase II Study of the Safety and Efficacy of XXX in the Treatment of Cognitive Deficits in Schizophrenia (CDS) in Non-smokers

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study of the Efficacy and Safety of XXX in Subjects with Acute Exacerbation of Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multicenter, Open-label, Single-arm Flexible Dose (20-80 mg Twice Daily, Phase III Study of XXX in Outpatients who complete (rollover) a previous XXX Study and a Study duration of up to 2 years after US XXX Monotherapy Launch

A Phase II, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Effect of Add-on XXX on Schizophrenia Negative Symptoms

A Phase III, 12-Week, Multicenter, Open-Label Extension Study In Subjects with Schizophrenia

The Predicting Response to Risperidone Treatment Through Identification of Early-onset of Antipsychotic Drug Action in Schizophrenia

A Double-Blind, Placebo-Controlled, Multicenter, Parallel Group Study to Assess Efficacy, Safety, and Tolerability of XXX as Augmentation Therapy to Improve Negative Symptoms and Cognition in Outpatients with Schizophrenia.

A Phase II, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Assess the Antipsychotic Efficacy of XXX in Patients with Schizophrenia

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study of the Efficacy and Safety of XXX in Subjects with Acute Exacerbation of Schizophrenia

A Phase II, Multicenter, Double-blind, Randomized, Fixed-dose, Parallel-group, 3-Week, Inpatient Treatment Study to Evaluate the Dose Response Relationship, Safety, Efficacy and Pharmacokinetics of XXX Compared with Placebo, using XXX as a Positive Control, in the Treatment of Acute Exacerbation of Schizophrenia

A Phase III, Multicenter, Open-label Study to Assess Hospitalization Rates in Adult Subjects with Schizophrenia Treated Prospectively for 6 Months with XXX Compared with 6-month Retrospective Treatment with Oral Antipsychotics in a Naturalistic Community Setting in the United States

A Double-blind, Placebo-controlled, Randomized Withdrawal Study of XXX for the Maintenance Treatment of Subjects with Schizophrenia

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Three Fixed Doses of XXX in the Treatment of Adults with Acute Schizophrenia

A randomised, double-blind, parallel-group, explorative study of the safety, tolerability and pharmacokinetics of daily dosing compared to a weekly dosing regime of XXX in patients with schizophrenia

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Three Fixed Doses of XXX in the Treatment of Adults With Acute Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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 III, Multicenter, Double-Blind Comparison of XXX and XXX in Patients with DSM-IV-TR Schizophrenia Followed by Open-Label Treatment with XXX

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

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

A 12-week, Randomized, Multicenter, Open-label, XXX Flexible Dose Study Assessing Efficacy, Safety and Tolerability of Two Switch Approaches in Schizophrenia Patients Currently Receiving XXX or XXX

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

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

A Phase II, Multicenter, Double-Blind, Placebo-Controlled Comparator Study of 2 Doses of XXX versus Placebo in Patients with DSM-IV-TR Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

A 17-Week, Phase II, Multi-center, 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 Phase II, Double-Blind Placebo-Controlled Randomized Withdrawal, Multi-center, Safety and Efficacy Study in Adults with Predominant Negative Symptoms and Clinically Stable Schizophrenia who are Taking Stable Dose of Antipsychotic Medication

A Randomized Phase II, Double-Blind, Placebo-Controlled, Multi-center Study of XXX as Add-on Therapy in Outpatients with Persistent Negative Symptoms of Schizophrenia Treated with A Stable Dose of a Second-Generation Antipsychotic

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 Prospective, Randomized, Active-controlled, Rater-blinded, International Study of the Prevention of Relapse Comparing XXX to XXX in Adults with Recently-Diagnosed Schizophrenia Who Are at High Risk of Relapse

A Phase IIa, Double-blind, Double-dummy, Placebo-controlled, Randomized, Parallel-Group Study to Assess the Efficacy, Safety, Tolerability and Pharmacokinetics of XXX in Adult Schizophrenic Patients

