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Collaborative Neuroscience Research, LLC
Collaborative Neuroscience Network, LLC
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CONTACT INFORMATION:

Site Selection and Information:
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AFFILIATIONS:

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19401 S. Vermont Avenue, Suite F-100
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12772 Valley View Street, Suite 3
Garden Grove, CA 92845

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

EDUCATION:

1992, Degree: D.O.
Midwestern University, Chicago College of Osteopathic Medicine

1984, Degree: Microbiology
San Diego State University

RESIDENCIES:

Residency in Family Medicine
Chief Resident, Inpatient Medicine, 1995
Residency, 1992- June 1995

CERTIFICATION AND LICENSURE:

Certified by the American Board of Family Practice
American College of Occupational and Environmental Medicine (ACOEM)
Licensed Osteopathic Physician and Surgeon, State of California, License No. 20A6475

PROFESSIONAL EXPERIENCE:

Investigator, 2019 - Present
Apex Innovative Sciences

Investigator, 2010 – Present
Collaborative Neuroscience Research, LLC, Long Beach, CA
Collaborative Neuroscience Network, LLC, Long Beach, CA

Private Practice, 2018-Present
Naples Medical Group Long Beach, CA

Staff Physician, 2010 – Present
Ocean View Psychiatric Health Facility, Long Beach, CA

Medical Review Officers, 2009 – Present
ACOEM Certified at Central Drug Systems

Private Practice, 2005 – 2018
Family Health Care of Long Beach, CA

Teaching Faculty, 1996 – Present
Long Beach Memorial Family Medicine Residency, Long Beach, CA

Active Staff, 1995 – Present
Long Beach Memorial Medical Center, Miller Children's Hospital and Memorial Women's Hospital, Long Beach, CA

Associate Professor, 1995 – Present
University of Irvine College of Medicine, Department of Family Medicine, Irvine, CA

Police Surgeon and Consultant, 1994 – Present
City of Long Beach Police Department, Long Beach, CA

Continued Experience:

Marina Family Medicine 2006 – 2008
Seal Beach Family Medical Group 1995 – 2006
Contract Physician for Long Beach Memorial Urgent Care 1995- 1996
Contract Physician for Manhattan Beach Care Station, 1994 – 1995
Contract Physician for Los Alamitos Family Medical Group, 1995

INVESTIGATOR EXPERIENCE:

Phase I-IV: Acute Back Muscle Spasm • ADHD • Addiction • Alzheimer's Disease • Anemia Anxiety • Asian Bridging • Asthma • Bioequivalence • Bipolar Disorder • Chronic Pain Constipation • Crohn's Disease • Dementia • Depression • Device • Diabetes (Type II) • Digital Driving Simulation • Epilepsy • Fibromyalgia • Friedreich's Ataxia • Healthy Hypercholesterolemia • Insomnia • Irritable Bowel Syndrome • Men's Health • Migraine Mild Cognitive Impairment • Multiple Sclerosis • Neuropathic Pain Painful Lumbar Radiculopathy • Parkinson's Disease • PTSD • Opioid-Induced Constipation Osteoarthritis • Schizophrenia • Women's Health • Vaccine

ADDITIONAL TREATMENT EXPERIENCE:

Acid Reflux • Dyslipidemia • High Blood Pressure • Hepatic and Renal Impaired • Hepatitis C Hyperlipidemia • Hypertension • Influenza • Obesity • Rheumatoid Arthritis

CLINICAL TRIAL EXPERIENCE:

PHASE I

Phase I Alzheimer's Disease /Mild Cognitive Impairment

A Single-Dose and Multiple-Dose, Dose-Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX in Healthy Subjects and Patients with Alzheimer's Disease

A Phase Ib Study of the Pharmacokinetics and Safety of XXX in Subjects with Mild Alzheimer's Disease who are Heterozygous or Homozygous for the ε4 Variant of the Apolipoprotein E Gene (APOE 4 Carriers)

