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Apex Innovative Sciences
Collaborative Neuroscience Research, LLC
Collaborative Neuroscience Network, LLC
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2600 Redondo Avenue, Suite 500
Long Beach, CA 90806

EDUCATION:

2003, Doctor of Medicine
Ross University School of Medicine, Portsmouth, Dominica

1997: BS in Biological Science
University of California – Irvine, Irvine, CA

RESIDENCIES:

Chief Resident
Warren Hospital Family Medicine Residency Program, Phillipsburg, NJ
Residency 2006 -2009

CERTIFICATION:

Licensed in California, December 2008
Diplomate American Board of Family Medicine

LICENSURE:

Licensed Physician and Surgeon, State of California, License No. A106386

PROFESSIONAL EXPERIENCE:

Investigator, 2019 - Present
Apex Innovative Sciences

Investigator, 2017- Present
Collaborative Neuroscience Research, LLC, Long Beach, CA
Collaborative Neuroscience Network, LLC, Long Beach, CA

Sub-Investigator, 2011- Present
Collaborative Neuroscience Research, LLC, Long Beach, CA
Collaborative Neuroscience Network, LLC, Long Beach, CA

Urgent Care/Family Medicine, 2012 – Present
Memorial Prompt Care, Huntington Beach, CA

Urgent Care, 2010- Present
Healthcare Partner Medical, Long Beach, CA.

Urgent Care, 2009 – 2012
Magan Medical Clinic, Covina, CA
Supervise PA's and treat common ailments, including Run Codes, laceration repairs, I & D abscesses, chest pain, Sport injuries, splinting, Asthma/COPD exacerbations.

RESEARCH:

Accuracy of albumin adjusted calcium versus ionized serum calcium in ICU patients. Presented at Warren Hospital for Research Symposium.

Research Coordinator, 2003-2006
VA Medical Center, Long Beach, CA
Investigation into Hemochromatosis – Prevalence among VA patients and possible alternative guidelines for screening.

CERTIFICATIONS:

BLS, ACLS

CLINICAL TRIAL EXPERIENCE:

Phase I • ADHD • Alzheimer's Disease • Anxiety • Asthma • Ataxia • Binge Eating Disorder
Bipolar Disorder • Chronic Pain • Constipation • Crohn's Disease • Depression • Diabetes
Driving Simulation • Essential Tremor • Ethno-Bridging • Healthy • Huntington's Disease
Hypercholesterolemia • Hypotension • Iron Deficiency Anemia • Irritable Bowel Syndrome
Men's and Women's Health • Migraine • Multiple Sclerosis • Nausea assoc. w/ Motion Sickness
Neuropathic Pain • Obsessive Compulsive Disorder • Opioid Induced Constipation
Opioid Use Disorder • Osteoarthritis • Painful Lumbar Radiculopathy • Parkinson's Disease
Post-Polio Syndrome • Schizophrenia and Schizoaffective Disorders • Spasticity
Stroke/Post-Stroke • Tardive Dyskinesia

CLINICAL TRIAL EXPERIENCE:

Phase I Alzheimer's Disease

A Phase I, Multiple-Dose, Dose-Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX in Participants with Alzheimer's Disease

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 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, 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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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 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

Phase I Depression

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

Phase I Ethno-Bridging

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 Normal

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

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 1 study) and Open Label Extension.

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 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, 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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

Phase I Parkinson's Disease

A Phase I, Randomized, Double-blind, Placebo-controlled Study of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Multiple Ascending Doses of XXX in Subjects with Parkinson's Disease

A Phase I, 2-Part, Open-label, Adaptive, Single and/or Multiple Oral Dose, Safety, Tolerability, and Food Effect Trial of XXX in Subjects with Parkinson's Disease

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

Phase I Schizophrenia and Schizoaffective Disorders

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

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 TRIAL 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 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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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, 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

Phase I Other Indications

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

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 Double-blind, Placebo-Controlled, Multiple Ascending Dose Study to Determine the Safety, Tolerability and Pharmacokinetics of XXX Oral Solution in Healthy Adults with an Open-Label Cohort of Patients with Huntington's Disease

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, 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

CLINICAL TRIAL EXPERIENCE (*continued*):

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 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 Studies

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

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)

CLINICAL TRIAL EXPERIENCE (*continued*):

