



Curriculum Vitae, Michael Alfano, J.D.



Michael Alfano, J.D.
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EDUCATION:

1995 Juris Doctor
Temple University School of Law, Philadelphia, PA

1990 B.S. Pharmacy
Philadelphia College of Pharmacy & Science, Philadelphia, PA

CONTINUING EDUCATION AND CERTIFICATIONS:

Registered Pharmacist in Pennsylvania and New Jersey
Member of Pennsylvania Bar
GCP Certification (CITI Program and Barnett International)
Cardiopulmonary Resuscitation (American Red Cross)

PROFESSIONAL EXPERIENCE:

Pharmacy Director, 2019-present
Apex Innovative Sciences

Pharmacy Director, 2018 – Present
Hassman Research Institute, LLC, Berlin & Marlton, NJ

Pharmacy Director/Senior Manager of Clinical Operations, 2015 – 2018
PRA Healthsciences, Marlton, NJ

Clinical Research Pharmacist, 2006 – 2015
CRI Lifetree, Marlton, NJ

PROFESSIONAL EXPERIENCE (continued):

Project Manager, 2010-2013
IMA Consulting, Chadds Ford, PA

Pharmacist, 2000 – Present

Engaged in activities for compounding of parenteral and oral dosage forms including capsule filling and over-encapsulation (including CRI WorldWide, PRA Healthsciences, and Phase I Units for GlaxoSmithKline and Astra Zeneca).

CLINICAL TRIAL EXPERIENCE:

Phase I-IV: Alzheimer's Disease • Asthma • Attention-Deficit/ Hyperactivity Disorder (ADHD)
Atopic Dermatitis • Axillary Hyperhidrosis • Bipolar Disorder • Borderline Personality Disorder
Cancer Screening • Chronic Pain • Cognition • COVID-19 • Depression • Dermatology
Diabetes • Diabetic Kidney Disease • Neuropathic Pain • Healthy • Hunter Syndrome • Influenza
Irritable Bowel Syndrome (IBS) • Lactose Intolerance • Migraine • Molluscum Contagiosum
Nonalcoholic Steatohepatitis (NASH) • Nonalcoholic Fatty Liver Disease (NAFLD)
Obsessive Compulsive Disorder • Opioid Use Disorder • Osteoarthritis • Osteoporosis
Overactive Bladder • Parkinson's Disease • Post Traumatic Stress Disorder • Pruritus • Psoriasis
Respiratory Illness • Rosacea • Schizophrenia or Schizoaffective Disorder
Vaccines • Women's Health

CLINICAL TRIAL EXPERIENCE:

Phase I Addiction

A Phase I, Randomized, Double-blind, Double-dummy, Active- and Placebo-controlled, Crossover Study to Assess the Abuse Potential of XXX Relative to Buprenorphine and Placebo in Healthy Experienced Recreational Drug Users

Phase I Depression

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

A Phase I, Two-Part, Double-Blind, Placebo-Controlled, Twice Daily Dose Study of XXX in Adult Participants with Major Depressive Disorder (Part B)

A Phase I Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of Single Doses of XXX in Healthy Volunteers and Subjects with Treatment-Resistant Depression

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

CLINICAL TRIAL EXPERIENCE (*continued*):

Phase I Diabetes

A Phase I, Multiple-Dose Study in Participants with Type 2 Diabetes Mellitus to Investigate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX

A Phase I, Randomized, Double-blind, Placebo-controlled, Ascending Multiple-dose Study to Determine the Safety and Tolerability, Pharmacokinetics, and Pharmacodynamics of Orally Administered XXX in Subjects with Type 2 Diabetes Mellitus

A Phase Ia/Ib, Dose-Escalating, Two-Part Study to Evaluate the Safety and Pharmacokinetics of Single and Multiple Doses of XXX in Subjects with Type 2 Diabetes Mellitus

Phase I Healthy

A Phase I, Randomized, SAD and MAD Study to Determine the Safety, Tolerability and PK of XXX in Older Adult and Elderly Healthy Volunteer

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

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

A randomized, double-blind, double-dummy, active- and placebo-controlled, crossover study to assess the abuse potential of XXX relative to ketamine and placebo in healthy experienced recreational drug users.

