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## AFFILIATIONS:

Berlin Medical Associates
175 Cross Keys Rd, Suite 300A
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Comprehensive Clinical Research
175 Cross Keys Road
Berlin, NJ 08009

## EDUCATION:

1976 M.D.
Thomas Jefferson Medical College, Philadelphia, PA

1972 B.A. - Major in Biology, Minors in Chemistry and Psychology
Swarthmore College, Swarthmore, PA

## RESIDENCY:

1978 – 1979 Chief Resident, Psychiatry
Thomas Jefferson University Hospital, Philadelphia, PA

1976 – 1980 Psychiatric Residency
Thomas Jefferson University Hospital, Philadelphia, PA

## LICENSURE:

State of New Jersey (active status)

Commonwealth of Pennsylvania (active status)

## CERTIFICATION:

2011 & 2014 ACLS
1980 American Board of Psychiatry and Neurology

## PROFESSIONAL EXPERIENCE:

***Investigator***, 2019 - present
Apex Innovative Sciences

***Investigator,*** May 2019 - Present
Hassman Research Institute, LLC., Berlin, NJ

***Senior Medical Director,*** October 2015 – April 2019
Intra-Cellular Therapies, Inc., Philadelphia, PA

***Psychiatric Medical Director & Principal/Sub-Investigator/Rater,*** 1999 – Sept. 2015
PRA International (Formally CRI Lifetree), Philadelphia, PA

***Medical Director, Inpatient Services,*** 1999 – 2000
Mercy Fitzgerald Hospital, Darby, PA

***President***, 1987 – 1999
Rainbow Healthcare Associates, Mount Laurel, NJ

***Medical Staff, Director,*** 1994 – 1999
Mental Health Unit, Rancocas Hospital

***Medical Staff, Chairman,*** 1994 – 1997
Dept of Psychiatry, South Jersey Hospital System, Bridgeton Division

***Medical Director,*** 1992 – 1996
Mental Health Unit, Underwood Memorial Hospital

***Psychiatry, Private Practice,*** 1980 – Present

## INVESTIGATOR EXPERIENCE:

Phase I-IV: Addiction • ADHD • Allergy • Alzheimer's Disease • Anxiety • Atopic Dermatitis
Axillary Hyperhidrosis • Bipolar Disorder • Borderline Personality Disorder
Cognitive Impairment • Crohn's Disease • Chronic Pain • Depression • Diabetes • Fibromyalgia
Healthy • Hepatitis C • Hot Flashes • Hypertensive • Influenza • Insomnia
Irritable Bowel Syndrome • Menopause • Migraine • Molluscum Contagiosum
Nonalcoholic Steatohepatitis (NASH) • Nonalcoholic Fatty Liver Disease (NAFLD) • Obesity
Obsessive Compulsive Disorder • Opioid-Induced Constipation • Osteoarthritis • Osteoporosis
Pain • Painful Diabetic Neuropathy • Painful Diabetic Polyneuropathy • Panic Disorder

## INVESTIGATOR EXPERIENCE (*continued*):

Parkinson's Disease • Peripheral Neuropathic Pain • Post-Traumatic Stress Disorder • Psoriasis
Respiratory • Schizophrenia and Schizoaffective Disorder • Seasonal Affective Disorder
Sexual Dysfunction • Tourette's Disorder • Women's Health

## CLINICAL TRIAL EXPERIENCE:

***Phase I – Addiction***

Two Phase I Ascending Single Doses Crossover, Placebo Controlled Study of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX Administered Orally to Subjects on Stable Methadone Maintenance

A Phase I Randomized, Double-Blind, 4-Period Crossover, Dose-Ranging Study to Determine the Effects on the Oral-Cecal Transit Time of Single Doses of XXX and the safety Tolerability of Multiple Doses of XXX in Stable Methadone Maintenance Subjects

***Phase I – Healthy***

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

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 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

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 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 Single-Center, Randomized, Double-blind, Single-dose, Crossover Study to Assess the Acceptability of XXX Following IV Administration in Healthy Volunteers

**CLINICAL TRIAL EXPERIENCE (*continued*):**

An Open-label, Randomized, Two-way, Crossover Trial of the Bioequivalence of 3 mg Oral Doses of XXX Commercial and Clinical Trial Tablets in Healthy Subjects

A Randomized, Crossover Trial to Assess Relative Bioavailability of 15-mg Doses of XXX as an Oral Syrup Suspension and Oral Tablet of Spray-dried XXX and to Determine the Pharmacokinetics and Pharmacodynamics of Following 15-mg Syrup Suspension or 15-, 7.5-, and 3.75-mg Tablet Doses in Healthy Subjects

An Phase I Open Label, Single Dose, Cross-over Study to Assess the Effect of XXX in the Fed and Fasted State

An Phase I Ascending, Single-Dose, Single-Blind, Randomized, Placebo-Controlled Study Assessing the Safety, Tolerability, and Pharmacokinetics of XXX in Healthy Subjects

Open-Label, Phase I Single-Dose Study to Evaluate XXX in Healthy Male and Female Volunteers Ages 18 to 50 Years Old

An Phase I open-label, parallel group, single session study comparing the pharmacokinetics of a single oral dose of XXX administered to healthy volunteer smokers and healthy volunteer non-smokers

***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 Study in Stabilized Schizophrenic Patients to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX and is administered from a Polyurethane Implant

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, Open-Label, Single Center, Single Ascending Dose study of the Safety, Tolerability, and Pharmacokinetic Profile of XXX 60mg, 90mg, and 120 mg

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

A 2010 Phase I, Mass Balance and Metabolism Study of XXX in Patients with Schizophrenia

**CLINICAL TRIAL EXPERIENCE (*continued*):**

An Open-Label, Single-Center, Single Dose, Phase I, First in Man Study of the Safety, Tolerability and Pharmacokinetic profile of XXX

A Phase I, Study Investigating the potential interaction between XXX and Antipsychotic Treatments in Subjects with Schizophrenia or Schizoaffective Disorder

A Phase I, Open-Label Study to Evaluate the Effect of Repeated Administration of XXX on the Pharmacokinetics of Quetiapine Fumarate Following Administration of the Immediate-Release Formulation of SEROQUEL® Tablets in Patients With Schizophrenia

A Phase Ib Inpatient, Randomized, Double-Blind, Placebo-Controlled, Crossover Study of the Safety and Efficacy of Two Fixed Doses of XXX in Adjunctive Treatment of Cognitive Deficits in Schizophrenia

An Phase I Open-label Parallel Arm Multiple Dose Tolerability, Pharmacokinetics and Safety Study in Adult Patients with Schizophrenia Following Administration of XXX IM Depot Formulation Once Every Four Weeks

A Phase I, Escalating, Single-Dose Followed by Multiple-Dose Treatment Study in Schizophrenic Patients and Food Effect Study in Healthy Subjects to Evaluate the Pharmacokinetics, Safety and Tolerability of XXX

Open-Label, Phase I Parallel, Randomized Study to Explore the In Vitro/In Vivo Correlation of XXX Long-Acting Formulations and the Comparability of XXX and XXX Formulations in Subjects with Schizophrenia

A Phase I, Randomized, Double-Blind, Crossover, Placebo-Controlled, Two-Stage Study to Assess The Residual Effects of XXX in Comparison to XXX in Healthy Elderly Female and Male Subjects

Local-Site Phase I Tolerability of Multiple-Dose Treatment With Deltoid Intramuscular Injection of XXX in Subjects With Chronic Schizophrenia

Comparative Phase I Single-Dose Pharmacokinetics and Safety of Gluteal and Deltoid IM Injection of Long-Acting Injectable XXX in Subjects with Chronic Stable Schizophrenia

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

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

## CLINICAL TRIAL EXPERIENCE (*continued*):

***Phase I – Other Indications***

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

A Phase Ib, Randomized, Single-Blind, Multiple-Dose Ranging Study Evaluating the Safety, Tolerability, Pharmacokinetics and Antiviral Activity of XXX in Subjects with Chronic Hepatitis C Virus Infection

A Phase I randomized, Placebo-Controlled, Double-Blind Study in Hypertensive Patients of the Blood Pressure Interaction between XXX and Anti-Hypertensive Medications (Calcium Channel Blockers, Beta Blockers, and ACE Inhibitors)

A Phase I, Safety and Pharmacokinetics Study of Single Dose XXX in Subjects with Crohn's Disease

XXX for Peanut Allergy: A Randomized, Double-Blind, Placebo Controlled Phase I Study in Adults and Pediatric Subjects

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Ascending Dose Study of Safety and Tolerability of XXX in Adult patients with Parkinson’s disease who are receiving Levodopa

A Phase I, Double-Blind, Placebo-Controlled, Safety and Tolerability Study of XXX Administered as Ascending Single-Dose, Subcutaneous Bolus Injections in Healthy Subjects Followed by a multiple dose cohort of patients with Stable Crohn’s Disease in Remission

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 Adults with Attention-Deficit Hyperactivity Disorder

A Phase I, Open-Label, Single-Dose Study of the Pharmacokinetic Properties of XXX in Obese or Overweight Elderly Subjects

A Phase I, Randomized, Double-Blind, Multiple-Ascending-Dose Trial to Evaluate the Safety, Tolerability and Pharmacokinetics of Orally-Administered XXX in Subjects with Type 2 Diabetes

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Phase I, 2-Part, Randomized, Subject and Investigator Blinded, Placebo-Controlled, Cross-over Trial to Evaluate the Safety, Tolerability and Pharmacokinetics of XXX in Obese, Adult Subjects with Asymptomatic Cholelithiasis

A Phase I Randomized, Double-Blind, Placebo-Controlled, 2 Period, Fixed-Sequence Study to Evaluate the Safety, Tolerability, and Pharmacokinetic Profile of Orally Administered XXX in Patients during and Between Their Acute Migraine Attacks

A Phase I Proof of Concept Study to Assess the Safety, Efficacy, and Pharmacokinetic Profile of XXX in the Acute Treatment of Migraine Headache

Effects Phase I of XXX on the Steady-State Pharmacokinetics of XXX or XXX in subjects with Depressive or Anxiety Disorders.