A Long-Term, Phase II, Multi-center, Randomized, Open-Label, Comparative Safety Study of XXX vs. Atypical Antipsychotic Standard of Care in Patients with DSM-IV-TRSchizophrenia

A Non-Interventional, Exploratory Study Designed to Evaluate the Test-Retest Reliability of the MATRICS Consensus Cognitive Battery When Administered Four Times Over a Four-Week Period in Patients Diagnosed with Schizophrenia

A Randomized, Double-Blind, Placebo-Controlled Add-On Trial of the Safety and Efficacy of XXX in Outpatient on XXX, XXX, XXX, or XXX with Prominent Negative or Disorganized Thought Symptoms

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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- and Active Comparator-Controlled Clinical Trial to Study the Safety and Efficacy of Two Doses of XXX in Acutely Psychotic Subjects 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 Phase IIa, Randomized, Double-blind, Placebo-Controlled, Parallel Group Study to Assess Pharmacodynamics, Pharmacokinetics, Safety and Tolerability of Oral Multiple Ascending Doses for XXX in Patients with Schizophrenia

A Multiple Dose Bioavailability Study Of XXX Tablets to the Reference Listed Drug Tablets at Steady State in Patients Under Fed Conditions

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-Controlled, XXX-Referenced, Parallel-Group Study of XXX in Subjects with Acute Exacerbations of Schizophrenia

A Randomized, Double-Blind, Parallel-Group, Flexible-Dose Study Exploring the Neurocognitive Effect of XXX vs. XXX in Patients with Schizophrenia Using MATRICS Consensus Cognitive Battery

A Long-Term Safety, Tolerability, and Effectiveness of XXX in Subjects with Schizophrenia or Schizoaffective Disorder: A Randomized, Active Comparitor-Controlled Trial

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

A Sixteen-Week, Multi-center, Open Label Study Evaluating the Safety, Tolerability, and Efficacy of Switching from XXX to XXX in Subjects Diagnosed with Schizophrenia or Schizoaffective Disorder

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A 24-Week, Multi-center, Double-Blind, Randomized, Parallel-Group, Dose Ranging Study of the Efficacy and Safety of Oral Doses of XXX and Placebo on Top of an Established Treatment Regimen of Either XXX, XXX or XXX Mono-Therapy in the Treatment of Cognitive Impairment in Schizophrenia

A Randomized, Double-Blind, Placebo-Controlled, Paralle-Group Study to Evaluate the Efficacy and Safety of Two Dosages of XXX ER in the Treatment of Subjects with Schizoaffective Disorder

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

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, 16-Week Study of the Safety and Efficacy of XXX Used as Augmenation Therapy in the Treatment of Patients with Chronic Schizophrenia Demonstrating an Inadequate Response to XXX or XXX Mono-Therapy

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, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of XXX ER Compared to XXX in Subjects with an Acute Exacerbation Schizophrenia

A Predicting Response to XXX Treatment Through Identification of Early-Onset of Antipsychotic Drug Action in Schizophrenia

A Randomized, Double Blind, Multi-center Study to Assess the Antipsychotic and Motor Effects of XXX When Administered in Combination with XXX or XXX to Schizophrenic Subjects

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 12-Week, International, Multi-center, Open Label, Non-comparative Study to Evaluate the Feasibility of Switching any Antipsychotic Treatment to Sustained-Release XXX in Patients with Schizophrenia

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

A Randomized, Double-Blind, Parallel-Group, Comparative Study of Flexibility Dosed XXX Administered Every Two Weeks in 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 a Long Acting Antipsychotic in Subjects with Schizophrenia

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

A Multi-center, Double-Blind, Flexible-Dose, Six-Month Trial Comparing the Efficacy and Safety of an Atypical Antipsychotic in Development with an Atypical Antipsychotic in Stable Subjects with Predominant, Persistent Negative Symptoms of Schizophrenia

A Randomized, Double-Blind, Placebo-Controlled and an Atypical Antipsychotic-Referenced, Parallel-Group Efficacy and Safety Study of Two Fixed Doses of an Atypical Antipsychotic in Development in the Treatment of Schizophrenia.