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Multiple Dose, Dose Escalation Study of XXX in Patients with Probable Alzheimer's Disease

A Randomized, Double-Blind, Placebo-Controlled, Phase Ib, Safety, Tolerability, and Pharmacokinetic Study of Multiple Ascending Doses of XXX in Patients with Mild Alzheimer's Disease

A Phase I XXX Assay development using blood specimens from clinically diagnosed Alzheimer's disease subjects and healthy, cognitively intact control subjects

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Single- and Multiple-Ascending Dose Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX in Subjects with Mild to Moderate Alzheimer's Disease

A Phase I Recovery of Naturally Occurring Human Tau Antibodies

CLINICAL RESEARCH EXPERIENCE (*continued*):

A Phase Ib, Randomized, Double-Blinded, Placebo-Controlled, Multiple- Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX in Subjects with Mild or Prodromal Alzheimer's Disease

A Phase I, Single-Dose and Multiple-Dose, Dose-Escalation Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX in Patients with Mild Cognitive Impairment due to Alzheimer's Disease or Mild to Moderate Alzheimer's Disease

A Phase Ib/II study to assess the Safety, Tolerability, and (CSF) Pharmacodynamic Effects of XXX in patients with mild cognitive impairment (MCI) due to Alzheimer's Disease (AD) and mild Alzheimer's Disease (AD)

A Phase Ib, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Determine the Safety, Tolerability, Pharmacokinetics, and Brain Metabolic Response, Using FDG PET, Following Administration of XXX Added to Standard of Care (Donepezil ± Memantine) in Participants with Mild to Moderate Alzheimer's Disease

A Phase I, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Effects of Multiple Doses of XXX on Cerebrospinal Fluid Biomarkers, Connectivity Magnetic Resonance Imaging, and Computerized Cognitive Tests in Subjects with Mild Alzheimer's Disease

A Phase I, 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

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

Phase I 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 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, 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)

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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, 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

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

Phase I Healthy Japanese Bridging

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 (Part A) and Single Dose Food Effect (Part B) Study to Assess the Safety, Tolerability, and Pharmacokinetics of XXX in Healthy Subjects

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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 Normal

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 XXX in Normal Healthy Subjects

A Phase I, Non-randomized, Open-label, 4-period, Crossover Study to Evaluate Single Escalating Doses of XXX Nasal Gel F2 Formulation in Healthy Volunteers

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

A randomized, placebo-controlled, double blind, single ascending and multiple ascending dose study to assess the safety, pharmacokinetics and pharmacodynamics of XXX in healthy volunteers and sickle cell disease patients (a first-in-human (FIH), Phase I study) and Open Label Extension.

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

A Placebo-Controlled, Double-Blind, Single 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, 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, 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, Multiple Ascending Dose Study to Determine the Safety, Tolerability and Pharmacokinetics of XXX Oral Solution in Healthy Adults

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

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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 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 Randomized, Double Blind, Placebo Controlled Trial to Study Difference in Cognitive Learning Associated with Repeated Self-Administration of Remote Computer Tablet-Based Application Assessing Dual-Task Performance Based on Amyloid Status in Healthy Elderly Volunteers

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

Phase I Multiple Sclerosis

A Phase I, Multicenter, Randomized, 12-Week, Open-Label Study to Evaluate the Multiple-Dose Pharmacokinetics and Pharmacodynamics of XXX in Patients with Relapsing Multiple Sclerosis

A Phase I Double-Blind, Placebo-Controlled, Single Ascending Dose Intravenous Infusion Study of XXX in Subjects with Multiple Sclerosis Immediately Following a Relapse

A Phase I, Double-Blind, Placebo-Controlled, Single Ascending Intravenous Infusion Study of XXX in Patients with Multiple Sclerosis

A Phase I, Multi-center, Open-Label Dose Escalation Study to Evaluate the Safety, Tolerability and Pharmacodynamic Activity of Intravenous XXX in subjects with Multiple Sclerosis