A Phase I, comparative study of the steady-state Pharmacokinetics of Lithium before and during multiple oral daily XXX dosing in patients with bipolar disorder.

***Phase II-IV***

***Addiction***

A phase IV, multi-national, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of XXX compared to placebo for smoking cessation through reduction.

An international, seven-week, double-blind, placebo-controlled, two parallel group study to assess the efficacy of XXX an aid to smoking cessation in cigarette smokers

Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety of XXX in the Treatment of Pathological Gambling

***ADHD - Adult***

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 40-week, Phase IV, Double-blind, Placebo-controlled, Multicenter, Randomized-withdrawal Study to Evaluate the Long-term Efficacy and Safety of XXX (clonidine hydrochloride) Extended-Release in Adult ADHD patients

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A 6 month, open label extension to 40 week, randomized, double-blind, placebo-controlled, multicenter efficacy and safety of XXX in the treatment of adult patients with childhood onset of ADHD

A Double-Blind, Randomized, Placebo-Controlled, Multicenter, Fixed-Dose Titration Study to Assess Efficacy, Safety, and Tolerability of XXX in Adults with Attention Deficit/Hyperactivity Disorder

A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled, study of the Safety and Efficacy of XXX as Adjunctive Therapy in the Treatment of Adult Attention-Deficit/ Hyperactivity Disorder

A Phase III, Randomized, Double-blind, Multi-center, Placebo-controlled, Parallel-group, Forced Dose Titration, Safety and Efficacy Study of XXX in Adults with Attention-Deficit Hyperactivity Disorder

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

A Randomized, Double–Blind, Placebo-Controlled, 4-Period Crossover Pilot Study of the Safety and Efficacy of Multiple Doses of XXX in Adults with Attention Deficit-Hyperactivity Disorder (ADHD)

A Double-Blind Study of Functional Outcomes with XXX - XXX and Placebo in Adult Outpatients with DSM-IV Attention Deficit/Hyperactivity Disorder

A 6-Month, Open-Label Extension to a Five-Week Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Fixed-Dose Study of the Efficacy and Safety of XXX (XXX XXX Extended-Release Capsules) Administered Once Daily in Adults with Attention-Deficit/Hyperactivity Disorder

A 5-Week Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Fixed-Dose Study of the Efficacy and Safety of XXX (Extended-Release Capsules) Administered Once Daily in Adults with Attention-Deficit/Hyperactivity Disorder

A Double-Blind, Placebo-Controlled, Phase II Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in Adults with Attention Deficit/Hyperactivity Disorder

A Double-Blind Study of Treatment Optimization with XXX XXX in Adults with DSM-IV Attention-Deficit/Hyperactivity Disorder

A randomized, Double-Blind, Placebo-Controlled, Parallel-Group study of XXX in adults with Attention Deficit Hyperactivity Disorder

**CLINICAL TRIAL EXPERIENCE (*continued*):**

Open label trial exploring switching a regimen form Oral Neuroleptics, other than XXX to XXX Depot Microspheres.

A 12-month, open-label study of XXX in adults with Attention Deficit Hyperactivity Disorder. A Phase III Study.

Long-Term, Open-Label Safety Study of XXX in Adult Outpatients with DSM-IV ADHD

A Phase III, Randomized, Double-Blind Comparison of Placebo and XXX Hydrochloride in Adult Outpatients with DSM-IV Attention Deficit Hyperactivity Disorder

***ADHD – Adolescent & Pediatric***

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 Long-Term, Open-Label, Safety Study of XXX in Children (6 to 11 years) and Adolescents (12 to 17 Years) with Attention Deficit/Hyperactivity Disorder-Associated with Insomnia

A Randomized, Placebo-Controlled, Double-Blind, Fixed-Dose Study of the Efficacy and Safety of XXX in Children and Adolescents 6 through 17 Years of Age with Attention -Deficit/ Hyperactivity Disorder -Associated with Insomnia

A Phase III, Long-Term, Open-Label, Safety Study of XXX in Children and Adolescents, 6 years and older with Attention-Deficit/Hyperactivity Disorder

Guiding Dose Increases in Patients Incompletely Responsive to Usual Doses of XXX in Determining Plasma XXX Concentrations: A Randomized, Double-Blind Study

A Phase III, Open-Label Safety and Efficacy Study of XXX Hydrochloride in Pediatric Outpatients (6 to 18 Years) with ADHD

Long-Term, Open-Label Safety Study of XXX in Patients 6 Years and Older

A Phase III, Open-Label Safety and Efficacy Study of XXX in Outpatients with ADHD Ages 6 to 18 Years

**CLINICAL TRIAL EXPERIENCE (*continued*):**

***Alzheimer's Disease***

A 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 XXX and to Test the Safety and Efficacy of XXX to Delay the Onset of MCI due to AD in Cognitively Normal Subjects

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

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

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of the Pharmacodynamics/ Efficacy, Safety, Tolerability and Pharmacokinetics of 3 Fixed Dosages of XXX in Patients with Mild to Moderate Alzheimer's Disease

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Safety and Efficacy Of XXX In Patients With Mild to Moderate Alzheimer's Disease

An Open Label Extension Study to Assess the Long-Term Safety and Tolerability of XXX in the Treatment of Mild Cognitive Impairment

Phase II, 12 Week, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study Evaluating the Safety and Efficacy of Three Fixed Doses of Oral XXX (30 mg QD, 60 mg BID and 120 mg BID) and XXX in Outpatients with Alzheimer's Disease

Placebo controlled evaluation of XXX in the treatment of Alzheimer's disease: Safety and efficacy of a controlled release formulation.

A randomized, Double-Blind, Placebo-controlled, evaluation of the safety and efficacy of XXX in-patients with moderate to severe dementia of the Alzheimer's type.

Randomized, 26-Week, Double-Blind, Placebo-Controlled Trial to Evaluate the Safety and Efficacy of XXX in the Treatment of Dementia Secondary to Cerebrovascular Disease

A Long-Term Study Evaluating the Safety and Tolerability of Four XXX Dosing Regimens in Patients with Moderate to Severe Dementia of the Alzheimer's Type

XXX in Patients at Risk for the Development of Alzheimer's Disease

**CLINICAL TRIAL EXPERIENCE (*continued*):**

Placebo-Controlled Evaluation of XXX in the Treatment of Alzheimer's Disease: Safety and Efficacy of a Controlled Release Formulation

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of Three Fixed Doses of XXX in the Treatment of Institutionalized Patients with Psychosis Associated with Dementia of the Alzheimer's Type

***Anxiety***

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

Multi-Center, Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Phase II Study of 2 Oral Dose Groups of XXX, with a Lorazepam Arm, in Subjects with Generalized Anxiety Disorder

An eight-week, multicenter, double-blind, placebo- and XXX-controlled study evaluating the efficacy, safety and tolerability of two fixed doses of XXX (250 mg bid and 100 mg bid) in outpatients with generalized anxiety disorder

A Comparison of XXX vs. Placebo in the Treatment of Insomnia Associated with Generalized Anxiety Disorder (GAD) when used concomitantly with XXX

An Eight Week Double-Blind, Placebo Controlled, Multi-Center Study with XXX as Positive Control, Evaluating The Efficacy, Safety, Tolerability of a Fixed Dose of XXX in Outpatients with GAD

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 5 Week Trial to Assess the Efficacy and Safety of XXX compared to Placebo and XXX in Patients with Generalized Anxiety Disorder

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

A Phase II, Randomized, Double-Blind, Placebo-controlled, Multi-center Study to Evaluate the Efficacy and Safety of Two Flexible Dosing Regiments of XXX in Patients with DSM-IV Defined Generalized Anxiety Disorder

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, 5-Week Trial to Assess the Efficacy And Safety of XXX Compared To Placebo and Alprazolam Extended-Release in Patients with Generalized Anxiety Disorder

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Comparison of XXX Extended Release, and Placebo in the Treatment of Generalized Anxiety Disorder

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

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

A 12-Month, Open-Label, Flexible-Dosage Study to Evaluate the Safety of XXX, at Dosages up to 16mg/day in Adults with Generalized Anxiety Disorder

XXX versus Placebo in Patients with Generalized Anxiety Disorder who Have Responded to Treatment with XXX

A randomized, Double-Blind, Placebo-controlled, flexible dosage trial to evaluate the efficacy and tolerability of XXX in patients with Generalized Anxiety Disorder (GAD).