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

A Multicenter, Open-Label, Long-Term Extension of Phase III Studies of XXX in Patients with Alzheimer's Disease

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group, Efficacy, and Safety Study of XXX in Patients with Early (Prodromal to Mild) 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, Open Label Extension Study for Continued Safety and Efficacy Evaluation of XXX in Patients with Mild Alzheimer's Disease

Two Independent Trials: Randomized, Double-Blind, Placebo Controlled, Parallel-Group, Multicenter, Phase II Study to Evaluate the Efficacy and Safety of XXX in Patients with Prodromal-to-Mild or Moderate Alzheimer's Disease

A Phase II, Randomized, Double-Blind, Placebo Controlled, parallel group study to evaluate the efficacy and safety of XXX in participants at risk for the onset of clinical symptoms of AD

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety of XXX in the Treatment of Agitation in Patients with Dementia

A Phase II/III, Randomized, Double-blind, Placebo-controlled Trial to Assess the Efficacy and Safety of XXX for the Treatment of Agitation in Subjects with Dementia of the Alzheimer's Type

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, 24-month, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group, Efficacy, Safety, Tolerability, Biomarker, and Pharmacokinetic Study of XXX in Early Alzheimer's Disease (The XXX Study)

A Phase III, Multicenter, Long-term, Extension Study of the Safety and Efficacy of XXX for the Treatment of Agitation in Patients with Dementia of the Alzheimer's Type

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy, Safety, and Tolerability of XXX for the treatment of agitation in patients with dementia of the Alzheimer's type

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group, Efficacy and Safety Study of XXX in Patients with Prodromal-to-mild Alzheimer's Disease

A Phase IIa, Randomized, Parallel Group, Placebo Controlled Study of 50 mg and 100 mg of XXX and Placebo in Subjects with Mild to Moderate Alzheimer's Disease Currently Treated with XXX and XXX

A Phase III, Randomized, Double-Blind, Placebo Controlled, Multi-Center Registration Trial To Evaluate The Efficacy And Safety Of TTP488 In Patients With Mild Alzheimer's Disease Receiving XXX And/Or XXX

A Phase III, 12-week, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy, Safety, and Tolerability of 3 Fixed Doses of XXX in the Treatment of Subjects with Agitation Associated with Dementia of the Alzheimer's Type

A 2-month, Observational, Rollover Trial to Evaluate the Safety of Subjects with Agitation Associated with Dementia of the Alzheimer's Type who were Previously Treated with XXX or Placebo in a Phase III, Double-blind Trial

A Phase III, Effect of XXX, an anti-amyloid beta monoclonal antibody, on the progression of Alzheimer's disease as compared with placebo

A Phase III, Double Blind, Randomized, Placebo Controlled, Parallel Group Study to Simultaneously Qualify a Biomarker Algorithm for Prognosis of Risk of Developing Mild Cognitive Impairment due to Alzheimer's Disease (MCI due to AD) and to Test the Safety and Efficacy of XXX to Delay the Onset of MCI due to AD in Cognitively Normal Subjects

An Open-Label, Extension Study of the Effects of XXX in Subjects with Alzheimer's Disease or Behavioral Variant Frontotemporal Dementia

A 26-Week Extension Study of the Safety and Clinical Effects of XXX in Subjects with Alzheimer's Disease Currently or Previously Receiving an Acetylcholinesterase Inhibitor Medication

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Placebo-Controlled, Parallel, 26-Week, Phase III Study of Two Doses of XXX , an Alpha-7 Nicotinic Acetylcholine Receptor Partial Agonist, or Placebo in Subjects with Mild to Moderate Probable Alzheimer's Disease with or without Acetylcholinesterase Inhibitor Medication

A Phase II/III randomized, placebo-controlled, parallel-group, double blind clinical trial to study the efficacy and safety of XXX in subjects with mild cognitive impairment due to Alzheimer's Disease (prodromal AD)

A Phase III Effect of XXX , an anti-amyloid beta monoclonal antibody, on the progression of Alzheimer's disease as compared with placebo

A Phase II,12-Week Safety Extension Study of Oral XXX for Treatment of Agitation and Aggression in Patients With Moderate to Severe Alzheimer's Disease

A Phase II six month, double-blind, randomized, placebo-controlled, parallel-group study to investigate the effects of daily administration of XXX in subjects with mild to moderate AD