A Multi-center, Open Label, Flexible-Dose, Parallel-Group Evaluation of the Cataractogenic Potential of an Atypical Antipsychotic and Another Atypical Antipsychotic in the Long-Term Treatment of Patients with Schizophrenia Or Schizoaffective Disorder

A Four-Week, Double Blind, Multi-center Study Comparing the Efficacy and Safety of an Atypical Antipsychotic to Another Atypical Antipsychotic in Subjects with Schizophrenia or Schizoaffective Disorder Needing Inpatient Care

A Multi-center, Randomized, Double-Blind Study on the Effects of an Atypical Antipsychotic on Overweight or Obese Patients Treated with Another Atypical Antipsychotic for Schizophrenia or Schizoaffective Disorder

A Double-Blind, Eight-Week, Placebo and an Atypical Antipsychotic-Controlled, Dose-Finding Study to Evaluate the Efficacy, Safety, and Tolerability of a Novel Antipsychotic in the Treatment of Patients with Schizophrenia or Schizoaffective Disorder

An Assessment of the Efficacy and Safety of Two Sublingual Doses of a Novel Antipsychotic in Subjects with Schizophrenia (in an Acutely, Exacerbated State) Compared to Placebo in a Multi-center, Randomized, Double-Blind, Fixed-Dose, Six-Week Trial with an Atypical Antipsycotic Positive Control Group

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

A Randomized, Double-Blind Study of the Safety and Efficacy of a Mood Stabilizer Plus an Atypical Antipsychotic vs. an Antipsychotic Alone in the Treatment of Schizophrenia

A Multi-center, Double-Blind, Placebo-Controlled, Randomized, Parallel-Group Evaluation of the Efficacy of a Flexible Dose of a Mood Stabilizer vs. Placebo as Add-On Therapy in Schizophrenia

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

A Trial of One Atypical Antipsychotic vs. Another Atypical Antipsychotic in the Treatment of Schizophrenic and Schizoaffective Subjects with Comorbid Depression

A Multi-center, Double-Blind, Randomized Comparison of the Efficacy and Safety of Two Atypical Antipsychotics in the Treatment of Patients with Schizophrenia

A XXX Qd vs. Bid Dosing in Schizophrenia: A Double-Blind, Parallel-Group, Phase III, Multi-center Study

A Multi-center, Double-Blind, Randomized Comparison of XXX and XXX in the Treatment of Hospitalized Subjects with Treatment Resistant Schizophrenia

A Double-Blind Placebo-Controlled, Dose-Response Comparison of the Safety and Efficacy of Three Doses of XXX and Three Doses of XXX in Schizophrenic Patients

An Open Label Assessment of the Long-Term Safety of XXX in the Treatment of Schizophrenic Patients

A Multi-center, Double-Blind, Placebo-Controlled, Randomized, Multiple Fixed-Dose Comparison of XXX and XXX in the Treatment of Hospitalized Subjects with Acute Exacerbation of Chronic or Subchronic Schizophrenia

A Fixed-Dose XXX vs. Placebo in the Treatment of Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multi-center, Double-Blind, Flexible-Dose, Long-Term Extension Trial of the Safety and Maintenance of Effect of an Atypical Antipsychotic in Development Using Another Atypical Antipsychotic Positive Control in Subjects.