XXX 30mg and 60mg Once Daily Versus Placebo in Generalized Anxiety Disorder. A Randomized Double-Blind Placebo and XXX -Controlled Fixed-Dose Parallel-Group Multicenter Study of 10 Weeks (Including a 2-week Single-Blind Placebo Period)

A randomized Double-Blind Placebo-Controlled, Parallel-Group, Fixed-Dose study of the efficacy, safety and tolerability of 60mg XXX extended release compared to Placebo in patients with generalized anxiety disorder.

A four-week double blind, placebo and active controlled, dose-ranging study of SL XXX 3 doses (5, 15, 50 mg per day) and Lorazepam (3 mg/day) in out-patients with Generalized Anxiety Disorder (GAD).

Flexible-Dose Comparison of the Safety and Efficacy of XXX and Placebo in the Treatment of Generalized Anxiety Disorder

A Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dose Study for XXX in Adolescent Outpatients with Social Anxiety Disorder

An Open-Label Extension Study of the Safety and Efficacy of XXX in Patients with Generalized Anxiety Disorder

XXX vs. Placebo in the Treatment of Generalized Anxiety Disorder

Flexible-Dose Comparison of the Safety and Efficacy of XXX and Placebo in the Treatment of Generalized Anxiety Disorder

## CLINICAL TRIAL EXPERIENCE (*continued*):

***Anxiety – Adolescent & Pediatric***

A Double-Blind, Multi-Center, Randomized, Parallel-Group, Placebo-Controlled Study Evaluating the Efficacy and Safety of Two Flexible-Dose Ranges of an Anxiolytic Agent in Children and Adolescents (Ages 6 to 17) with Generalized Anxiety Disorder (GAD). The product is currently marketed for use in adults.

A Double-Blind, Placebo-Controlled Study of XXX in Children and Adolescents with Generalized Anxiety Disorder

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

A 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 with Bipolar I Disorder

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

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

A Randomized, Double-Blind, Active- and Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX as Maintenance Treatment after an Acute Manic or Mixed Episode Associated with Bipolar 1 Disorder

A randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and tolerability of XXX 1000-2500 mg/d in the treatment of manic episodes of bipolar I disorder over 3 weeks with an extension study

A Phase III, Four-Week, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Multicenter, Efficacy and Safety Study of XXX in Bipolar I Disorder Subjects with Acute Symptoms of Mania

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Multicenter, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled Phase III Study of the Efficacy and Safety of XXX as Monotherapy in Adult Patients with Acute Bipolar Mania

A Randomized, Double-Blind, Active- and Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX ER as Maintenance Treatment after an Acute Manic or Mixed Episode Associated with Bipolar 1 Disorder

A Randomized, Double-Blind, Active and Placebo Controlled, Parallel-Group, Multi-Center Study to Evaluate the Efficacy and Safety of Flexibly Dosed XXX Compared with Flexibly-Dosed XXX and Placebo in the Treatment of Acute Manic and Mixed Episodes Associated with Bipolar I Disorder

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

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

A Randomized, Double-Blind, Placebo-Controlled, Multi-center Study to Evaluate the Efficacy, Safety and Tolerability of XXX Combined with XXX or XXX in the Treatment of Manic Episodes of Bipolar I Disorder Over Six Weeks with an Extension Study

A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy and Tolerability of XXX 1000-2000 Mg/D in the Treatment of Manic Episodes of Bipolar I Disorder Over 3 Weeks with an Extension Study

A Three –Week, Double-Blind, Multi-Center, Placebo-Controlled Study Evaluating the Efficacy and Safety of Add-On Oral XXX in Subjects with Acute Mania Treated with XXX or XXX

A Prospective, Randomized, Double-Blind, Placebo-Controlled Study of the Effectiveness and Safety of XXX XXX Augmentation in Adult Patients with Frequently-Relapsing Bipolar Disorder

A Randomized, Double-Blind, Placebo-Controlled Study to Explore the Efficacy and Safety of XXX Long-Acting Intramuscular Injectable in the Prevention of Mood Episodes in Bipolar I Disorder, with Open-Label Extension

A Phase III, Randomized, Placebo-Controlled, Double-Blind Trial Evaluating the Safety and Efficacy of XXX XXX vs. XXX and Placebo in In-Patients with an Acute Manic Episode with Two Extension Studies

**CLINICAL TRIAL EXPERIENCE (*continued*):**

Differences in Cognitive Function due to Acute Sedative Effects of XXX and XXX in Stable Bipolar I Disorder Outpatients

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

A Multicenter, Randomized, Double-Blind, Placebo Controlled Study of XXX Monotherapy in the Treatment of Acutely Manic Patients with Bipolar I Disorder

A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Tolerability of XXX 1000-2500 Mg/D in the Treatment of Manic Episodes of Bipolar I Disorder over 3 weeks and its extension study

A Phase III, Randomized, Placebo-Controlled, Double-Blind Trial Evaluating the Safety and Efficacy of Sublingual XXX vs. XXX and Placebo in In-Patients with an Acute Manic Episode and its extension study

A Multicenter, Randomized, Parallel-group, Double-blind, Phase III Comparison of the Efficacy and Safety of XXX XXX (oral tablets 400 mg to 800 mg daily in divided doses) to Placebo when used as Adjunct to Mood Stabilizers (XXX or XXX) in the Maintenance Treatment of Bipolar I Disorder in Adult Patients

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

XXX / XXX Combination versus XXX in the Treatment of Bipolar I Depression

XXX versus Placebo as Add-On Treatment in Subjects with Bipolar Disorder in the Outpatient Setting

The Efficacy and Safety of Flexible-Dose Ranges of XXX vs. Placebo or XXX in the Treatment of Manic or Mixed Episodes Associated with Bipolar I Disorder

Placebo-Controlled XXX Monotherapy in the Treatment of Bipolar I Depression

***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

**CLINICAL TRIAL EXPERIENCE (*continued*):**

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

***Depression***

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

Phase IV Concept Elicitation and Cognitive Debriefing Interviews in Adults with Major Depressive Disorder and Sleep Disturbance

A Phase II, 6-week, multicenter, randomized, double-blind, double-dummy, placebo-controlled, parallel group study with a Quetiapine XR arm to evaluate the efficacy, tolerability and safety of XXX in patients with Major Depressive Disorder

A Phase 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

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Randomized, Double-Blind, Placebo-Controlled Trial of XXX Administered Orally to Subjects with Major Depressive Disorder

Interventional, open-label, long-term extension study to evaluate the safety and tolerability of XXX as adjunctive treatment in patients with major depressive disorder

Interventional, randomized, double-blind, parallel-group, placebo-controlled, fixed-dose study to evaluate the efficacy and safety of XXX (1 and 3mg/day) as adjunctive treatment in elderly patients with major depressive disorder with an inadequate response to antidepressant treatment

A double-blind, randomized, placebo-controlled, parallel group, dose frequency study of XXX in subjects with treatment-resistant depression

A 2012 Phase II, Double-Blind, Placebo-Controlled, Randomized Withdrawal, Parallel Efficacy and Safety Study of XXX in subjects with Inadequate/Partial Response to Antidepressants during the Current Episode of Major Depressive Disorder

A Multicenter, Randomized, Double-blind, Parallel Group, Placebo-controlled, Phase IIb Efficacy and Safety Study of Adjunctive XXX in Patients with Major Depressive Disorder (MDD) and a History of Inadequate Response to Antidepressants

A Randomized, 6-Week, Double-Blind, Placebo-Controlled, Fixed-Dose, Parallel-Group Study of XXX for the Treatment of Major Depressive Disorder with Mixed Features.

A Double-blind, Placebo-controlled Study of XXX as Adjunctive Therapy In Major Depressive Disorder.

A Randomized, 6-Week, Double-Blind, Placebo-Controlled, Fixed-Dose, Parallel-Group Study of XXX for the Treatment of Major Depressive Disorder with Mixed Features.

A Double-Blind, Placebo Controlled Evaluation of the Safety and Efficacy of XXX in Patients with Bipolar Depression

A Double-Blind, Placebo-Controlled, Fixed-Dose Study of XXX in patients with Major Depressive Disorder

A Randomized, Placebo-Controlled, Double-Blind, Study of XXX Flexible-Dose of 12 to 18 mg once daily as adjunctive treatment for patients with Major Depressive Disorder who are Partial Responders to Selective Serotonin Reuptake Inhibitor Treatment

A Phase II, Randomized, Double-Blind, Multiple-Dose Level, Placebo-Controlled, Single Intravenous Dose, Parallel Efficacy and Safety Study of XXX in Subjects with Inadequate/ Partial Response to Antidepressants during the current Episode of Major Depressive Disorder

**CLINICAL TRIAL EXPERIENCE (*continued*):**

Antidepressant-Induced Sleepiness, Cognitive Symptoms and/or Fatigue During XXX Treatment of MDD

A Double-Blind, Paroxetine and Placebo-Controlled Study of 50mg/day and 100mg/day of XXX among outpatients with Major Depressive Disorder who have responded inadequately to prior standard antidepressants

A Phase IV, Multicenter, Randomized, 8-Week, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy of 2 Fixed Doses (50 and 100 MG/Day) of XXX Sustained-Release Formulation (DVS SR) in Adult Outpatients with Major Depressive Disorder.