A Prospective, Randomized, Double-Blind, Placebo-Controlled, Phase II Efficacy and Safety Study of XXX for Treatment of Agitation and Aggression in Patients With Moderate to Severe Alzheimer's Disease

A Phase III Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 18-month Safety and Efficacy Study of XXX in Subjects with Mild Alzheimer's Disease

A Phase II Placebo-controlled, Double-blind, Parallel-group, Bayesian Adaptive Randomization Design and Dose Regimen-finding Study to Evaluate Safety, Tolerability and Efficacy of XXX in Subjects With Early Alzheimer's Disease

A Phase II, Long-Term Safety and Tolerability of XXX in Subjects with Mild-to-Moderate Alzheimer's Disease on Stable Doses of XXX: An Open-Label Extension Study for Subjects Completing Study XXX

A Phase II, Randomized, Placebo Controlled, Parallel-Group, Double Blind Efficacy and Safety Trial of XXX in Subjects with Mild to Moderate Alzheimer's Disease

A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX in Subjects With Mild-to-Moderate Alzheimer's Disease on Stable Doses of Acetylcholinesterase Inhibitors

A Phase III Randomized, Double-blind, Placebo-Controlled Study of the Safety and Effectiveness of XXX for the Treatment of Mild to Moderate Alzheimer's Disease (AD)

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IIIb Study of Subjects With Alzheimer's Disease Who Discontinued Treatment in XXX Phase III Clinical Studies XXX or Who Completed Studies XXX but did not Enroll in Study XXX

A Phase IIb, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Biomarker, Safety, and Pharmacokinetic Study of XXX Administered Subcutaneously at Monthly Intervals in Subjects with Mild to Moderate Alzheimer 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 III, Open Label Extension of XXX Evaluating XXX in Patients with Alzheimer's Disease

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Efficacy and Safety Trial of XXX in Subjects With Mild to Moderate Alzheimer Disease Who Are Apolipoprotein E ε4 Non-Carriers

Ataxia

A Phase II Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety, Tolerability, and Efficacy of XXX in Adults with Spinocerebellar Ataxia (Synchrony-1)

A Randomized, Double-Blind, Controlled, Phase II/III Study to Assess Efficacy, Long Term Safety and Tolerability of XXX in Subjects with Friedreich's Ataxia

A Phase IIb/III, Randomized, Double-blind, Placebo-controlled Trial of XXX in Adult Subjects with Spinocerebellar Ataxia

A Phase IIb/III, Randomized, Double-blind, Placebo-controlled Trial of XXX in Adult Subjects with Spinocerebellar Ataxia

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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 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

CLINICAL TRIAL EXPERIENCE (*continued*):

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 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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

A Phase 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

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

Hypotension

A Phase III, 24-week, Multi-center, Randomized Withdrawal Study of XXX in Treating Symptomatic Neurogenic Orthostatic Hypotension in Subjects with Primary Autonomic Failure

A Phase III, 4-week, Multi-center, Randomized, Double-blind, Placebo-controlled, Parallel-group Study of XXX in Treating Symptomatic Neurogenic Orthostatic Hypotension in Subjects with Primary Autonomic Failure

A Phase II Study to Assess the Effect and Safety of XXX in Subjects with Neurogenic Orthostatic Hypotension

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)

CLINICAL TRIAL EXPERIENCE (*continued*):

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

Migraine

A Phase III, 12-Month Study to Evaluate the Safety and Tolerability of XXX (Nasal Powder) in the Acute Treatment of Migraine

A Phase II/III Open-label, Long-Term, Safety Trial of XXX Intranasal (IN) for the Acute Treatment of Migraine

A Phase II: Double-Blind, Randomized, Placebo Controlled, Dose-Ranging Trial of XXX for the Acute Treatment of Migraine

A Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Single Doses of XXX Nasal Powder in the Acute Treatment of Migraine

A Phase III, Multicenter, Randomized, Open-label Study to Evaluate the Longterm Safety and Tolerability of Oral XXX for the Prevention of Migraine in Patients with Episodic Migraine

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

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

A Phase III, Double-Blind, Randomized, Placebo Controlled, Safety and Efficacy Trial of XXX Orally Disintegrating Tablet (ODT) for the Acute Treatment of Migraine