CLINICAL RESEARCH EXPERIENCE (*continued*):

Phase I Parkinson's Disease

A Phase I Randomized multi-center, open-label, crossover pharmacokinetic study of XXX and an oral dose of XXX under fed conditions in patients with Parkinson's Disease

A Phase Ib, Multicenter, Randomized, Placebo-controlled, Double-blind Study to Determine the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX in Subjects with Parkinson's Disease

A Phase I, Open-Label Study to Assess the Pharmacokinetics, Pharmacodynamics, Safety and Tolerability of Repeated Doses of XXX, and Effect on Levodopa Pharmacokinetics, in Subjects with Parkinson's Disease

A Phase I, Double-Blind, Placebo-Controlled Study to Determine Safety, Tolerability, Pharmacokinetics of XXX at Multiple Ascending Dose in Subjects with Parkinson's Disease

A Phase I, Double-blind, Sponsor Open, Randomized, Placebo-controlled, Single Ascending Dose Study to Investigate the Safety, Tolerability, and Pharmacokinetics of XXX Co-Administered with XXX in Subjects with Idiopathic Parkinson's Disease

A Phase Ib, 2-Period, Open Label, Multicenter, Dose Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX In Subjects with Parkinson`s Disease and Motor Fluctuations

A Phase I, Randomized, Double-blinded, Multiple Ascending Dose Study in Patients with Early-stage Parkinson's Disease to Evaluate the Pharmacokinetics and Safety of XXX Following Intramuscular Injections

A Phase I, randomized, double-blinded, multiple ascending dose study in patients with early-stage Parkinson's disease to evaluate the pharmacokinetics and safety of XXX following intramuscular injections

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Multiple Ascending Dose Study of XXX Administered By Intravenous Infusion in Patients with Parkinson's Disease

A Phase I, Open-Label, Single Group, Multiple-Dose, Study to Evaluate the Pharmacokinetics of XXX following 24-hr Application in Patients Diagnosed with Parkinson's Disease

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Ascending Dose Study of Safety and Tolerability of XXX in Adult Patients with Parkinson's Disease Who Are Receiving XXX Advanced Parkinson's Disease

CLINICAL RESEARCH EXPERIENCE (*continued*):

Phase I Schizophrenia or Schizoaffective Disorder

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 months and 12 months)

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 versus INVEGA SUSTENNA® in Patients with Schizophrenia and/or Schizoaffective Disorders

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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 Pilot Study of Digital Health Technology Assessments in Schizophrenia

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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

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

Phase I Other Indications

A Phase I, Single-Ascending and Repeat-Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX n participants with dyslipidemia (Part A and B)

A Phase I, Interventional, Randomized, Double-blind, Crossover, Placebo controlled, Exploratory Study Investigating the Effects of XXX on BOLD fMRI Signals and Sleep Parameters in Patients with PTSD

CLINICAL RESEARCH EXPERIENCE (*continued*):

A Phase I, Study to Facilitate Discussion Sessions Between Individual Patients and Sponsor's Staff to Understand the Experience of their Medical Condition and Elicit Feedback on Potential Product Designs AND Assist with Establishing a Patient Advisory Panel for Regular Feedback on Prototypes of Product Designs and Features on a Recurring Basis

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

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

A Phase Ib, Parallel Group, Double-Blind, Randomized, Placebo Controlled to Evaluate the Safety, Pharmacokinetics, and Efficacy of a Single Dose of XXX Administered Intravenously in Patients with Frequent Episodic Migraines

A Phase I, Open-Label, Randomized, Parallel Group, Crossover Study to Compare the Pharmacokinetics of XXX in Migraine Subjects During an Acute Migraine Attack and During a Non-Migraine Period

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 RESEARCH EXPERIENCE (*continued*):

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

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

A 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

Addiction

A Multi-center, Multi-region, Observational Smoking Cessation Study to Understand the Biological or Functional Changes Related to Smoking Cessation in Apparently Healthy Smokers who are Continuously Abstinent from Smoking for One Year