A Phase I, Open-label, Fixed-sequence, Crossover Study on the Effects of XXX on the Pharmacokinetics of an Oral Contraceptive in Healthy Female Subjects

A Phase I Study to Evaluate the Pharmacokinetic Profiles of Modified Release (MR) Formulations of XXX in Healthy Adult Subjects

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

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 Phase I, Double-blind, Sponsor-open, Placebo-controlled, First-In-Human Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single Ascending Dose of XXX in Healthy Subjects

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase I, Randomized, Double-blind, Placebo-controlled, Single-Ascending-Dose Trial to Evaluate the Safety, Tolerability, Immunogenicity, and Pharmacokinetics of Intravenous XXX in Normal Healthy Volunteers

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Combined Single and Multiple Ascending Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX Oral Solution in Healthy Subjects (Part B MAD)

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Combined Single and Multiple Ascending Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX Oral Solution in Healthy Subjects (Part A SAD)

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

A Double-blinded, Placebo-controlled, Sequential Cohort, Single-dose Escalation, Phase I Study to Evaluate the Safety and Single Dose Pharmacokinetics of XXX, a Reactive Species Decomposition Accelerant, in Healthy Volunteers - A First in Human Clinical Study

A Phase I, Randomized, Double-Blind, Placebo-Controlled Study of the Effects on Quantitative Electroencephalography and Event-Related Potential of Two Sequential Doses of XXX in Healthy Adult Males

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-blind, Placebo- and Active-controlled, 3-way Crossover, Phase I Study to Evaluate the Effect of XXX at Therapeutic and Supratherapeutic Concentrations Following a 2-dose XXX Regimen on the QT Interval in Healthy Male and Female Subjects

Phase I Schizophrenia

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

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

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

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

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

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

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 I Randomized, Open-Label, Parallel, Single-Dose Study to Evaluate the Pharmacokinetic Characteristics of XXX of Two Formulations versus INVEGA SUSTENNA® after Intramuscular Injection in Schizophrenia Patients

CLINICAL TRIAL EXPERIENCE (continued):

A Safety/Tolerance Study to Evaluate a New Titration Scheme in Patients With Bipolar I Disorder or 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, Open-label, Sequential Dose Escalation Cohort Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX Long Acting Injectable (LAI) in Subjects with Schizophrenia

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

CLINICAL TRIAL EXPERIENCE (*continued*):

Phase I Other Indications

A Phase I, Randomized, Open-label, Fixed Sequence, 2-Period Comparative Bioavailability Study of XXX Solution when Administered to Migraine Subjects as Nasal Spray During a Migraine Attack Versus A Non-Migraine Period (Comparative Bioavailability)

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

A Phase Ib, Randomized, Double-blind, Placebo-controlled, Ascending-dose Study of XXX to Treat Symptoms of Acute Opioid Withdrawal in Patients with Opioid Use Disorder who are Physically Dependent on Opioids

A Phase I, Randomized, 3-Period, Crossover Study to Investigate the Effects of XXX on Measures of Drowsiness and Cognitive Function Compared to XXX and Placebo

A Phase Ib Double-Blind, Randomized, Placebo-Controlled Study of Single and Repeat Dose Administration of XXX in Moderate to Severe, Painful Osteoarthritis of the Knee

A Phase I, Open-Label, Single Ascending Dose Study to Assess the Safety and Pharmacokinetics of XXX in Patients with Osteoarthritis of the Knee

A Phase I Randomized, Double Blind, Placebo Controlled, Multiple Ascending Dose Study to evaluate the Safety, Tolerability, and Pharmacokinetic Properties of XXX Administered Subcutaneously in Subjects with Nonalcoholic Steatohepatitis (NASH) or with nonalcoholic fatty liver disease (NAFLD) and at increased risk of NASH

A Phase I Study of Potential Treatment-Responsive Biomarkers in Hunter Syndrome

A Phase Ib Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of XXX in Subjects with Nonalcoholic Steatohepatitis (NASH)

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

An Open label, two-part study to evaluate the impact of an improved first-time user experience on engagement with reSET and reSET-O (reSET/O) in patients with substance use disorder

A Phase I, Open-Label Study to Evaluate the Pharmacokinetics and Safety of XXX in Subjects with Impaired Hepatic Function