A Prospective, Randomized, Vehicle-Controlled, Double-Blind, Phase II Study to Assess the Safety, Tolerability, and Efficacy of XXX Delivered as an Intranasal Spray for Preventive Treatment in Subjects with Episodic Migraine

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Multicenter, Randomized, Proof-of-Concept, Double-Blind, Placebo-Controlled, Parallel-Group Study Comparing the Efficacy and Safety of 1 Subcutaneous Dose Regimen of XXX Versus Placebo for the Prevention of Persistent Posttraumatic Headache (PPTH)

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

A Multicenter, Open Label, Long-Term Safety Study of XXX in Patients with Acute Migraines

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

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

A Open Label Trial to Evaluate the Safety of XXX Administered Intravenously in Patients with Chronic Migraines

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

A Multicenter, Randomized, Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of Oral XXX in the Acute Treatment of Migraine With or Without Aura

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Single Attack Study to Evaluate the Efficacy, Safety and Tolerability of Oral XXX in the Acute Treatment of Migraine

An Observational Research Study: Prospective Cohort Study to Describe Patient-Reported Outcomes in Subjects with Migraine Eligible for Prophylaxis

A Phase III, Multicenter, Randomized, Double-Blind, Parallel-Group Study Evaluating the Long-Term Safety, Tolerability, and Efficacy of Subcutaneous Administration of XXX for the Preventive Treatment of Migraine

A Phase III, Multicenter, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Parallel-Group Study Comparing the Efficacy and Safety of 2 dose regimens of subcutaneous administration of XXX versus Placebo for the Preventive Treatment of Episodic Migraine

A Phase III, Multicenter, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Parallel-Group Study Comparing the Efficacy and Safety of 2 dose regimens of subcutaneous administration of XXX versus Placebo for the Preventive Treatment of Chronic Migraine

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Open Label Trial to Evaluate the Safety of XXX Administered Intravenously in Patients with Migraine

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

A Phase II, Randomized, Placebo-Controlled, Double-Blind, Double-Dummy, Four-Treatment, Three-Period Crossover Study Evaluating Efficacy of a Single Dose of XXX in Patients with Migraine Headache with or without aura

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

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

A Randomized, Multicenter, Double-Blind, Placebo Controlled, Two-Arm Study Evaluating Efficacy of a Single Dose XXX (10 mg vs. Placebo) in Patients with Acute Migraine Headache With or Without Aura

A Phase IIb, Randomized, Doub-Blind, Placebo-Controlled Study of XXX in Patients with Episodic Migraine

A Multicenter, Double-Blind, Placebo-Controlled, Parallel Group, Multi-dose Study to Compare the Efficacy and Safety of Subcutaneous XXX with Placebo for the Preventive Treatment of Chronic Migraine

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Study Comparing the Efficacy and Safety of Two Doses of Subcutaneous XXX with Placebo for the Preventive Treatment of High Frequency Episodic Migraine (HFEM)

A Phase II, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of XXX in Episodic Migraine Prevention, Dosed monthly by subcutaneous (SC) injection

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of XXX in Patients with Migraine

A Phase II, Randomized, Double-Blind, Placebo-Controlled Proof-of-Concept Study of XXX for Migraine Prophylaxis in Patients with Migraine

CLINICAL TRIAL EXPERIENCE (*continued*):

Multiple Sclerosis

A Phase III, randomized, double-blind, efficacy and safety study comparing XXX to placebo in participants with primary progressive multiple sclerosis

A Phase III, Randomized, Double-blind, Efficacy and Safety Study Comparing XXX to Placebo in Participants With Nonrelapsing Secondary Progressive Multiple Sclerosis

A Phase III, Double-blind, Randomized, Placebo-controlled, Parallel-group Trial of the Efficacy and Safety of XXX Spray as Add-on Therapy in Patients with Spasticity Due to Multiple Sclerosis

A Phase III, Multicenter, Randomized, Parallel Group, Double Blind, Double Dummy, Active Controlled Study of XXX Compared with XXX , in Participants with Relapsing Multiple Sclerosis to Evaluate Efficacy and Safety followed by OLE

A Phase III, Multicenter, Randomized, Parallel Group, Double Blind, Double Dummy, Active Controlled Study of XXX with an Active Control Group Interferon Beta 1a XXX, in Participants with Relapsing Multiple Sclerosis to Evaluate Efficacy and Safety.