Alzheimer's Disease

A Phase II Prospective, Randomized, Double-Blind, Dose-Comparison Concurrent Control Study to Assess the Safety and Tolerability of XXX Infusions in Subjects with Mild to Moderate 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 XXX

A 24 Week Open-Label Extension to Study XXX

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 (ACTION)

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 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 AND A Phase III, Multi-center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Efficacy and Safety Trial of XXX in Subjects With Mild to Moderate Alzheimer Disease Who Are Apolipoprotein E4 Carriers

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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

Anxiety

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

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

A Prospective Randomized Clinical Study to Evaluate the Clinical Impact of Pharmacogenetic-Guided Treatment for Depression and Anxiety

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

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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

Depression

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 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 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, Two-Part Study of XXX as an Adjunctive Therapy in 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 Phase III Randomized, Double-Blind, Placebo-controlled Study Evaluating the Efficacy and Safety of XXX in the Treatment of Adults with Severe Postpartum Depression

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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

Evaluation and Documentation of the Content Validity of a Measure of Excessive Daytime Sleepiness in Patients 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

A Phase III, Open-label, 1-year Study of the Safety, Tolerability, and Need for Re-treatment with XXX in Adult Subjects with Major Depressive Disorder

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

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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 IIa Study to Compare the Safety, Tolerability and Initial Efficacy of XXX IR, given with XXX in Patients with Major Depressive Disorder

A Double-Blind, Placebo-Controlled, Fixed-Dose Study of XXX in Patients 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, Open-label, 8-Week Study of Safety and Efficacy for Adjunctive XXX Treatment in Adults with Parkinson's Disease and Inadequately Controlled Depression

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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

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 II, Double-Blind, Placebo-Controlled, Multicenter Study of XXX as Adjunctive Treatment to a monoaminergic antidepressant in Adults with 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 IIb Two-Stage, Multicenter, Double-blind, Randomized, Parallel Group, Active- and Placebo-Controlled, Adaptive Dose Finding Study to Assess the Efficacy and Safety of XXX as Adjunctive Therapy to an Antidepressant in Adult Subjects with Major Depressive Disorder who have Responded Inadequately to Antidepressant Therapy

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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

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 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 Efficacy and Safety Study of XXX for the Adjunctive Treatment of Major Depressive Disorder

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

A Double-Blind, Randomized, Multi-center, Placebo-Controlled, Relapse Prevention Study with XXX in Out-Patient 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 Double-Blind, Placebo-Controlled Study of XXX as Adjunctive Therapy in Major Depressive 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 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

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

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

A 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

Diabetes

A Phase III, Randomized, Double-Blind, Active-Controlled Study to Evaluate the Effects of XXX vs. XXX in Subjects with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control by Metformin

CLINICAL RESEARCH EXPERIENCE (*continued*):

A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Add-on Study of XXX in Adults with Uncontrolled Type 2 Diabetes on Metformin Therapy

A Phase II, A Randomized, Double-blind, Parallel Group, Multicenter, Placebo-controlled, Dose-ranging Study to Evaluate the Glycemic Effects, Safety, and Tolerability of XXX Delayed-Release in Subjects with Type 2 Diabetes Mellitus

A Multiple dose trial examining dose range, escalation and efficacy of oral XXX in subjects with Type 2 Diabetes

A Phase III, Randomized, Active Comparator, Double-Blind, Multi-Center Study to Compare the Efficacy, Safety and Tolerability of XXX as Add-on Therapy to Metformin in Patients with Type 2 Diabetes

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Daily Oral XXX 25 mg and 50 mg Compared to Placebo When Used in Combination with XXX in Subjects with Type 2 Diabetes

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy, Safety and Tolerability of XXX in Patients with Type 2 Diabetes

A 26-week, multi-centre, multinational, open-label, 2-arm parallel, randomized, treat-to-target trial in insulin naïve subjects with T2DM inadequately controlled on a maximum tolerated dose or maximum dose according to local label of XXX in conjunction with XXX