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase Ib, Multi-center, Randomized, Double-blind, Vehicle-controlled Study Assessing the Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of XXX in Subjects with Atopic Dermatitis

A Phase I, Multiple Dose Clinical Trial to Study the Safety, Tolerability, Pharmacodynamics, and Pharmacokinetics of XXX in Type 2 Diabetes Mellitus Patients

Phase II-IV

ADHD

A Phase IV, Multicenter, 2-part Study Composed of a 1-Year Randomized, Double-blind, Parallel-group, Placebo-controlled, Active-comparator, Dose-optimization Evaluation followed by a 1-Year Open-label Evaluation to Assess the Safety and Efficacy of XXX in Children and Adolescents aged 6 to 17 Years with Attention-deficit/Hyperactivity Disorder

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, 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 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX Extended-Release Tablets for the Treatment of Impulsive Aggression in Pediatric Patients with Attention Deficit/Hyperactivity Disorder (ADHD) in Conjunction with Standard ADHD Treatment

A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX Extended-Release Tablets for the Treatment of Impulsive Aggression in Pediatric Patients with Attention Deficit/Hyperactivity Disorder (ADHD) in Conjunction with Standard ADHD Treatment

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multicenter, Dose-Optimized, Open-Label Safety Study with XXX in Children with Attention-Deficit/Hyperactivity Disorder

A Phase III, Randomized, Double Blind, Placebo Controlled Study to evaluate the Efficacy and Safety of XXX Extended-Release Tablets for the Treatment of Impulsive Aggression in Pediatric Patients with Attention Deficit/Hyperactivity Disorder(ADHD) in Conjunction with Standard ADHD Treatment

Alzheimer's Disease

A Phase II, Randomized, Double-blind, Placebo-controlled, 3-Arm Parallel Design Study to Evaluate the Effects of XXX in Patients with Early Stage Alzheimer's Disease

Bipolar Disorder

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of XXX for 4 weeks in the Treatment of Patients with Acute Manic Episodes Associated with Bipolar I Disorder

A Phase III Multicenter, Randomized, Double-blind, Placebo-controlled Study to determine Efficacy and Safety of Two Dose Levels of XXX in Bipolar I Disorder Patients with Acute Agitation

A 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 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

Borderline Personality Disorder

A Phase II Randomized, Double-blinded, Placebo-controlled Parallel Group Trial to Examine the Efficacy and Safety of 4 Oral Doses of XXX Once Daily Over 12 week Treatment Period in Patients with Borderline Personality Disorder.

A Phase III, Multicenter, Open-Label Trial to Evaluate the Safety and Tolerability of XXX in the Treatment of Adult Subjects with Borderline Personality Disorder

A Phase III, Short-term, Multicenter, Randomized, Flexible-dose, Double-blind Trial of XXX Versus Placebo for the Treatment of Adults With Borderline Personality Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

Depression

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

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

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

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

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

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 II, Open-Label Study to Assess the Long-term Safety and Efficacy of XXX in Subjects with Treatment Resistant Depression

A Phase II, Randomized, Double-blind, Placebo-controlled Study of XXX for Relapse Prevention in 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 II, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study of the Safety and Efficacy of XXX in the Treatment of Adults with Major Depressive Disorder

A Phase III, Randomized, Double-Blind Study Comparing the Efficacy and Safety of XXX Plus Sertraline Versus Placebo Plus Sertraline in Adults 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 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 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 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, 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 III Randomized, Double-blind, Placebo-controlled, Multicenter Study of XXX in the Prevention of Relapse in Patients 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 Phase IIa, Double-Blind, Placebo-Controlled, Fixed-Dose Study of XXX in Patients with Major Depressive Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

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

An 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 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 Study of the Long-term Safety and Tolerability of XXX for the Adjunctive Treatment of Major Depressive Disorder in Adults who Have an Inadequate Response to Antidepressant Therapy

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

A double-blind, placebo-controlled, fixed dose study of XXX in patients with major depressive disorder

A Double-Blind, Fixed-Dose Study of XXX in Adult Patients with Major Depressive Disorder

Dermatology

A Phase III Randomized, Double-blind, Placebo-controlled, Efficacy Study of the Neurokinin-1 Receptor Antagonist XXX in Patients with Atopic Dermatitis