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Dose-Ranging, Multi-Center Trial to Evaluate the Efficacy and Safety of XXX Injection for the Treatment of Upper Limb Spasticity in Adults After Stroke or Traumatic Brain Injury

A Phase III Multicenter, Open-Label Safety and Efficacy Study of XXX Extended Release Capsules in Patients with Multiple Sclerosis and Walking Impairment

A Phase III, 3-Arm, Multicenter, Double-Blind, Placebo-Controlled, Randomized Study to Assess the Efficacy and Safety of XXX Extended Release Capsules in Multiple Sclerosis Patients with Walking Impairment

A Phase III, Open-Label Study to Evaluate the Long-Term Safety of XXX Extended-Release Tablets in Multiple Sclerosis Patients with Spasticity

A Phase III, Randomized, Double-Blind, Placebo-Controlled Parallel Group Study to Investigate the Safety and Efficacy of XXX Extended-Release Tablets for the Treatment of Spasticity in Patients with Multiple Sclerosis

A Phase III XXX In Multiple Sclerosis Treatment Effects XXX Study. A 120 week, Phase III, randomized, multi-center, double-blinded, double-dummy, active-controlled study that is primarily designed to assess the ARR and safety/ tolerability of XXX as compared to XXX placebo in subjects with RMS

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study in Subjects With Relapsing Multiple Sclerosis to Evaluate the Efficacy and Safety of XXX as an Add-On Therapy to Anti-Inflammatory Disease-Modifying Therapies

A Phase III Study in Subjects with Relapsing Remitting Multiple Sclerosis to Evaluate the Tolerability of XXX and XXX

A Phase III, Open Label Study to Evaluate the Long-term Safety and Tolerability of XXX in Subjects with Relapsing Remitting Multiple Sclerosis

A Phase III, Open-label study to Assess the Effects of XXX on lymphocyte subsets in subjects with relapsing-remitting multiple sclerosis

A Phase III, multi-site, open-label extension trial of oral XXX in relapsing multiple sclerosis

A Phase III, Multi-center, Randomized, Double-blind, Double-dummy, Active controlled, Parallel Group Study to Evaluate the Efficacy and Safety of XXX Administered Orally to Relapsing Multiple Sclerosis Patients

A Multicenter, treatment blind Phase IIIb study to evaluate whether 6 week up-titration in XXX dose is effective in reducing the Incidence of Gastro-Intestinal adverse events in relapsing-remitting Multiple Sclerosis patients

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy of XXX on Reducing Disability Progression in Subjects With Secondary Progressive Multiple Sclerosis (SPMS)

A Phase II/III, Multi-center, Randomized, Double-blind, Placebo-controlled (Part A) and Double-blind, Double-dummy, Active-controlled (Part B), Parallel Group Study to Evaluate the Efficacy and Safety of XXX Administered Orally to Relapsing Multiple Sclerosis Patients

A Prospective, Single-Arm, Clinical-Setting Study to Describe Efficacy, Tolerability and Convenience of XXX Treatment Using Patient Reported Outcomes (PROs) in Relapsing Multiple Sclerosis (RMS) Patients

A Double-Blind, Randomized, Placebo-Controlled, Parallel Group Trial to Evaluate the Duration of Action of XXX in Subjects with Spasticity due to Multiple Sclerosis

A Phase III, Randomized, Double-Blind, Parallel Group Study to Compare the Safety and Efficacy of Increasing Doses of XXX Extended Release Tablets to Placebo and XXX Tablets, for the Treatment of Spasticity in Patients with Multiple Sclerosis

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, randomized, partially blind, placebo-controlled, proof-of-concept study to assess the effect of a single infusion of XXX on disease activity as measured by brain MRI scans in patients with relapsing-remitting multiple sclerosis

A Phase III, Open-Label, Randomized, Multi-Center, Parallel-Arm Study to Assess the Safety and Tolerability of XXX 40 mg/mL Three Times a Week Compared to 20 mg/mL Daily Subcutaneous Injections in Subjects with Relapsing-Remitting Multiple Sclerosis

A Phase III, Open Label, 26-Week Study Assessing XXX Safety and Efficacy in Subjects with Spasticity Associated with Multiple Sclerosis with an Addendum Open-Label, 36-Week Study Assessing XXX Safety in Subjects with Spasticity Associated with Multiple Sclerosis