A Phase III, 6-Month, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of XXX in Insulin-Naïve Patients with Type 2 Diabetes Mellitus not Adequately Controlled with Oral Antihyperglycemic Drugs with a 6-month Comparative Extension Period

Epilepsy

A Phase III Study that is Analyzing the Effectiveness and Safety of XXX Injections for Patients with Epilepsy that Receive Antiepileptic Drugs, but Still Experience Acute Repetitive Seizures (Bouts or Clusters of Seizures) that Require Treatment

A Double-Blind, Randomized, Historical Control Study of the Safety and Efficacy of XXX Monotherapy in Subjects with Partial Epilepsy Not Well Controlled by Current Antiepileptic Drugs to be Managed by XXX to Evaluate the Safety and Efficacy of an Investigational Product as Monotherapy in Subjects with Partial Epilepsy Unresponsive to Current Antiepileptic Drugs (AED) in Comparison to Historical- Pseudo -Placebo Control Groups

CLINICAL RESEARCH EXPERIENCE (*continued*):

A Double-Blind, Randomized, Historical-Controlled, Multi-Center Efficacy and Safety Study of XXX as Monotherapy in Patients With Refractory Partial Seizures & An Open-Label Multi-Center Extension Study to Determine Long Term Safety and Efficacy of XXX as Monotherapy in Patients With Partial Seizures

Fibromyalgia

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX in Subjects With Fibromyalgia

A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Proof of Concept Study of the Efficacy and Safety of XXX for Treatment of Patients with Fibromyalgia

A Phase III, Open-label Extension Study of XXX for 52 Weeks in Pain Associated with Fibromyalgia

A Phase III, Randomized, Double-blind, Double-dummy, Placebo- and Active-controlled, Multi-center Study of XXX in Subjects with Pain Associated with Fibromyalgia

Insomnia

A Long-Term Multicenter, Randomized, Double-Blind, Controlled, Parallel-Group Study of the Safety and Efficacy of XXX in Subjects With Insomnia Disorder

Irritable Bowel Syndrome

A Phase III, Open-Label, Long-Term Safety and Tolerability Study of XXX in Patients with Irritable Bowel Syndrome with Constipation (IBS-C)

A Second Phase III, Randomized, 12-Week, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of XXX in Patients with Irritable Bowel Syndrome with Constipation (IBS-C)

A Phase III Study to Assess Repeat Treatment Efficacy and Safety of XXX in Subjects with Irritable Bowel Syndrome with Diarrhea (IBS-D)

A 12-Week, Randomized, Double-Blind, Placebo-Controlled Study of XXX in Subjects with Diarrhea-Predominant Irritable Bowel Syndrome

A Phase III Randomized, Double-blind, Placebo-controlled, Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in the Treatment of Patients With Diarrhea-Predominant Irritable Bowel Syndrome

CLINICAL RESEARCH EXPERIENCE (*continued*):

Pain

A Safety and Efficacy Evaluation of XXX Laxative in Adults Experiencing Non-Idiopathic Constipation

A Double-blind, Randomized, Placebo-controlled, 24-week, Phase III Study Recruiting Males Over the Age of 50 and Post-menopausal Females with Documented Knee OA and Moderate Knee Pain

A Randomized Withdrawal, Double-blind, Placebo-controlled Phase III Trial to Evaluate the Efficacy and Safety of XXX® Tablet, XXX, in Patients with Moderate-to-Severe Chronic Low Back Pain

A Phase III, Multicenter Long-Term Observational Study of Subjects from XXX Studies Who Undergo a Total Knee, Hip, or Shoulder Replacement

A Phase III, Randomized, Double Blind, Placebo and Active-Controlled, Multicenter, Parallel-Group Study of the Analgesic Efficacy and Safety of XXX in Adult Patients with Chronic Low Back Pain