A Phase II, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Oral XXX for Moderate to Severe Puritis in Adult Subjects with Atopic Dermatitis

A Phase III, Multi-Center, Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Study Comparing the Efficacy and Safety of XXX and Vehicle Gel Once Daily in the Treatment of Molluscum Contagiosum

A Phase IIb, Randomized, Double-Blind, Vehicle-controlled, Parallel-group, Dose Ranging Study to Assess Efficacy, Safety, Tolerability, and Pharmacokinetics of XXX Topical Cream Applied Once or Twice Daily for 12 weeks in Participants with Mild to Moderate Chronic Plaque Psoriasis

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Double-Blind, Randomized, 8-Week, Vehicle-Controlled Efficacy and Safety Study of XXX Cream Followed by a Long-Term Safety Extension Period in Adolescents and Adults With Atopic Dermatitis

A Randomized, Double-blind, Placebo-controlled, Efficacy Study of the Neurokinin-1 Receptor Antagonist XXX in Patients with Atopic Dermatitis

An Exploratory, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Phase II Study to Evaluate the Safety, Tolerability, and Efficacy of XXX Ointment for the Symptomatic Treatment of Persistent Pruritus and Psoriasis in Subjects Being Treated with Calcipotriene Ointment

A Multicenter, Randomized, Double-blind, Parallel Group, Vehicle-controlled Study to Evaluate the Safety and Efficacy of 1% and 3% Topical XXX Gel (Hy01) in Patients with Papulopustular Rosacea

Diabetes

A Phase IIa Randomized, Double-blind, Placebo-controlled, Study to Evaluate the Efficacy and Safety of XXX in Subjects with Diabetic Kidney Disease

A Phase II, Multicenter, Randomized, Double blind, Placebo- controlled, Parallel Dose Cohort Study to Evaluate the Efficacy and Safety of Twelve Once-Weekly Subcutaneous Doses of XXX in Subjects with Type 2 Diabetes (T2DM) Not Well Controlled by Metformin

A Phase III, Randomized, Multicenter, Open-Label, Parallel-Group Clinical Study Comparing the Safety and Efficacy of XXX in Type 1 Diabetes Mellitus Patients

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate XXX in Subjects With Type 2 Diabetes Mellitus Who Are Not Adequately Controlled by Metformin Alone

A Phase III, Randomized, Multi-center, Double-Blind, Parallel-Group Clinical Study Comparing the Efficacy and Safety of XXX Produced by Two Manufacturing Processes in Type 1 Diabetes Mellitus Patients

A 12-week, Phase II, Randomized, Double-blind, Placebo-controlled, Parallel Group Study To Evaluate The Efficacy And Safety Of Once Daily XXX Administration In Adults With Type 2 Diabetes Mellitus Inadequately Controlled On Metformin

Migraine

A Phase III, Multicenter, Open-Label 52-Week Extension Study To Evaluate The Long-Term Safety And Tolerability Of Oral XXX For The Prevention Of Migraine In Participants With Chronic Or Episodic Migraine

CLINICAL TRIAL EXPERIENCE (*continued*):

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

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy, Safety, and Tolerability of Oral XXX for the Prophylaxis of Migraine in Participants with Episodic Migraine Who Have Previously Failed 2 to 4 Classes of Oral Prophylactic Treatments

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 Randomized, Double-blind, Single-dose, Placebo-controlled Study to Assess the Efficacy and Safety of XXX for the treatment of acute Migraine in adults with prior inadequate response

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 Phase III, Open-label, Long-term, Safety Study of XXX (100 mg and 200 mg) in the Acute Treatment Of Migraine

A Phase III, Study of Three Doses of XXX (50 mg, 100 mg and 200 mg) Compared to Placebo in the Acute Treatment of Migraine: A Randomized, Double-blind, Placebo-controlled Parallel Group Study

Non-Alcoholic Steatohepatitis (NASH)

A Phase IIa Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of XXX in Patients with Nonalcoholic Steatohepatitis (NASH)

A Phase IIa, Randomized, Double-blind, Placebo-controlled Study Evaluating the Safety and Efficacy of XXX in Subjects with Non Alcoholic Steatohepatitis (NASH)

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX for the Treatment of Liver Fibrosis in Adult Subjects with Nonalcoholic Steatohepatitis (NASH)