An Open Label, 26-Week Study Assessing XXX Safety and Efficacy in Subjects with Spasticity Associated with Multiple Sclerosis

A Randomized, Double Blind, Placebo-Controlled Efficacy and Safety Study of XXX in Subjects with Spasticity due to Multiple Sclerosis

A Multicenter, Observational, Open-Label, Single-Arm Study of XXX in Early Relapsing-Remitting Multiple Sclerosis in Anti-JCV Antibody Negative Patients

A Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of Two Doses of Oral XXX Extended Release Tablets (5 mg and 10 mg twice daily) in Patients with Multiple Sclerosis

Pain

A Phase II, Randomized, Double-blind, Placebo and Active Comparator-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of XXX in the Treatment of Diabetic Peripheral Neuropathic 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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Randomized, Double-blind, Placebo-and Active-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of XXX for the Treatment of Diabetic Peripheral Neuropathic Pain

A Phase II, Randomized, Double-blind, Placebo-controlled, Dose-range finding Study to Assess the Efficacy and Safety of Intramuscular Injections of Human Placenta-derived Cells (XXX) in Subjects with Diabetic Peripheral Neuropathy

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 Multicenter, randomized, double-blind, placebo-controlled trial to assess the safety and efficacy of XXX in Subjects with Type 2 Diabetes and Diabetic Peripheral Neuropathy

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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 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 Phase III,double-blind, randomized, placebo-controlled, multicenter study evaluating the efficacy and safety of XXX in subjects with Painful Diabetic Peripheral Neuropathy

A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Study Assessing the Efficacy, Safety and Tolerability of XXX for the Pain of Diabetic Peripheral Neuropathy

A Randomized, Double-Blind, Placebo and Active Comparator-Controlled Study of XXX for Treatment of Neuropathic Pain Associated with Diabetic Peripheral Neuropathy

A Phase II, Multinational, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study of Efficacy and Safety of XXX 20MG and 120MG Twice Daily for 4 Weeks in Patients with Chronic Peripheral Neuropathic 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 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 Phase II, Multicenter, Randomized, Double-Blind, Placebo, Active Controlled Study Comparing the Analgesic Efficacy and Safety of XXX to Placebo in Subjects with Diabetic Neuropathic Pain

A Phase II, 52-week, Open-label, Long-term Treatment Evaluation of the Safety and Efficacy of XXX in subjects with moderate to severe Chronic Pain

CLINICAL TRIAL EXPERIENCE (*continued*):

Men's and Women'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

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

Parkinson's Disease

A Randomized, Double-Blind, Placebo-Controlled, 2-Period Crossover, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Oral XXX in Parkinson's Patients with Cognitive Impairment and an Elevated Risk of Falls

A Phase II, Open-Label Evaluation of the Safety and Tolerability of XXX in Participants with Parkinson's Disease Mild Cognitive Impairment

A Phase III, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Flexible-Dose, 27-Week Trial to Evaluate the Efficacy, Safety, and Tolerability of XXX as Adjunctive Therapy for Parkinson's Disease in Levodopa-Treated Adults With Motor Fluctuations

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of XXX in Parkinson's Disease Patients with Motor Fluctuations

A Phase III, Multicenter, Randomized, Active-controlled, Double-blind, Double Dummy, Parallel Group Clinical Trial, Investigating the Efficacy, Safety, and Tolerability of Continuous Subcutaneous XXX Infusion in Comparison to Oral IR-LD/CD in Subjects with Parkinson's Disease Experiencing Motor Fluctuations

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Fixed-dosage, Phase IIa Study Comparing 3 Dosages of XXX (10, or 30, or 75 mg administered orally [or 50 mg based on interim analysis] once a day [QD]) with Placebo over 12 weeks in Subjects with Mild-to-Moderate PDD.) Effect of XXX on Cognition in Mild to Moderate Parkinson's Disease Dementia (PDD) (The XXX Study)

A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Pharmacokinetics, and Pharmacodynamics of XXX in Subjects with Parkinson's Disease

A Phase IIa, Double-Blind, Placebo-Controlled, Two-Part study to investigate the safety and efficacy of increasing doses of XXX in Parkinson's Disease (PD) Subjects with motor fluctuations

A Phase III, Multicenter, Open-Label Study to Evaluate the Safety and Tolerability of XXX in Patients with Parkinson's Disease