A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter Study of the Analgesic Efficacy and Safety of a Dose Titration Regimen for the Subcutaneous Administration of XXX in Patients with Osteoarthritis of the Hip or Knee

An Open-Label Extension (OLE), Long-term Safety and Tolerability Study of XXX in Patients with Chronic Idiopathic Constipation (CIC)

A Randomized, 12-Week, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of XXX in Patients with Chronic Idiopathic Constipation

A Randomized Double-blind, Placebo-controlled, Parallel-group, Multicenter, Phase III Study to Evaluate the Cardiovascular Safety of XXX for the Treatment of Opioid-induced Constipation in Subjects with Non-malignant Pain Receiving Opioid Therapy

A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel-group Study of XXX in the Treatment of Opioid-induced Constipation in Subjects with Non-malignant Pain Receiving Opioid Therapy

A Phase III, 6-Month, Open-Label, Extension Study to Evaluate the Safety of XXX at 15 to 90 mg Every 12 Hours for Relief of Moderate to Severe Pain in Patients With Chronic Low Back Pain Who Require Opioid Treatment for an Extended Period of Time

CLINICAL RESEARCH EXPERIENCE (*continued*):

A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase III Study to Evaluate the Efficacy and Safety of XXX for the Treatment of Opioid-Induced Constipation in Adults Taking Opioid Therapy for Chronic Non-Cancer Pain

A Phase II Multicenter, Randomized, Double-Blinded, Placebo-Controlled Study Using a Bayesian Adaptive Design to Assess the Efficacy, Safety, Tolerability, and Serum Exposure of Multiple Doses of XXX in Subjects with Painful Lumbar Radiculopathy

A Phase III, 12-Week, Randomized, Double-Blind, Placebo-Controlled, Randomized-Withdrawal Study to Evaluate the Efficacy and Safety of XXX at 30 to 90 mg Every 12 Hours for Relief of Moderate to Severe Pain in Opioid-Experienced Patients With Chronic Low Back Pain Who Require Opioid Treatment for an Extended Period of Time

A Phase III, Open Label Long Term Safety Study: An Open-Label Study to Assess the Long-Term Safety of XXX in Patients with Opioid-Induced Constipation (OIC)

A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase III Study to Evaluate the Efficacy and Safety of XXX for the Treatment of Opioid-Induced Constipation in Adults taking Opioid Therapy for Chronic Non-Cancer Pain AND A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase III Study to Evaluate the Long-Term Safety and Tolerability of XXX for the Treatment of Opioid-Induced Constipation in Adults taking Opioid Therapy for Chronic Non-Cancer Pain

A Randomized, Placebo-Controlled Trial of XXX Added to Nonsteroidal Anti-inflammatory Drugs in Patients with Knee Pain due to Osteoarthritis who have had Suboptimal Response to Nonsteroidal Anti-inflammatory Drug Treatment

A Randomized, Double-Blind, Parallel-Group Study of XXX vs. Oxycodone (IR) for the Treatment of Acute Low Back Pain

A Randomized, Double-Blind, Placebo Controlled, Parallel Group Study of XXX in Adult Migraineurs

A Randomized, Multi-center, Double-Blind, Parallel-Group Trial with Controlled Adjustment of Dose Assessing the Analgesic Efficacy and Safety of a New Analgesic Compared with Placebo in Subjects with Painful Diabetic Peripheral Neuropathy

A Phase IIb Repeat Dosing Clinical Trial of XXX in Subjects with Moderately Severe Diabetic Neuropathy

CLINICAL RESEARCH EXPERIENCE (*continued*):

Post-Traumatic Stress Disorder

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

A Phase III, Multicenter, Randomized, Double-blind, Trial of Fixed-dose XXX as Combination Therapy with Sertraline in the Treatment of Adults with Post-traumatic Stress Disorder

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

A 40-Week Open-Label Extension Study to Evaluate XXX SL Taken Daily at Bedtime in Patients with PTSD