A Multi-center, Double-Blind, Randomized, Controlled, Multiple Fixed Dose and Dose Regimen Comparison of XXX and XXX in the Prevention of Psychotic Relapse in Outpatients with Chronic or Subchronic Schizophrenia

An Open Label Assessment of the Long-Term Safety of 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

A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel- Group Study to Evaluate the Efficacy and Safety of Flexible-dose XXX ER in the Treatment of Patients With Schizoaffective Disorder

A Phase IIIa, 24-month, Prospective, Randomized, Active-Controlled, Open-Label, Rater-Blinded, Multicenter, International Study of the Prevention of Relapse Comparing Long-Acting Injectable XXX to Treatment as Usual with Oral Antipsychotic Monotherapy in Adults with Schizophrenia

A Phase IV, Randomized, Double-Blind, Placebo- and Active-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of a Fixed Dosage of 1.5 mg/Day of XXX Extended Release (ER) in the Treatment of Subjects with Schizophrenia

A Phase IV Study to Measure Drug Satisfaction of Patients with Schizophrenia After Switching from XXX to XXX

Other Indications

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

Noninterventional, single-arm, prospective, observational study. Evaluate positive detection accuracy of XXX and XXX patches of Digital Medicine System with placebo tablets.

A randomized, double-blind, placebo-controlled study to investigate the efficacy of XXX in subjects affected by motion sickness during travel

A Randomized, Double-Blind, Placebo-Controlled Phase III Study of the Safety, Efficacy, and Pharmacokinetics of XXX Nasal Gel for the Prevention and Treatment of Nausea Associated with Motion Sickness in Senior Subjects with Open Label Follow-Up

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Placebo Controlled, Double-Dummy Phase 3 Study to Assess Cognitive Safety of XXX Nasal Gel.

A Randomized, Double-blind, Placebo-controlled, Phase III Study of the Safety and Efficacy of XXX Nasal Gel on Ocean Going Vessels for the Prevention and Treatment of Nausea Associated with Motion Sickness

A Phase II/III Randomized, Double-blind, Placebo-controlled Trial of XXX in Subjects with Obsessive Compulsive Disorder

A Phase III, 12-week, Randomized, Double-blind, Parallel-group, Placebo-controlled, Fixed-dosed, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in Adults with Moderate to Severe Binge Eating Disorder

A Phase IV, Randomized, Double-Blind, Parallel Group, Placebo- and Active-Controlled, Study Evaluating the Effect of XXX 10 and 20 mg/day vs XXX 20 mg/day on Sexual Functioning in Healthy Subjects

A Phase III, Open-Label, Depot XXX Treatment Extension Study in Subjects With Opioid Use Disorder

Cognitive Interviews of the Suicide Ideation and Behavior Assessment Tool (SIBAT) with Clinicians XXX

A XXX Wearable Device Trial: Adverse events from time of consent to study procedures until approximately 30 days after completion of procedures

A Phase II, Open-label, Flexibly-dosed, 6-month Extension Safety Study of XXX in the Treatment of Adults with Binge-eating Disorder

A Phase II, 12 week, Randomized, Double blind, Parallel group, Placebo-controlled, Flexibly dosed, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in Adults with Moderate to Severe Binge Eating Disorder

A Phase III, Open-Label, Long-Term Safety and Tolerability Study of XXX in Treatment-Seeking Subjects With Opioid Use Disorder

A Mapping and Validation of the Suicide Ideation and Behavior Assessment Tool in Patients at Various Levels of Risk for Suicide

A Phase III Randomized, Double-Blind, Placebo-Controlled, Multicenter Study To Assess the Efficacy, Safety, and Tolerability of Multiple Subcutaneous Injections of XXX [100 mg and 300 mg]) Over 24 Weeks in Treatment-Seeking Subjects with Opioid Use Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

Validation Test Plan XXX System (The system is designed to enable mental health patients to measure and monitor their medication adherence as well as other information such as mood, rest, and activity.)

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Trial with an Open-label Extension Phase to Evaluate the Efficacy and Safety of Subcutaneously Administered XXX in Premenopausal Women with Hypoactive Sexual Desire Disorder (HSDD) (with or without Decreased Arousal)

A 28-Week Open Label Extension Study Evaluating the Safety and Tolerability of XXX in Subjects with Mild Cognitive Impairment

A Phase II, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating the Efficacy, Safety, and Pharmacokinetic Behavior of Orally Administered XXX in Subjects with Drug-Induced Tardive Dyskinesia

A One-Year, Multi-center, Randomized, Double-Blind, Placebo-Controlled Evaluation of the Efficacy and Safety of a Medication Prescribed for Memory Impairment and Dementia in Subjects with Mild Cognitive Impairment.