A Randomized, Double-blind, Placebo Controlled, 3-part, Adaptive Design, Multicenter Study to Assess Safety, Tolerability and Efficacy of XXX in Patients with Non-Alcoholic Steatohepatitis (NASH)

Obsessive Compulsive Disorder

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

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

Opioid Use Disorder

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

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

A Phase III, Open-Label Multicenter Study Assessing the Long-Term Safety of a Once-Weekly and Once-Monthly, Long-Acting Subcutaneous Injection Depot of XXX in Adult Outpatients With Opioid Use Disorder

A Phase III, Randomized, Double-Blind, Active-Controlled, Parallel Group, Multi-center Trial Assessing the Efficacy and Safety of a Once-Weekly and Once-Monthly, Long-Acting Subcutaneous Injectable Depot of XXX in Treatment of Adult Outpatients With Opioid Use Disorder

A Phase II, Open-label, Partially Randomized, 3 Treatment Groups, Multi-Site Study Assessing Pharmacokinetics After Administration of the Once-Weekly and Once-Monthly, Long-Acting Subcutaneous Injectable Depot of XXX at Different Injection Sites in Opioid-Dependent Subjects With Chronic Pain

A Phase III Study to Evaluate the Safety, Tolerability, and Efficacy of XXX for Use in Conjunction With XXX in Adults With Opioid Use Disorder Prior to First Dose of XXX

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel Group Study to Evaluate the Safety, Tolerability, and Efficacy of XXX for Use in Conjunction With XXX in Adults With Opioid Use Disorder Transitioning From XXX Maintenance Prior to First Dose of XXX

A Phase II, Proof-of-Concept Study of XXX, an Alpha-7 Nicotinic Acetylcholine Receptor Agonist, Versus Placebo in Subjects With Nicotine Dependence

Pain

A Phase III, 12-Week, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of XXX Topical System (Patch) in Subjects With Osteoarthritis Pain of the Knee

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

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of XXX in Patients With Diabetic Neuropathic Pain

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel-Group Study to Evaluate the Efficacy and Safety of XXX in Subjects with Diabetic Peripheral Neuropathic 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 Phase II, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Parallel-Group Study to Evaluate the Safety, Tolerability, and Efficacy of XXX in Subjects With Irritable Bowel Syndrome Experiencing Abdominal Pain

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Single-Dose Study of XXX in Moderate to Severe, Painful Osteoarthritis of the Knee

A Phase III Open-label, 8-Week Study to Compare the Comfort and Ease of Use of Five Different Treatment Regimens for XXX Intra-articular Injection in Subjects With Chronic, Moderate-to-Severe Osteoarthritis Knee Pain

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX in Patients With Moderate-to-Severe Chronic Low Back Pain and Osteoarthritis of the Hip or Knee

A Phase III, Open-Label 52-week Study to Assess the Long-Term Safety of XXX in Opioid-Induced Constipation (OIC) in Patients With Non-Cancer-Related Pain

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX in Patients With Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC)

Post-Traumatic Stress Disorder

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

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

Schizophrenia / Schizoaffective Disorder

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

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

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

A Phase II, multi-center, randomized, double-blind, parallel group, placebo-controlled trial of the efficacy and safety of XXX vs placebo in patients with an acute exacerbation of schizophrenia or schizoaffective disorder

A Phase III Multicenter, Randomized, Double-blind, Placebo-controlled Study to determine Efficacy and Safety of XXX in Agitation associated 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 II, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XXX as an Adjunctive Treatment in Adult Patients with Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

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 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 Patients with Schizophrenia

A Phase III, Interventional, Randomized, Double-blind, Active-controlled Study of the Efficacy of XXX in Patients With Early-in-disease or Late-in-disease Treatment-resistant Schizophrenia

A Phase II, Randomized, Double-blind, Placebo-controlled Study to Assess the Effects of XXX in Patients with Negative Symptoms of Schizophrenia

A Phase II Study to Assess the Safety, Tolerability, and Efficacy of XXX in Hospitalized Adults with DSM-5 Schizophrenia

A Phase IIa, Randomized, Double-Blind, Placebo-Controlled, Parallel-group Study to Assess the Safety and Efficacy of XXX as Add-on Treatment for Cognitive Impairment in Subjects with Schizophrenia on Stable Doses of Antipsychotic Medication