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

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

A Phase II, 12-week, Open Label, Multicenter, Extension Study to XXX to Evaluate the safety and efficacy of XXX taken daily at bedtime in patients with military-related PTSD and related conditions

A Phase II, Double-Blind, Randomized, Multicenter, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX SL Tablets Taken at Bedtime in Subjects with Military Related PTSD

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

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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 Randomized, Double-blind, Active Comparator-Controlled Study to Evaluate the Long-term Safety and Tolerability of XXX in Subjects 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

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

A Phase IV, Open-label Study to Assess the Safety, Tolerability, Pharmacokinetics, and Efficacy of 180 mg XXX Subcutaneous Injection XXX Following a Switch From 6 mg Oral XXX in Patients With Clinically Stable 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 IIIb Multi-Center, Open-Label, Mirror-Image, Trial in Adult Subjects with Schizophrenia Treated Prospectively for 6-months with XXX

A Phase II Randomized, Double-blinded, Placebo-controlled Parallel Group Trial to Examine the Efficacy and Safety of XXX an Oral IP Once Daily with Adjunctive Computer-Assisted Cognitive Training over 12-week Treatment Period in Patients with Schizophrenia

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

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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

A Phase III Study to Evaluate 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 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 III, Open-Label, Multi-Center Trial to Assess the Safety and Effectiveness of XXX in Patients with Schizophrenia

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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

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 II, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX as Adjunctive Treatment for the Negative Symptoms of Schizophrenia

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Adjunctive XXX for the Treatment of Schizophrenia

Pilot study for Validation Test Plan XXX study

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

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

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

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

XXX for Cannabis Use Disorder in 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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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

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

A Phase II, Randomized, Multicenter, Safety, Tolerability, and Dose-Ranging Study of XXX, a component of XXX, in adults with Schizophrenia treated with XXX

A Phase III Study to Determine the Antipsychotic Efficacy and Safety of XXX in Adult Subjects with Acute Exacerbation of Schizophrenia

A Phase III, Open-Label, Long-Term Safety and Tolerability Study of XXX in the Treatment of Subjects with 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, Randomized, Double-blind, Placebo- and Active-controlled, Multi-center Study to Assess the Antipsychotic Efficacy of XXX in Patients 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, Multi-Center, Randomized, 12-Week, Double-blind, Parallel-Group, Placebo-Controlled Study to Evaluate the 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

CLINICAL RESEARCH EXPERIENCE (*continued*):

A Randomized, Double-blind, Placebo-controlled, Parallel, 26-Week, Phase III Study of 2 Doses of XXX or Placebo as an Adjunctive Pro-cognitive Treatment in Schizophrenia

A Phase III Multicenter 26-Week Extension Study to Evaluate the Safety and Clinical Effects of Prolonged Exposure to1 and 2 mg Doses of XXX as an Adjunctive Pro-cognitive Treatment in Subjects with Schizophrenia on Chronic Stable Atypical Antipsychotic Therapy

A Phase II, Multi-center Study with Open-label and Randomized Double-blind Placebo-controlled Withdrawal Phases to Evaluate the Efficacy, Safety, and Tolerability of XXX in Adults with Schizophrenia and Predominant Negative Symptoms who are Clinically Stable and taking Stable Doses of Atypical Antipsychotic Medication

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

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

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

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

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

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

A Multi-center, Double-Blind, Randomized, Placebo-Controlled, Study to Evaluate the Long-Term Efficacy, Safety, and Tolerability of an Intramuscular Depot Formulation of XXX in Patients with Schizophrenia

A 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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

Tardive Dyskinesia

A Phase IV, Double-Blind, Placebo-Controlled, Randomized Withdrawal Study to Evaluate the Persistence of Effect and Safety of XXX for the Treatment of Tardive Dyskinesia

A Phase IV, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Potential for Clinical Dependence and Withdrawal Symptoms Associated with XXX