A Phase III, Long-Term, Open-Label, Flexible-Dose, Extension Study Evaluating the Safety and Tolerability of XXX (15mg and 20mg) in subjects with Major Depressive Disorder

A Phase III, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Fixed-Dose study comparing the efficacy and safety of 2 Doses (10 & 20 mg) of XXX in Acute Treatments of Adults with Major Depressive Disorder

XXX versus Placebo in the Acute Treatment of Patients with Major Depressive Disorder and Associated Painful Physical Symptoms

A 4-Week, Randomized, Double-blind, Parallel Group, Placebo-Controlled, Study to investigate the safety and efficacy of XXX as a monotherapy in patients with Treatment Resistant Major Depression

A Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-controlled, Phase III, Long-Term Safety and Tolerability Study of XXX as an Adjunct to an Antidepressant in Patients with Major Depressive Disorder who Exhibit an Inadequate response to Antidepressant Therapy

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

A 52-Week, multi-center, open-label, study of the safety and tolerability of XXX sublingual tablets in patients with Major Depressive Disorder

An 8-week, randomized, double-blind, placebo-controlled, parallel-group, multi-center study of the efficacy and safety of XXX 0.5mg and 1mg sublingual tablets administered once daily in patients with Major Depressive Disorder

A 6 month, open-label, flexible-dosage (150-200mg/day) Extension Study of the Safety and Efficacy of XXX Treatment as Adjunctive Therapy in Adults with Major Depression associated with Bipolar I Disorder

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Double-Blind, Placebo-Controlled, Parallel Group, Fixed Dose Study to evaluate the efficacy and safety of XXX Treatment as adjunctive therapy in adult patients with MDD associated with Bipolar I Disorder

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

A Long-Term, Open-Label, Extension Study of XXX in Adults with Major Depressive Disorder

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

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

A Randomized, Double-Blind Comparison of XXX and Placebo and Long Term Treatment of XXX in Adult Patients with Major Depressive Disorder

A Phase III, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Duloxetine-Referenced, Fixed Dose Study Comparing the Efficacy and Safety of XXX in Acute Treatment of Major Depressive Disorder in Elderly Patients

A Phase IIb, Multicenter, Randomized, Double-blind, Parallel Group, Placebo-controlled Efficacy and Safety Study of Adjunctive XXX in Subjects with Severe Major Depressive Disorder (MDD) and a History of Poor Response to Antidepressants

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

An eight-week, multicenter, double-blind, placebo- and XXX-controlled study evaluating the efficacy and tolerability of two fixed doses of XXX (250 mg bid and 100 mg bid) in outpatients with major depressive disorder

A Randomized, Double-blind, Two-arm Study Comparing the Efficacy and Safety of XXX and Placebo in the Treatment of Unipolar Major Depressive Disorder

A Comparison of XXX vs. Placebo in the Treatment of Insomnia Associated with Newly Diagnosed Major Depressive Disorder (MDD) or Untreated MDD Relapse, When Used Concomitantly with XXX

A Phase II Double-Blind, Placebo-Controlled Study Evaluating the Pharmacodynamics Effects of Two Fixed Does of XXX on Hypothalamic-Pituitary-Adrenal Axis Function in Outpatients with MDD

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Multi-Center, Randomized, 24-52-Week, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety and Tolerability of XXX Once Daily In The Prevention of Relapse of Depressive Symptoms In Outpatients with MDD who Achieved an Initial Response to 12 Weeks of Open-Label Treatment with XXX Once Daily

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

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

A Multi-Center, Double-blind, Randomized, Parallel-group, Placebo-controlled Phase III Study of the Efficacy and Safety of XXX as Mono-therapy in the Treatment of patients with Major Depressive Disorder

Multi-Center, Randomized, Double-blind, Placebo-Controlled Study of the Efficacy and Tolerability of XXX Therapy Initiated with XXX Versus XXX Mono-therapy in Subjects with Insomnia and Co-Existing Major Depressive Disorder

XXX as an Antidepressant Augmentation Agent in Treatment Refractory Unipolar Depression

A Randomized, Double-Blind, Placebo-Controlled Study of Safety and Efficacy of XXX (XXX) in the Treatment of Psychotic Symptoms in Patients with Major Depressive Disorder with Psychotic Features

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

A Three-Week, Randomized Study to Assess the Tolerability of 2 Fixed Doses (200mg and 500mg) of XXX in Adult Subjects with Major Depressive Disorder

A Multi-Center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Fixed-Dose Study Evaluating the Efficacy, Safety and Tolerability of Two Doses (20mg and 60mg) of a Once-Daily Oral Formulation of XXX in Subjects with Major Depressive Disorder for a Treatment Period of Eight Weeks

Double-Blind Flexible Dose Comparison of the Safety and Efficacy of XXX and Placebo in the Treatment of Major Depressive Disorder

A Double-Blind, Multicenter Study Evaluating the Efficacy And Safety of one Fixed Dose of XXX (700 Mg/Day) Versus Placebo and XXX (20 Mg/Day) in Patients with a Recurrent Major Depressive Episode

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of 8 weeks of Oral XXX (XXX) Tablets [C-IV] (200mg Once Daily) as Adjunctive Treatment for Excessive Sleepiness in Adults with Major Depressive Disorder, Sleepiness and Fatigue, Followed by a 12-week Open-Label Period

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Three Fixed Doses (50 Mg, 100 Mg, Or 200 Mg) of XXX in Adult Outpatients with Major Depressive Disorder

Depression Response to XXX in Adults with Major Depressive Disorder (DREAMDD): A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 8-Week, Safety and Efficacy Study of XXX 3 mg Compared to Placebo in Subjects with Insomnia Related to Major Depressive Disorder

Validation of Daily Telephone Self-Assessment in the Study of Antidepressant Treatment Outcome

Effectiveness of XXX in Treating Persistent Anxiety in Depressed Patients on Stable Doses of SSRI's

XXX versus XXX Extended Release in the Treatment of Major Depressive Disorder

XXX versus Placebo in the Treatment of Elderly Patients with Major Depressive Disorder

A Double-Blind, Multi-Center, Randomized, Placebo-Controlled, Efficacy and Safety Trial of XXX and XXX in Subjects with Major Depressive Disorder

An 8-Week, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Multicenter, Fixed Dose Study Comparing the Efficacy and Safety of XXX or XXX to Placebo in Moderately to Severely Depressed Patients with Major Depressive Disorder

Double-Blind Fixed Dose Comparison of the Safety and Efficacy of 20 mg/day XXX and 225 mg/day XXX XR in the Treatment of Major Depressive Disorder

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

Open-Label Extension Trial in Children and Adolescents with Major Depressive Disorder who participated in one of The Short-Term XXX ER Safety and Efficacy Trials.

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Flexible Dose, Safety and Efficacy trial of XXX ER in Outpatient Children and Adolescents with Major Depressive Disorder

**CLINICAL TRIAL EXPERIENCE (*continued*):**

An Open Label Pilot Study to Evaluate the Safety and Efficacy of XXX (XXX) Titrated to 200mg Daily, in Conjunction with Fluoxetine 20mg or XXX 20mg, in Patients with Mild to Moderate Depression with Attendant Symptoms of Fatigue and Lethargy within a Primary Care Setting

XXX Once-Daily Dosing versus Placebo in Patients with Major Depression and Pain

The Addition of XXX to Sertraline in Treatment Resistant Depression without Psychotic Features – A Pilot Study

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of Safety and Efficacy of XXX in Patients with Major Depressive Disorder with Psychotic Features Who are not Receiving Antidepressants or Antipsychotics

In-patient, Phase III, randomized, Double-Blind, Placebo-Controlled study of the safety and efficacy of XXX in patients with Major Depressive Disorder with Psychotic features

A double-blind Placebo and Paroxetine controlled, Multi-Center, dose ranging study evaluating the efficacy and safety of XXX in out-patients with Major Depressive Disorder

A randomized, Double-Blind, parallel-group, Placebo-Controlled, study evaluating efficacy and safety of three doses of XXX versus Placebo in patients with Major Depressive Disorder

A phase IIB, seven-week, Double-Blind, Placebo-and Paroxetine-Controlled Multi-Center study to evaluate the safety and efficacy of oral XXX in out-patients with major depressive disorder and associated somatic symptoms

A Phase II, randomized, Double-Blind, Placebo-Controlled, Dose-Ranging study of fixed doses of Oral XXX and Prozac in the treatment of out-patients with moderate depression

A Double-Blind, randomized, Placebo and Paroxetine-controlled, Multi-Center, Dose-Finding Trial with XXX in out-patients with moderate to severe major depressive disorder