A Phase II, Study to Assess the PK and Pharmacodynamics (PD) of XXX in Patients With Advanced Parkinson's Disease

A Phase III, Randomized, Double-blind, Placebo-Controlled Study Investigating the Efficacy and Safety of XXX in Parkinson's Disease Patients With Motor Response Fluctuations (OFF Phenomena)

A Phase III, 12-Month, Dose-Level Blinded Study Investigating the Safety and Efficacy of XXX in Parkinson's Disease Patients With Motor Response Fluctuations (OFF Phenomena)

A Phase IV, 24-Week, Multicenter, Randomized, Double-blind, Placebo-Controlled, Add-on, Parallel-Group Study to Assess the Effect of XXX on Cognition in Patients with Parkinson's Disease

A Phase IIa, Multi Centre, Double-Blind, Randomized, Placebo-controlled, Parallel-group Safety and Tolerability Study to Assess the Safety and Tolerability of oral XXX in Patients with Parkinson's Disease

An Extended Release XXX Safety and Efficacy Study in Levodopa-Induced Dyskinesia

A Phase II, Randomized, Open-Label, Crossover Study to Compare XXX to an Immediate-Release Carbidopa/Levodopa Tablet in Patients with Advanced Parkinson's Disease with Motor Fluctuations

A Phase III,40-Week, Active-Controlled, Double-Blind, Double-Dummy Extension Study of XXX in Subjects With Moderate to Severe Parkinson's Disease

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, 12-Week, Double-Blind, Placebo-Controlled Efficacy and Safety Study of XXX in Subjects with Moderate to Severe Parkinson's Disease

Schizophrenia and Schizoaffective Disorders

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

XXX Patch Acceptance Study (This study aims to assess the acceptability of the XXX patches against each other and the XXX patch.)

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

Stroke/ Post-stroke

A Phase III, Extension Study to Evaluate the Long-Term Safety, Tolerability and Efficacy of XXX Extended-Release Tablets for the Treatment of Chronic Post-Ischemic Stroke Walking Deficits in Subjects Who Participated in the XXX Study

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Extension Study to Evaluate the Long-Term Safety, Tolerability and Efficacy of XXX Extended-Release Tablets for the Treatment of Chronic Post-Ischemic Stroke Walking Deficits in Subjects Who Participated in the XXX Study

A **R**andomized, Double-blind, **E**valuation in **S**econdary Stroke **P**revention Comparing the **E**ffica**C**y and Safety of the Oral **T**hrombin Inhibitor XXX (110 mg or 150 mg, Oral b.i.d.) Versus XXX (100 mg Oral q.d.) in Patients With **E**mbolic **S**troke of **U**ndetermined **S**ource (RESPECT ESUS)

A Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Two Dose Strengths of XXX Extended Release Tablets for Treatment of Stable Walking Deficits in Post-Ischemic Stroke

A Prospective, double-blind, placebo-controlled, randomized, multi-center study with an open-label extension period to investigate the efficacy and safety of XXX in the treatment of post-stroke spasticity of the lower limb

Other Indications

A Phase II, Double-blind, Placebo-controlled, Randomized Study Evaluating the Efficacy, Safety, and Tolerability of XXX in the Treatment of Individuals with Essential Tremor

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.

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II/III, Multicenter, Prospective, Randomized, Placebo-controlled, Double-blind, Parallel-group Clinical Trial to Assess the Efficacy and Safety of Immune Globulin Intravenous (Human) XXX in Patients with Post-Polio Syndrome

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 II, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Dose-Ranging, Multi-Center Trial to Evaluate the Efficacy and Safety of XXX Injection for the Treatment of Upper Limb Spasticity in Adults After Stroke or Traumatic Brain Injury

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, 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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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 Phase II, Randomized, Double-Blind, 6-Sequence, Placebo-Controlled, 2-Period Multicenter Crossover Study to Evaluate the Safety and Efficacy of XXX in Subjects with Spasticity due to Spinal Cord Injury

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

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 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 Phase II, Randomized, Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group Study Comparing XXX with Placebo in Subjects with Age-Associated Memory Impairment (AAMI)

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 Prospective, double-blind, placebo-controlled, randomized, multi-center study with an open-label extension period to investigate the efficacy and safety of XXX in the treatment of post-stroke spasticity of the lower limb

CLINICAL TRIAL EXPERIENCE (*continued*):

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