A Phase III, Open-Label Rollover Study for Continuing XXX Administration for the Treatment of Tardive Dyskinesia

A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel, Fixed-dose Study to Assess the Efficacy, Safety, and Tolerability of XXX for the Treatment of Tardive Dyskinesia

A Phase III, Open-label, Safety and Tolerability Study of XXX for the Treatment of Tardive Dyskinesia

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

Vaccine

A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity and Efficacy of XXX Vaccine Candidates Against COVID 19 in Healthy Adults

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

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

Women's and Men's Health

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

A Phase III, Active-Controlled, Safety and Efficacy Trial of XXX Oral Testosterone in Hypogonadal Men

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XX in Subjects with Moderate to Severe Endometriosis-Associated Pain

A Phase III Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Effects of XXX on Bone Mineral Density (BMD) and Overall Safety in the Treatment of Osteoporosis in Postmenopausal Women Previously Treated with an Oral XXX

A Phase IIb Study to Evaluate the Safety and Efficacy of XXX in Pre-Menopausal Women with Heavy Menstrual Bleeding associated with Uterine Fibroids

Other Indications

A Phase III, 14-Day, Double-blind, Randomized, Placebo-Controlled, Multicenter Study of the Efficacy and Safety of XXX in Subjects with Pain Due to Acute Back Muscle Spasm

A Phase III, Multicenter, 48-week Open-Label Safety Study of Adjunctive XXX in Subjects With Obsessive Compulsive Disorder

A Phase III, Randomized, Double-blind, Placebo-controlled Trial of Adjunctive XXX in Obsessive Compulsive Disorder

A Phase II, Adaptive, Randomized, Placebo-controlled, Double-blind, Multi-center Study of Oral XXX , a Pyruvate Kinase Activator in Patients With Sickle Cell Disease

APhase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity and Efficacy of XXX Vaccine Candidates Against COVID 19 in Healthy Adults

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

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

CLINICAL RESEARCH EXPERIENCE (*continued*):

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

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 III, Randomised, Open-label, Comparative Safety and Efficacy Trial of Intravenous XXX and XXX in Subjects with Iron Deficiency Anaemia who are Intolerant or Unresponsive to Oral Iron Therapy or in whom the Haemoglobin Measurement in Investigators' Opinion were Sufficiently Low as to Require Rapid Repletion of Iron Stores to Minimize the Risk of Receiving a Blood Transfusion

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, 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 Randomized, Double-blind, Placebo-controlled, Multicenter, Phase II Study to Evaluate the Efficacy and Safety of 12 weeks of Treatment with Two Different Doses of Oral Study Drug as Compared to Placebo, Followed by a 12 week Open-label Treatment Period with Study Drug, in Patients with Moderate to Severe Active Crohn’s Disease

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

A Phase II, Double-Blind, Placebo-Controlled, Randomized study to assess the Efficacy, Safety, and Tolerability of following Multiple Intravenous Doses in Hypercholesterolemic subjects on maximum dose of XXX or XXX

ABSTRACTS AND PUBLICATIONS:

"Plasma Sialyltransferase, Total and Iso-Enzyme Activity in the Diagnosis of Colon Cancer" Journal of Clinical Biochemistry, (1) 46-48 (1982) and XI International Congress of Clinical Chemistry

Clinical Researcher, University of California at San Diego, Study entitled: "Rates of Decline in Pulmonary Function Over a 20 Year Period" done on San Diego Firemen

"Development and Administration of an HIV/AIDS Screening Program" presented by invitation of the American Public Health Association at the 114th Annual Meeting,
Sept 28 – Oct 2, 1986 in Las Vegas, Nevada

PROFESSIONAL ORGANIZATIONS/MEMBERSHIPS:

Member of American Academy of Family Physicians
California Academy of Family Physicians, Long Beach Chapter
American College of Occupational and Environmental Medicine (ACOEM)
American Osteopathic Association
Honorary member of Long Beach Police Officers Association
Memorial Healthcare IPA