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of Safety an Efficacy of XXX in Patients with Major Depressive Disorder with Psychotic Features

Continuation Treatment with Once-Weekly Modified-Release XXX

A Multi-Center, Randomized, Double-Blind, Fluoxetine- and Placebo-Controlled Study of The Efficacy and Safety of XXX Orally Disintegrating Tablets in Subject with Major Depressive Disorder

XXX Once-Daily Dosing Versus Placebo in the Acute Treatment of Major Depression

**CLINICAL TRIAL EXPERIENCE (*continued*):**

Switching Subjects from Citalopram, Paroxetine, or Sertraline to Once-Weekly Modified-Release XXX in Maintenance of Response for Depression

An Evaluation of the Safety and Efficacy of XXX in the Prevention of Depression Recurrence

A Double-Blind, Randomized, Placebo- and XXX- Controlled, Multi-Center Dose finding Trial in Outpatients with Moderate to Severe Major Depressive Disorder

A Double-Blind, Placebo-Controlled Comparative Efficacy Study of XXX ER and Sertraline in Producing Remission in Outpatients with Major Depressive Disorder

A Double-Blind, Multi-Center Extension Trial in Subjects who Suffer from Major Depressive Disorder with Atypical Features who Participated in the Placebo and Fluoxetine Study of XXX

XXX Once-Daily Dosing Versus Placebo in the Acute Treatment of Major Depression

Olanzapine Plus XXX Combination Therapy in Treatment Resistant Depression: A Dose Ranging Study

Placebo-Controlled Evaluation of the Safety and Efficacy of XXX in the Prevention of Depression Relapse

Fixed-Dose Comparison of the Safety and Efficacy of XXX and Placebo in the Treatment of Major Depressive Disorder

XXX, Placebo and XXX Comparison in Patients with Major Depressive Disorder

A Double-Blind, Multi-Center, Randomized, Placebo-Controlled Efficacy and Safety Study of XXX and Fluoxetine in Subjects who Suffer from Major Depressive Disorder with Atypical Features

A Multi-Center, Double-Blind, Flexible-Dose Safety Trial Comparing XXX to XXX in the Treatment of Depressed Patients

Multi-Center, Randomized, Double-Blind, Sertraline-Controlled Study of the Efficacy and Safety of XXX in Subjects with Major Depressive Disorder who Failed on SSRI Treatment Due to Lack of Efficacy

***Depression – Adolescent & Pediatric***

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

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Fixed Dose, Safety and Efficacy Trial of XXX in Outpatient Children and Adolescents with Major Depressive Disorder and its extension study

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Fixed Dose, Safety and Efficacy Trial of XXX in Outpatient Children and Adolescents with Major Depressive Disorder

A Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXX in Pediatric Depression

A Randomized, Multi-Center, 8-Week, Double-Blind, Placebo-Controlled Flexible Dose Study to Evaluate the Efficacy and Safety of XXX in Children and Adolescents with Major Depressive Disorder

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Efficacy and Safety Study of XXX in Outpatient Children and Adolescents with Major Depressive Disorder

Open-Label Extension Study of the Safety and Efficacy of XXX in Children and Adolescents with Depression

An Open-Label, Long Term Safety Study of XXX in Children and Adolescents with Major Depressive Disorder

A 2000 Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXX in Children and Adolescents with Depression

***Depression - Elderly***

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

XXX Open-Label Treatment of Depression

A Randomized, Double-Blind, Placebo-Controlled Trial of XXX I In Depressed Patients at Least 75 Years of Age

Double-Blind, Multi-Center, Randomized, Paroxetine-Controlled Study of the Efficacy and Safety of XXX in Subjects with Major Depressive Disorder who Are at least 65 Years of Age

***Dermatology***

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

**CLINICAL TRIAL EXPERIENCE (*continued*):**

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

***Diabetes***

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 Study to Assess the Pharmacokinetics and Ability for Pediatric Patients with Type 2 Diabetes to swallow XXX Tablet.

A Multi-Center, Randomized, Double-Blind, Parallel-Group, Multiple-Dose Study Assessing the Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of XXX in Patients with Type 2 Diabetes Mellitus

A Phase II, Multi-center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study of XXX in Patients with Type 2 Diabetes Mellitus and Inadequate Glycemic Control with Metformin Therapy

An Open-Label, Stepwise Basal Insulin Dose Titration Study Using Continuous Subcutaneous Insulin Infusion (CSII)in Oral Anti-Diabetic Drug-Treated Type 2 Diabetes Mellitus Subjects Followed by a 10-Week Out-Patient Maintenance Phase

***Fibromyalgia***

A multicenter, randomized, double-blind, placebo-controlled switch study to evaluate the safety, tolerability and efficacy XXX in patients with an inadequate response to Duloxetine for the treatment of Fibromyalgia

A Phase III Pivotal, Multi-Center, Double-Blind, Randomized, Placebo-Controlled Mono-Therapy Study of XXX for Treatment of Fibromyalgia

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Adaptive-Design Efficacy, Safety and Tolerability Study of 4 Fixed Oral Doses of XXX in Adult Outpatients with Fibromyalgia Syndrome

A multicenter, randomized, double-blind, placebo-controlled, parallel group, adaptive-design efficacy, safety and tolerability study of 4 fixed oral doses of XXX in adult outpatients with fibromyalgia syndrome

***Hepatitis C***

A Multi-center, Open Label, Parallel Group Trial to Evaluate the Pharmacokinetic Interactions between XXX and XXX given in Combination with Ribavirin for 24 weeks, and their Combined Effect on the Pharmacokinetics of Tenofovir, Raltegravir, Caffeine, Tolbutamide and Midazolam in Treatment Naive Patients and Prior Treatment Relapse or Partial Responder Patients with Genotype 1 Chronic Hepatitis C Infection

A Double-Blind, Randomized, Placebo-Controlled, Single and Multiple-Dose Ranging Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Antiviral Activity of XXX in Treatment Naive Subjects with Chronic Hepatitis C Virus Infection

A Randomized, Double-Blind, Dose Escalation, Fusion, First Time in Human Study to assess the Safety, Tolerability, Pharmacokinetics, and Antiviral Activity of Single and Repeat Doses of XXX in Chronically Infected Hepatitis C Subjects

A Randomized, Double-Blind, Dose Escalation, Fusion, First Time in Human Study to assess the Safety, Tolerability, Pharmacokinetics, and Antiviral Activity of Single and Repeat Doses of XXX in Chronically Infected Hepatitis C Subjects

***Insomnia***

Efficacy and safety of XXX on Sleep Maintenance Insomnia: a 12 week multicenter, randomized, double-blind, placebo-controlled study followed by an open treatment phase extension with XXX for 40 weeks period

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Long-Term Safety and Efficacy

***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

**CLINICAL TRIAL EXPERIENCE (*continued*):**

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.

***Non-Alcoholic Steatohepatitis (NASH)***

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

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

A Phase II, Twelve Week, Double-Blind and Placebo-Controlled Study to Evaluate the Safety and Efficacy of Two Doses of XXX (1.5mg and 3.0mg) in Subjects with Obsessive Compulsive Disorder

***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-Controlled, Single-Dose Study of XXX in Moderate to Severe, Painful Osteoarthritis of the Knee

An Open-Label, Multicenter Study to Assess the Long-Term Safety of XXX Tablets 20 to 120 mg Once-daily in Subjects with moderate to Severe Chronic Nonmalignant and Nonneuropathic Pain.

**CLINICAL TRIAL EXPERIENCE (*continued*):**

An open-label 52-week study to assess the long-term safety of XXXX in Opioid-Induced Constipation (OIC) in patients with Non-Cancer-Related Pain.

A 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)

A Phase II, Randomized, Double-blind, Placebo-controlled, Study to Evaluate the Safety and Efficacy of XXX (100 mg) in Subjects with Opioid-induced Constipation

A Randomized, Double-blind, Placebo-controlled, Parallel-group Study of XXXX for the Treatment of Opioid-induced Constipation (OIC) in Subjects with Non-malignant Chronic Pain Receiving Opioid Therapy.