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Risperidone Extended-Release Injectable Suspension XXX for Subcutaneous Use as Maintenance Treatment in Adult Patients with Schizophrenia

A Phase 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, 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

CLINICAL TRIAL EXPERIENCE (*continued*):

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, 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 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 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

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

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

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, Randomized, Multicenter, Safety, Tolerability, and Dose-Ranging Study of Samidorphan, a Component of XXX, in Adults With Schizophrenia Treated With XXX

A Phase IV, Fifteen-Month, Prospective, Randomized, Active Controlled, Open-Label, Flexible Dose, Study of XXX Compared with Oral Antipsychotic Treatment in Delaying Time to Treatment Failure in Adults with Schizophrenia who have been recently Released from Jail

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

Women's Health

A Phase III, Randomized Double-blind Placebo Controlled Study to Evaluate the Efficacy and Safety of XXX for the Treatment of Moderate to Severe Vasomotor Symptoms in Postmenopausal Women (XXX Study I)

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-blind, Multicenter Integrated Phase I/III Study in Postmenopausal Women With Osteoporosis to Compare the Pharmacokinetics, Pharmacodynamics, Efficacy, Safety and Immunogenicity of XXX and XXX

A Randomized, Placebo-Controlled, Double-Blind Phase III Clinical Study to Investigate the Long-Term Safety of XXX in Women Suffering From Vasomotor Symptoms (Hot Flashes) Associated with Menopause

A Phase III, Randomized, Placebo-controlled, 12-week Double-blind Study, followed by a Single-arm Open-label Treatment Period, to Assess the Efficacy and Safety of XXX in Women Suffering From Moderate to Severe Vasomotor Symptoms (Hot Flashes) Associated with Menopause

Other Indications

A Phase III, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of XXX for the Prevention of SARS-CoV-2 mediated COVID-19 in Adults Aged 18 Years and Older.

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

Prospective Specimen Collection from Self-reported Drug Users for the Design and Development of XXX Drugs of Abuse Assays

Hair, Urine, and Saliva Procurement Protocol for the Development of Drugs of Abuse Tests

A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of XXX, a Non-replicating XXX Vaccine, for the Prevention of COVID-19

The XXX study is a prospective, observational multi-site study without randomization. The primary objective of the study is to evaluate the performance characteristics of a blood-based XXX test to detect colorectal cancer in a screen-relevant, average risk population.

A Multi-center, Randomized, Double-blind, and Placebo-controlled Phase II Clinical Study to Investigate the Safety and Efficacy of Two Doses of XXX Compared to Placebo in Subjects With Acute Uncomplicated Influenza

A Multicenter, Randomized, Double-Blinded, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of Topically Applied XXX Gel, 15% in Subjects with Axillary Hyperhidrosis

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multicenter, Randomized, Double Blind, Placebo-Controlled, Phase III Study to Determine if XXX Prevents Clinically Symptomatic Respiratory Illness in the Elderly

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Tolerability of XXX Infusions in Subjects With Parkinson's Disease and Cognitive Impairment

A Phase II Randomized, Double-blind, Placebo-controlled, Parallel Group Trial to Assess the Efficacy and Safety of XXX versus Placebo after 12 weeks of Treatment in Patients with Nonalcoholic Fatty Liver Disease (NAFLD) with or without Type 2 Diabetes Mellitus

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy, Durability, Safety, and Tolerability of XXX in Patients with Lactose Intolerance.

An International Phase III, Randomized, Double-Blind, Placebo- and Active XXX-Controlled Multicenter Extension Study to Evaluate the Long-Term Safety and Efficacy of XXX in Patients with Symptoms of Overactive Bladder

A Randomized, Single-dose, Double-blind, Double-dummy, Four-period, Four-sequence, Four-treatment, Placebo and Active-controlled, Comparative, Multiple-center, Crossover-design, Bronchoprovocation Study to Evaluate the Pharmacodynamic Equivalence of XXX to XXX in Patients with Stable, Mild Asthma

An International Phase III, Randomized, Double-Blind, Placebo- and Active XXX-Controlled Multicenter Study to Evaluate the Safety and Efficacy of XXX in Patients with Symptoms of Overactive Bladder