PUBLICATIONS:

Peer Reviewed Publications

Cohen, E. A., Hassman, H. H., Ereshefsky, L., Walling, D. P., Grindell, V. M., Keefe, R. S. E., Wyka., K., & Horan, W. P. (2020). Placebo response mitigation with a participant-focused psychoeducational procedure: A randomized, single-blind, all placebo study in major depressive and psychotic disorders. *Neuropsychopharmacology, published on-line: https://www.nature.com/articles/s41386-020-00911-5.*

Goenjian AK, Steinberg AM, Walling D, Bishop S, Karayan I, Pynoos R. 25-year follow-up of treated and not-treated adolescents after the Spitak earthquake: course and predictors of PTSD and depression. *Psychol Med. 2020 Jan 14:1-13. doi: 10.1017/S0033291719003891. [Epub ahead of print] PMID: 31931901 [PubMed - as supplied by publisher]*

Walling DP, Banerjee A, Dawra V, Boyer S, Schmidt CJ, DeMartinis N. Phosphodiesterase 10A Inhibitor Monotherapy Is Not an Effective Treatment of Acute Schizophrenia. *J Clin Psychopharmacol. 2019 Nov/Dec;39(6):575-582. doi: 10.1097/JCP.0000000000001128. PMID: 31688451 [PubMed - in process]*

PUBLICATIONS (*continued*):

Hard ML, Wehr A, von Moltke L, Du Y, Farwick S, Walling DP, Sonnenberg J. Pharmacokinetics and safety of deltoid or gluteal injection of aripiprazole lauroxil NanoCrystal® Dispersion used for initiation of the long-acting antipsychotic aripiprazole lauroxil. *Ther Adv Psychopharmacol. 2019 Jul 2;9:2045125319859964. doi: 10.1177/ 2045125319859964. eCollection 2019. PMID: 31308935 [PubMed] Free PMC Article*

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Brown D, Nakagome K, Cordes J, Brenner R, Gründer G, Keefe RSE, Riesenberg R, Walling DP, Daniels K, Wang L, McGinniss J, Sand M. Evaluation of the Efficacy, Safety, and Tolerability of BI 409306, a Novel Phosphodiesterase 9 Inhibitor, in Cognitive Impairment in Schizophrenia: A Randomized, Double-Blind, Placebo-Controlled, Phase II Trial. *Schizophr Bull. 2019 Mar 7;45(2):350-359. doi: 10.1093/schbul/sby049. PMID: 29718385 [PubMed - in process] Free PMC Article*

Fu DJ, Turkoz I, Walling D, Lindenmayer JP, Schooler NR, Alphs L. Paliperidone palmitate once-monthly maintains improvement in functioning domains of the Personal and Social Performance scale compared with placebo in subjects with schizoaffective disorder. *Schizophr Res. 2018 Feb;192:185-193. doi: 10.1016/j.schres.2017.04.004. Epub 2017 Apr 26. PMID: 28454922 [PubMed - indexed for MEDLINE] Free Article*

Bain EE, Shafner L, Walling DP, Othman AA, Chuang-Stein C, Hinkle J, Hanina A. Use of a Novel Artificial Intelligence Platform on Mobile Devices to Assess Dosing Compliance in a Phase 2 Clinical Trial in Subjects With Schizophrenia. *JMIR Mhealth Uhealth. 2017 Feb 21;5(2):e18. doi: 10.2196/mhealth.7030. PMID: 28223265 [PubMed] Free PMC Article*

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Fu DJ, Turkoz I, Simonson RB, Walling D, Schooler N, Lindenmayer JP, Canuso C, Alphs L. Paliperidone Palmitate Once-Monthly Injectable Treatment for Acute Exacerbations of Schizoaffective Disorder. *J Clin Psychopharmacol. 2016 Aug;36(4):372-6. doi: 10.1097/ JCP.0000000000000535.*