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Dose-Escalation Study to Assess the Safety, Tolerability, and Clinical Activity of XXX in Subjects with Opioid-Induced Constipation

A Randomized, Multicenter, Double-Blind, Parallel-Group trial to assess the analgesic efficacy and safety of XXX compared with placebo in subjects with painful diabetic peripheral neuropathy

A Phase IIa, Double-Blind, Randomized, Parallel-Group, Multi-center Study to evaluate the Analgesic Efficacy of 28 days Oral Administration of XXX Compared with Placebo in Patients with Painful Diabetic Polyneuropathy

A Phase IIa, Double-Blind, Randomized, Parallel-Group, Multi-Center Study to Evaluate the Analgesic Efficacy of 28 Days Oral Administration of XXX with One-Dose Escalation Compared to Placebo in Peripheral Neuropathic Pain Patients with Mechanical Hypersensitivity

A Phase II Randomized, Double-Blind, Multi Dose, Active-and Placebo Controlled, Multi-Center, Parallel Group Study of the Analgesic Effects of XXX in Adult Patients with Chronic Low Back Pain

A Phase IIa, Double-Blind, Randomized, Parallel-Group, Multi-Center study to Evaluate the Analgesic Efficacy of 28 Days Oral Administration of XXX Compared with Placebo in Patients with Painful Diabetic Neuropathy

A multicenter, randomized, long term study of the safety of XXX in patients with chronic low back pain

A Multicenter, Randomized, Single-Dose Pharmacokinetic Study of XXX Administered Followed by either a 2-Hour or an Overnight Fast to Subjects with Chronic Nonmalignant Pain

**CLINICAL TRIAL EXPERIENCE (*continued*):**

Evaluation of Safety, Tolerability and Pharmacokinetics of 200 µg Single Dose of XXX XXX XXX Administered Buccally to Opioid-Tolerant Cancer Patients

***Panic Disorder***

A Randomized, Double-Blind, Placebo-Controlled Study of Continuation Treatment with XXX in the Treatment of Adolescents with a Primary Diagnosis of Panic Disorder

An Open-Label Study to Assess the Safety and Tolerability of XXX in the Treatment of Adolescents with Panic Disorder or Anxiety with Panic Attacks

A Randomized, Double-Blind, Placebo-Controlled Study of XXX in the Treatment of Adolescents with a Primary Diagnosis of Panic Disorder

A Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dose Study of XXX Extended-Release Capsules in Adult Outpatients with Panic Disorder

Flexible-Dose Comparison of the Safety and Efficacy of XXX, and Placebo in the Treatment of Panic Disorder

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

A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dosage Study to Evaluate the Efficacy and Safety of XXX, at Dosages up to 16mg/day, in the Treatment of Chronic Post-Traumatic Stress Disorder in Adults

***Schizophrenia and 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 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

**CLINICAL TRIAL EXPERIENCE (*continued*):**

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 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 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

An Exploratory, Multicenter, Open-label, Flexible-dose XXX Trial in Adults With Acute Schizophrenia

A Single-arm Study to Evaluate Adherence to Treatment with, and Safety and Tolerability of, the XXX System in Subjects with Schizophrenia or Bipolar I Disorder Who Are Currently treated with Oral XXX

A Randomized, double-blind placebo controlled study to evaluate the efficacy and safety of low dose XXX in acutely psychotic subjects with schizophrenia.

A 12 week, randomized, double-blind, placebo-controlled, parallel group study to evaluate the effects of once daily doses of XXX on cognition, in stable schizophrenia patients

A Phase II, Randomized, multicenter, safety, tolerability, and dose ranging study of XXX, a component of XXX in adults with schizophrenia treated with Olanzapine.

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

A 26 Week, Multicenter, Open Label, Extension Study of XXX Intramuscular Depot in patients with Schizophrenia

**CLINICAL TRIAL EXPERIENCE (*continued*):**

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

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

A Randomized, double-blind placebo-controlled study to evaluate the efficacy and safety of low-dose XXX in acutely psychotic subjects with Schizophrenia

A 12 week, randomized, double-blind, placebo-controlled, parallel group study to evaluate the effects of once daily doses of XXX on cognition, in stable schizophrenia patients

A 26 Week, Multicenter, Open Label, Extension Study of Aripiprazole Intramuscular Depot XXX in patients with Schizophrenia

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

A Multicenter, 40-Week Extension Study to Evaluate the Safety and Clinical Effects of Prolonged Exposure to 1 and 2 mg Doses of XXX an Alpha-7 Nicotinic Acetylcholine Receptor Agonist, as an Adjunctive Pro Cognitive Treatment in Subjects with Schizophrenia on Chronic Stable Atypical Antipsychotic Therapy

A Randomized, Placebo-Controlled, Parallel, 12 Week, Phase III Study of 2 Doses of an Alpha-7 Nicotinic Acetylcholine Receptor Agonist XXX or Placebo as an Adjunctive Pro-Cognitive Treatment in Schizophrenia Subjects on Chronic Stable Atypical Antipsychotic Therapy

A Double-Blind, Placebo-Controlled, Randomized withdrawal study of XXX for the maintenance treatment of subjects with Schizophrenia

12-week, Phase III, multicenter, randomized, double-blind, placebo-controlled, trial of XXX Intramuscular Depot XXX in the Acute Treatment of Adults with Schizophrenia

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

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

An open-label study to evaluate the safety, tolerability, and pharmacokinetics of two XXX depot formulations followed by a dose-ranging phase of one selected formulation in schizophrenic patients given depot injections every 28 days.

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Phase II, III, multicenter, randomized, 4-week double-blind, parallel group, placebo and active-controlled trial of safety and efficacy of XXX vs. placebo in patients with an acute exacerbation of schizophrenia

Evaluation of the effects of sequential multiple-dose regimens of XXX on Cardiac Repolarization in Patients with Schizophrenia

A Phase III, multi-center, randomized, 24 week, double-blind, parallel-group, placebo-controlled study to evaluate the efficacy and safety of XXX in stable patients with persistent, predominant negative symptoms of schizophrenia treated with antipsychotics followed by 28-week double-blind treatment period

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 II, Double-Blind, Randomized, Placebo-Controlled, Two-Period Cross-Over Study to Evaluate the Efficacy and Safety of XXX for the Treatment of Tardive Dyskinesia in subjects with Schizophrenia or Schizoaffective Disorder.

A Multi-center, randomized, double-blind, placebo-controlled, parallel group study to evaluate prevention of relapse in patients with schizophrenia receiving either flexible dose XXX or placebo in long term use (up to 26 weeks) followed by up to 52 weeks of open-label extension

An Open-Label, Parallel Group, Multiple-Dose Study to Evaluate the Pharmacokinetics, Safety and Tolerability of XXX Patch (Risperidone Transdermal Drug Delivery System) following 24-Hour Application in Schizophrenic Patients compared to Oral Risperidone Tablet.

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

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

A Phase III, Multicenter, Double-Blind, Placebo-Controlled study of 3 Doses of XXX monohydrate in the Acute Treatment of Patients with DSM-IV-TR Schizophrenia

A double-blind, placebo-controlled, randomized withdrawal study of XXX for the maintenance treatment of subjects with schizophrenia.

An Open-Label study to evaluate the safety, tolerability, and pharmacokinetics of two XXX depot formulations followed by a dose ranging phase of one selected formulation in schizophrenic patients given depot injections every 28 days

**CLINICAL TRIAL EXPERIENCE (*continued*):**

An Open-Label study to evaluate the safety, tolerability, and pharmacokinetics of two XXX depot formulations followed by a dose ranging phase of one selected formulation in schizophrenic patients given depot injections every 28 days

A Randomized, Double-Blind, Placebo-Controlled, cross-over, single dose study to evaluate the effects of XXX on cognitive functions in patients with stable schizophrenia including a one-week multiple dose extension to assess the persistence of observed effects

A 12-Week, Randomized, Multi-Center, Open-Label, XXX, (12-24 mg/day) Flexible dose Study assessing Efficacy, Safety and Tolerability of Two Switch approaches in Schizophrenia Patients Currently Receiving Risperidone, Olanzapine, or Aripiprazole

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

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

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

A randomized double-blind, placebo controlled, parallel group study to evaluate the cognitive enhancing effects of XXX in stable patients with Schizophrenia

A Randomized, Double-Blind, Placebo-Controlled, cross-over, single dose study to evaluate the effects of XXX on cognitive functions in patients with stable schizophrenia including a one-week multiple dose extension to assess the persistence of observed effects

A 2010 Randomized Phase II, Double-Blind, Placebo-Controlled, Multi-Center Study of XXX as Add-on Therapy in Outpatients with Persistent Negative Symptoms of Schizophrenia Treated with a Stable Dose of a Second-Generation Antipsychotic

A Phase IIa, Multicenter, Double-Blind, Randomized, Parallel Group, 4-week Inpatient, Treatment Study to Evaluate the Safety, and Efficacy of two fixed doses XXX Compared to Placebo, using risperidone as an active control, in the treatment of acute exacerbation of Schizophrenia

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Phase II, Multicenter Study with Open Label and Randomized Double-Blind Placebo-Controlled withdrawal phases to evaluate efficacy, safety and tolerability of XXX in Adults with Schizophrenia and Predominant Negative Symptoms who are clinically stable and taking stable doses of Atypical Antipsychotic Medication

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

A Long-Term, Phase II, Multi-Center, Randomized, Open-Label, Comparative Safety Study of XXX Versus A typical Antipsychotic Standard of Care in Patients with DSM-IV-TR Schizophrenia

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

A 2008 Phase III, Randomized, Double-Blind, Active Comparator-Controlled Clinical Trial to study the Safety and Efficacy of XXX in Subjects with Schizophrenia

A Phase III, Double-Blind, Placebo and Active Comparator Controlled Clinical Trial to Study the Efficiency and Safety of Two Doses of XXX in Acutely Psychotic Subjects of Schizophrenia

A Phase III, Randomized, Placebo- and Active Comparator-Controlled Clinical Trial to Study the Safety and Efficacy of Two Doses of XXX in Acutely Psychotic Patients with Schizophrenia