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Bailey, J.N, Goenjian, A.K. Noble. E.P., Walling, D.P. Ritchie, T. Goenjian, H.A. (2010) PTSD and dopaminergic genes, DRD2 and DAT, in multigenerational families exposed to the Spitak earthquake. *Psychiatry Research 2010 Aug 15;178(3):507-10. doi: 10.1016/j.psychres. 2010.04.043.*

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Goenjian, A.K., Noble, E.P., Walling, D.P., Goenjian, H.A., Karayan, I.S., Ritchie, T., Bailey, J.N. (2008) Heritabilities of symptoms of posttraumatic stress disorder, anxiety and depression in earthquake exposed Armenian families. *Psychiatric Genetics 2008 Dec;18(6):261-6. doi: 10.1097/YPG.0b013e3283060f48.*

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Walling, D., & Baker, J. (1996) Hypnosis Training in Psychology Internship Programs. *American Journal of Clinical Hypnosis 1996 Jan; 38. (3) 219-223.*

Other Publications

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Walling, David P. (1993) "Self-Concept in High Achieving Women: A Comparison of Medical and Nursing Educators." Doctoral Dissertation. University of Southern California.

ABSTRACTS & POSTERS:

Abstracts and Posters

Cohen, E. A., Hassman, H. H., Walling, D. P., Grindell, V. M., Wyka, K., Lobb, J. M., Hough, D., Joseph, A. V., Ball, R. R., Glass, S. J., & Ereshefsky, L. (April, 2021). Giving voice to patients with Schizophrenia or Schizoaffective Disorder: Preferences for clinical trial methodologies and COVID19 mitigations. Poster presented at the International Society for CNS Clinical Trials and Methodology (ISCTM) Annual Scientific Meeting, Virtual.

Cohen, E. A., Hassman, H. H., Walling, D. P., Grindell, V. M., Wyka, K., Hough, D., Lobb, J. M., Joseph, A. V., Glass, S. J., Ball, R. R., and Ereshefsky, L. (November, 2020). Preferences of the Opioid Use Disorder patient: Clinical trial methodologies and COVID19 mitigations that motivate participation. Poster presented at the Annual International / Canadian Society of Addiction Medicine (I/CSAM) Conference, Virtual.

ABSTRACTS & POSTERS (*continued*):

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.

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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.

Fu, D.J., Turkoz, I., Simonson, B., Walling, D., Schooler, N., Lindenmayer, J-P., Alphs, L. Paliperidone Palmitate Long-Acting Injectable Delays Psychotic and Mood Symptom Relapse in Schizoaffective Disorder. Abstract presented at the World Psychiatric Association – September 2014: Madrid, Spain.

Fu, D.J.; Alphs, L.; Lindenmayer, J-P.; Schooler, N.; Simonson, B.; Turkoz, I.; Walling, D. Paliperidone Palmitate Delays Relapse and Maintains Functioning in Patients with Stabilized Psychotic and Mood Symptoms of Schizoaffective Disorder. Abstract presented at the ASCP Annual Meeting – June 2014; Hollywood, FL.

Fu, D.J.; Turkoz, I; Simonson, R.B; Walling, D; Schooler, N; Lindenmayer, J-P.; Alphs, L. Paliperidone Palmitate Delays Relapse in Patients with Schizoaffective Disorder. Abstract presented at the Society of Biological Psychiatry – May 2014; New York, NY.

Fu, D.J.; Turkoz, I; Simonson, R.B; Walling, D; Schooler, N; Lindenmayer, J-P.; Alphs, L. Paliperidone Palmitate Long-Acting Injectable in Acute Exacerbation of Schizoaffective Disorder. Abstract Presented at the International Conference on Schizophrenia Research - April 2013: Orlando, FL.

ABSTRACTS & POSTERS (*continued*):

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