A Phase IIa, Randomized, Double-Blind, Placebo-Controlled, Add-On Therapy, 2-Period Cross-Over Clinical Trial to Evaluate the Safety and Efficacy of XXX for the Treatment of Cognitive Impairment in Patients With Schizophrenia

A Phase IIa, Multi-center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled study to evaluate the safety and efficacy of XXX as adjunctive treatment in combination with a preexisting antipsychotic in patients with cognitive impairment associated with Schizophrenia

A Phase III Randomized, Double-Blind, Placebo- and Active Comparator-Controlled Clinical Trial to Study the Efficacy and Safety of Two Doses of XXX in Acutely Psychotic Subjects With Schizophrenia (Pearl 3) with an Extension study

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

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

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Phase II, Randomized, Double-Blind, Placebo-Controlled, XXX-Referenced, Parallel-Group, Adaptive-Design Study of the Efficacy, Safety and Tolerability Of XXX in Subjects with Acute Exacerbations of Schizophrenia

A Phase IIa, Single-Blind, Placebo Controlled Trial to Evaluate the Pro-Cognitive Effects of XXX in Patients with Schizophrenia

A Single-arm Evaluation of the Safety of XXX in Subjects with Schizophrenia or Schizoaffective Disorder with Hepatic Disease

A Phase IIa, Multi-center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled study to evaluate the safety and efficacy of XXX as adjunctive treatment in combination with a preexisting antipsychotic in patients with cognitive impairment associated with Schizophrenia

A Phase III, Randomized, Placebo- and Active Comparator-Controlled Clinical Trial to Study the Safety and Efficacy of Two Doses of XXX in Acutely Psychotic Patients with Schizophrenia

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

A Phase II, Multicenter, Double-Blind, Randomized, Fixed Dose, Parallel Group, 3-Week Inpatient Treatment Study to Evaluate the Safety, Efficacy and Pharmacokinetics of XXX compared with Placebo in the Treatment of Acute Exacerbation of Schizophrenia

A Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of Two Dosages of XXX in the Treatment of Subjects with Schizoaffective Disorder

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

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

A Multi Centre, Double-Blind, Double-Dummy, Placebo-Controlled, Randomized, Adaptive, Dose-Range Study to Evaluate the Safety and Efficacy of XXX Administered Once Daily for 12 Weeks in Adults with Schizophrenia

A Randomized, Open-Label Study Comparing the Effects of XXX Depot with Oral XXX on Treatment Outcomes in Outpatients with Schizophrenia

Exploratory Study of Exposure to XXX and its Metabolite XXX in individuals Prescribed XXX and/or Subjects Enrolled in AstraZeneca Study

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose Response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses of XXX in Subjects with Schizophrenia

A randomized, double blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of XXX compared to XXX in subjects with an acute exacerbation schizophrenia

A Randomized, Double-Blind, Placebo-Controlled, XXX Referenced, Parallel Group, Safety, Efficacy and Tolerability Study of XXX versus Placebo in Subjects with Acute Exacerbation of Schizophrenia

A randomized, double-blind, placebo- and ziprasidone-controlled, multicenter study to evaluate the efficacy, safety and tolerability of a XXX given b.i.d. for 28 days to schizophrenic patients in acute exacerbation followed by a long-term treatment phase

A Multicenter, Double-blind, Placebo-controlled, 16-Week Study of XXX Used as Dual Therapy in the Treatment of Patients with Chronic Stable Schizophrenia or Schizoaffective Disorder Demonstrating an Inadequate Response to Quetiapine or Risperidone Monotherapy

A multicenter, randomized, double-blind, fixed-dose, efficacy and safety trial of XXX vs. placebo as augmentation therapy in schizophrenic subjects currently receiving risperidone (2 or 3 mg b.i.d.)

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

A Multicenter, Randomized, Double-Blind, Parallel-Group Fixed-Dose Study of the Effect on Weight of XXX versus XXX in the Treatment of Outpatients with Schizophrenia with an extension study

A double-blind, placebo-controlled, dose-ranging, parallel-group study in adults with cognitive impairment associated with schizophrenia

Comparative Single-Dose Pharmacokinetic and Safety of Gluteal and Deltoid Intramuscular Injection of Long Acting XXX in Subjects with Chronic Stable Schizophrenia

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Evaluating XXX in the Prevention of Recurrence in Subjects with Schizophrenia

Open-Label, Parallel, Randomized, Dose Proportionality Pharmacokinetic Study of XXX after Intramuscular Injection of XXX XXX in the Deltoid or Gluteal Muscle in Subjects with Schizophrenia

**CLINICAL TRIAL EXPERIENCE (*continued*):**

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

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Evaluating XXX XXX in the Prevention of Recurrence in Subjects with Schizophrenia

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

A Multicenter, Double-Blind, Flexible-Dose, 6-Month Trial Comparing the Efficacy and Safety of XXX with Olanzapine in Stable Subjects with Predominant, Persistent Negative Symptoms of Schizophrenia with an Extension Study

A Multicenter, Randomized, Double-Blind, Flexible-Dose, 6-Week Trial of the Efficacy and Safety of XXX Compared with Placebo Using XXX Positive Control in Subjects with an Acute Exacerbation of Schizophrenia with an Extension Study

A Multi-Center, Double–Bind, Placebo-Controlled, Randomized, Parallel Group Evaluation of the Efficacy of a Flexible Dose of XXX versus Placebo as Add-On Therapy in Schizophrenia

A Multicenter, Double-Blind, Double-Dummy, Placebo-Controlled, Randomized, Parallel Group Study of the Efficacy and Safety of XXX versus Placebo and XXX in Subjects with Schizophrenia

A Randomized, Double-Blind, Placebo-Controlled and XXX-Referenced, Parallel-Group Efficacy and Safety Study of Two Fixed Doses of XXX in the Treatment of Schizophrenia

A 52-Week, Prospective, Randomized, Double-Blind, Multi-Center Study of Relapse Following Transition From Oral Antipsychotic Medication to Two Different Doses (25 or 50 Mg Given Every Two Weeks) of XXX Long-Acting Microspheres (XXX) in Adults with Schizophrenia or Schizoaffective Disorder

A Randomized, Double-Bind, Placebo and Active Controlled, Parallel-Group, Dose Response Study to Evaluate the Efficacy and Safety of Two-Fixed Dosages of Extended Release XXX (6 and 12mg/day) and XXX (10mg/day), with Open-Label Extension in the Treatment of Subjects with Schizophrenia

A Study of XXX as an Adjunctive Treatment to Atypical Antipsychotic Medications in Outpatients with Schizophrenia and Associated Cognitive Deficits

The Comparison of Efficacy and Safety of Continuing XXX to Switching to XXX in Overweight or Obese Patients with Schizophrenia or Schizoaffective Disorder

**CLINICAL TRIAL EXPERIENCE (*continued*):**

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

Double-Blind Randomized Study Comparing Intramuscular XXX Depot with Placebo in the Treatment of Patients with Schizophrenia

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

A Double-Blind, Fixed Dose Study of XXX and Placebo in the Treatment of Schizophrenia and its extension study

A Multicenter, Double-Blind, Flexible-Dose, 6-Month Trial Comparing the Efficacy and Safety of XXX with XXX in Stable Subjects with Predominant, Persistent Negative Symptoms of Schizophrenia

A Four-Week Double Blind Multi-Center Study Comparing the Efficacy and Safety of XXX to XXX in Subjects with Schizophrenia or Schizoaffective Disorder Needing Inpatient Care

A Multicenter, Randomized, Double-Blind, Flexible-Dose, 6-Week Trial of the Efficacy and Safety of XXX Compared With Placebo using XXX Positive Control in Subjects with an Acute Exacerbation of Schizophrenia

A Multi-Center, Double–Blind, Placebo-Controlled, Randomized, Parallel Group Evaluation of the Efficacy of a Flexible Dose of XXX versus Placebo as Add-On Therapy In Schizophrenia

A Randomized, Double-Blind, Placebo-Controlled and XXX -Referenced, Parallel-Group Efficacy and Safety Study of Two Fixed Doses of XXX in the Treatment of Schizophrenia

A Randomized Double-Blind, Placebo-Controlled, Dose-Response Study of XXX in Subjects with Schizophrenia who have Predominantly Negative Symptoms

A Randomized, Double-Blind, Placebo and Active Controlled, Parallel-Group, Dose Response Study to Evaluate the Efficacy and Safety of Two Fixed Dosages of Extended Release XXX XXX (6 and 12mg/day) and XXX (10mg/day), with Open-Label Extension, in the Treatment of Subjects with Schizophrenia

A Randomized, Double-Blind Study of the Safety and Efficacy of XXX plus an Atypical Antipsychotic vs. an Atypical Antipsychotic Alone in the Treatment of Schizophrenia

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Dose-Finding Clinical Trial to Evaluate the Efficacy and Safety of Three Doses of XXX (2.5 Mg, 5 Mg, 10 Mg) Compared to XXX 10 Mg and Placebo in Patients with Acute Phase Schizophrenia

**CLINICAL TRIAL EXPERIENCE (*continued*):**

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

A Study of Two Doses of XXX as an Adjunctive Treatment to XXX in Male Outpatients with Schizophrenia and Associated Cognitive Deficits

A 52-week, Prospective, Randomized, Double-Blind, Multi-Center Study of Relapse Following Transition from Oral Antipsychotic Medication to Two Different Doses (25 or 50 mg Given Every Two Weeks) of XXX Long-Acting XXX (XXX) in Adults with Schizophrenia or Schizoaffective Disorder.

A Multicenter, Double-Blind, Double-Dummy, Placebo-Controlled, Randomized, Parallel Group Evaluation of the Efficacy and Safety of a Fixed-Dose of XXX versus Placebo versus XXX in Patients with Schizophrenia

A Multi-Center, Double-Blind, Randomized Comparison of the Efficacy and Safety of XXX and XXX in the Treatment of Patients with Schizophrenia

The Assessment of XXX for the Treatment of Olanzapine-Associated Weight Gain in Patients with Schizophrenia and Related Disorders and Bipolar Disorder

An Outpatient Open-Label Comparison of the XXX effects of Aripiprazole to Olanzapine Administered Orally in Patients with Psychosis

An Outpatient Open-Label Follow-Up of the Long-Term Safety of XXX Administered Orally in Patients with Psychosis

***Seasonal Affective Disorder***

A 6.5 Month, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Comparison of 150-300mg/Day of Extended Release XXX XXX and Placebo for the Prevention of Seasonal Affective Disorder in Subjects with a History of Seasonal Affective Disorder

***Sexual Dysfunction***

A randomized, Double-Blind, Parallel-Group, Active-Controlled, Flexible-Dose study evaluating the Effect of XXX of sexual functioning in adults with well-treated major depressive disorder experiencing selective Serotonin Reuptake Inhibitor -Induced Sexual Dysfunction.

A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Phase III Safety of XXX in Women taking a Selective Serotonin or Serotonin-Norepinephrine Reuptake Inhibitor with Decreased Sexual Desire and Distress

**CLINICAL TRIAL EXPERIENCE (*continued*):**

***Women's Health***

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 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

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, 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 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 10-week, double-blind, multi-center trial comparing XXX with placebo in subjects with Chron’s Disease

A 6 month, multicenter, randomized safety, tolerability, pharmacokinetic and preliminary efficacy study of XXX in adolescents with Tourette’s Disorder

STD Test Collection Kit Validation Study

## GCP TRAINING:

| | |
|---|---|
| 01/27/12 | DWD Associates- GCP/ICH GCP Training |
| 11/15/08 | Medical Research Management's Investigator Perspective – FDA GCP/ICH GCP Training |
| 10/27/07 | Medical Research Management's CRC and US GCP/ICH CGP Training Seminar |

## PROFESSIONAL AFFILIATIONS, SOCIETIES AND MEMBERSHIPS:

| | |
|---|---|
| 1989 – Present | Gloucester County Medical Society |
| 1984 – Present | South Jersey Psychiatric Association |
| 1982 – Present | Philadelphia Psychiatric Society |
| 1979 – 1989 | Philadelphia County Medical Society |
| 1979 – 1989 | Pennsylvania Medical Society |
| 1978 – Present | Pennsylvania Psychiatric Society |
| 1977 – Present | American Medical Association |
| 1977 – Present | American Psychiatric Association<br>Alternate Falk Fellow – 1978 |

## HOSPITAL AND ADMINISTRATIVE APPOINTMENTS:

Lourdes Medical Center of Burlington County
2005 – Present Medical Staff

Hampton Behavioral Center
2001 – Present Medical Staff

Joint Commission on Accreditation of Healthcare Organizations
1994 – 1996 Healthcare Network
1988 – 1996 Hospital Accreditation Program
1985 – 1988 Consultant Surveyor, Accreditation Programs for Psychiatric Facilities

South Jersey Hospital System
1993 – 1996 Chairman, Department of Psychiatry
1990 – 1997 Chairman, Medical Staff Quality Improvement Committee

Center for Addictive Diseases
1985 – 1989 Executive Medical Director

Camden County Health Services Center
1984 – 1989 Clinical Director
1984 – 1989 Chairman, Quality Assurance Committee
1984 – 1989 President, Medical Staff

Temple University School of Medicine
1983 – 1984 Clinical Asst. Residency Director, Dept. of Psychiatry

## HOSPITAL AND ADMINISTRATIVE APPOINTMENTS (*continued*):

Belmont Center for Comprehensive Treatment
1983 – 1984 Chairman, Medical Records Committee
1983 – 1984 Secretary/Treasurer, Medical Staff
1983 – 1984 Acting Clinical Director
1982 – 1984 Director, Outpatient Department

JYC Einstein Daroff Geriatric Day Treatment Program
3/1981 – 12/1981 Medical Director

Albert Einstein Medical Center, Daroff Division
1980 – 1982 Staff Psychiatrists
1980 – 1981 Director of Education

Veterans Administration Hospital
4/1980 – 9/1980 Staff Psychiatrist

Crozer Chester Medical Center
1979 – 1980 Crisis Center Psychiatrists

## ADVISORY BOARDS:

### FACULTY APPOINTMENTS:

Education Programs Faculty, 1989 – 1997
Joint Commission on Accreditation of Healthcare Organizations

Clinical Assistant Professor of Psychiatry, 1985 – 1998
Robert Wood Johnson School of Medicine at Rutgers University

Adjunct Clinical Assistant Professor of Psychiatry and Human Behavior, 1983 – 1991
Thomas Jefferson University

Clinical Assistant Professor of Psychiatry, 1982 – Present
Temple University School of Medicine

### STAFF APPOINTMENTS:

Admitting Privileges, 2005
Lourdes Medical Center of Burlington County, Willingboro, NJ

Courtesy Privileges, 2001 – Present
Hampton Behavioral Center, Westhampton, NJ

**ADVISORY BOARDS (*continued*):**

Active Medical Staff, 1994 – Present
Mercy Fitzgerald Hospital and Mercy Community Hospital

Active Staff, 1993 – 1995
Parkview Hospital

Courtesy Privileges Medical Staff, 1992 – Present
Rancocas Hospital

Active Staff, 1991 – 1995
Graduate Hospital

Active Staff, 1991 – 1995
Mt. Sinai Hospital

Active Staff, 1990 – 1999
Newcomb Medical Center

Chairman, Medical Staff Quality Improvement Committee, 1990 – 1996
South Jersey Hospital System

Attending Medical Staff, 1990 – 1995
Zurbrugg Hospital

Active/Courtesy Staff, 1989 – Present
Underwood-Memorial Hospital

Attending Medical Staff, 1989 – 1999
South Jersey Hospital System

Attending Medical Staff, 1986 – 1995
Kennedy Memorial Hospital

Courtesy Staff, 1984 – 1991
Camden County Health Services Center

Attending Medical Staff, 1982 – Present
Belmont Comprehensive Center

Attending Medical Staff, 1980 – 1991
Thomas Jefferson University Hospital

## PUBLICATIONS:

### PUBLISHED ARTICLES

Manuscript for The Journal of Clinical Psychiatry – "*Effects of Tiagabine plus Fluoxetine or Escitalopram in Patients with Disturbed Sleep Associated with Mild to Moderate Depression, an Open-Label Pilot Study*"

ACNP Poster – "*Cognitive Function and Acute Sedative Effects of and Quetiapine in Patients with Stable Bipolar I Disorder, a Randomized Double-Blind, Crossover Study*"

### CLINICAL ABSTRACTS AND POSTERS

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

Cohen, E. A., Hassman, H. H., Walling, D. P., Wyka, K., Horan, W. P., Keefe, R. S., Grindell, V. M., Glass, S. J., Ball, R. R., Styczynski, J., Lobb, J. M., & Ereshefsky, L. (May, 2020). The Placebo-Control Reminder Script in depression and psychosis trials: An antidote for the placebo and nocebo response. Poster presented at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting, Miami, FL.

Hassman, H. H., Cohen, E. A., Walling, D. P., Wyka, K., Grindell, V. M., Glass, S. J., Ball, R. R., Styczysnki, J., Lobb, J. M., Hazzard-Randolph, D., Joseph, A. V., and Ereshefsky, L. (2020, April). The Placebo conundrum: Mitigating the response at the site level. Poster presented at the Annual Meeting of the Schizophrenia International Research Society (SIRS), Florence, Italy.

Cohen, E. A., Hassman, H. H., Walling, D. P., Wyka, K., Ball, R. R., Joseph, A. V., Lobb, J. M., Hazzard-Randolph, D., Ereshefsky, L., Grindell, V., Glass, S. J., Styczynski, J. (2019, November). Broadening the Empirical Exploration of the Placebo-Control Reminder Script to Reduce Placebo and Nocebo Effects: A Preliminary Data Analysis of Subjects with Schizophrenia and Schizoaffective Disorders. Poster presented at the Annual Meeting of the CNS Summit Conference, Boca Raton, FL.

Adjunctive Modafinil at Initiation of Treatment with a Selective Serotonin Reuptake Inhibitor Enhances the Degree and Onset of Therapeutic Effects in Patients with Major Depressive Disorder and Fatigue, 2004.