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CEO, Apex Innovative Sciences
CEO, Hassman Research Institute, LLC

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CONTACT INFORMATION:

Site Selection and Information:
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AFFILIATIONS:

Berlin Medical Associates
175 Cross Keys Rd, Suite 300A
Berlin, NJ 08009

Comprehensive Clinical Research
175 Cross Keys Road
Berlin, NJ 08009

EDUCATION:

1979 - 1983	PA Osteopathic Physician and Surgeon, D.O. Philadelphia College of Osteopathic Medicine, Philadelphia, PA
1978 - 1979	Drexel University, Philadelphia
1974 - 1978	BS, Fairleigh Dickinson University, Madison, NJ

INTERNSHIP:

1983 - 1984 Rotating Internship
University of Medicine and Dentistry, John F. Kennedy Memorial Hospital
Stratford, Cherry Hill, and Washington Township Divisions, NJ

CERTIFICATION:

Board Certified in Family Practice

LICENSURE:

Available upon request

PROFESSIONAL EXPERIENCE:

Chief Executive Officer, 2019-present
Apex Innovative Sciences

Chief Executive Officer and Principal Investigator, 2016 - present
Hassman Research Institute, LLC, Berlin, NJ

Principal Investigator/ Sub-Investigator, 2015 - present
Comprehensive Clinical Research, Berlin, NJ

Senior Vice President/ PI/ Sub-I/ Rater, 2013 - 2014
PRA Health Sciences (Formerly CRI Lifetree)
Raleigh, NC, Marlton, NJ, Philadelphia, PA

Chief Scientific Officer, 1999 - 2013
CRI Lifetree, Marlton, NJ, Philadelphia, PA

Board Member, 2008 - Present
Our Lady of Lourdes Medical Center IRB, Camden, NJ

National Board of Directors, 2008 - Present
Devereux Foundation, Villanova, PA 19085

Executive Vice President, Corporate Development, 1994 - 1998
FPA Medical Management, Inc., San Diego, CA

Chief Medical Officer, 1984 - 1998
Clinical Managed Care Research, San Diego, CA

General Practitioner, 1984 - 1993
Family Practice Associates of San Diego, Inc., San Diego, CA

HOSPITAL AND ADMINISTRATIVE APPOINTMENTS:

2005 - Present	Lourdes Medical Center of Burlington County, NJ
2004 - Present	Kirkbride Hospital, Philadelphia, PA
2001 - 2005	Hampton Behavioral Health Center, Westhampton, NJ
1998 - Present	Department of Family Practice at Kennedy Memorial Hospital - University Medical Center
1991 - 1995	Hillside Hospital (Closed)
1990 - 1996	Mercy Hospital
1984 - 1998	Grossmont Hospital
1984 - 1987	Alvarado Hospital

INVESTIGATOR EXPERIENCE:

Phase I-IV: Addiction • ADHD (adult, pediatric, adolescent) • Allergies • Alzheimer's Disease
Anxiety • Binge Eating Disorder • Bipolar Disorder • Chronic Pain • Cognition
Dementia • Depression • Fibromyalgia • Healthy • Insomnia • Migraine • Mood Disorders
Neuropathic Pain • Obesity • Obsessive Compulsive Disorder • Panic Disorder
Post-Traumatic Stress Disorder • Parkinson's Disease
Schizophrenia and Schizoaffective Disorders • Smoking Cessation
Type 2 Diabetes • Women's Health

ADDITIONAL TREATMENT EXPERIENCE:

Atopic Dermatitis • Cheviak Bigasdh Syndrome • Crohn's Disease • Bronchitis (chronic, acute)
Gastric Ulcer • Hepatitis C • Hypertension • Neurogenic Orthostatic Hypotension • Osteoarthritis
Pediculicide • Pneumonia • Respiratory Tract Disease • Skin Infection • Sinusitis
Urinary Tract Infection • Viral Syndrome

CLINICAL TRIAL EXPERIENCE:

Phase I Addiction

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

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

Phase I Depression

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

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

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

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

Phase I Diabetes

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

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

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

A Phase Ib, Randomized, Blinded, Placebo-controlled, Multiple Ascending-dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Subcutaneous XXX in patients with Type 2 diabetes mellitus and Nonalcoholic fatty liver disease

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

A Phase I, 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

Phase I Healthy

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

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

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

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

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

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

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

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

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

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

A Phase I, Randomized, Double-blind, Placebo-controlled Parallel Group Study of Multiple Doses of XXX Challenge, to Evaluate the Electrophysiology. Safety, Tolerability and Pharmacokinetics in Healthy Subjects

A Phase I Double-blind, Placebo-controlled Crossover Study of XXX Using Ketamine Challenge, to Evaluate Safety, Tolerability, Pharmacokinetics and Pharmacodynamic Response Using PET Imaging in Healthy Subjects

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase I, Double-blind, Placebo-controlled, Crossover Study of XXX Using a Ketamine Challenge to Evaluate the Electrophysiology, Safety, Tolerability, and Pharmacokinetics in Healthy Subjects

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

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

A Phase Ib Randomized, Active Controlled, Double-Blind, Cross-Over Pharmacokinetic/ Pharmacodynamic and Safety Study in Healthy Adults after Single-Dose XXX Injection

A Phase I, 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 XXX Following 15-mg Syrup Suspension or 15-, 7.5-, and 3.75-mg Tablet Doses in Healthy Subjects

A 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 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Effects on Neurophysiological Biomarkers of XXX Oral Treatment in Subjects with Schizophrenia and Normal Healthy Volunteers

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

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

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

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

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

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

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

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

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

A Safety/Tolerance Study to Evaluate a New Titration Scheme in Patients With Bipolar I Disorder or Schizophrenia

A Phase I, Randomized, Double-blind, Placebo-controlled, Ascending Dose study to Determine Efficacy, Pharmacokinetic and Safety of XXX in Agitation associated with Schizophrenia or Schizoaffective Disorder

A Phase Ib, Open-label, Multiple-dose, Randomized, Parallel-arm, Safety, Tolerability, and Pharmacokinetic Trial of XXX Intramuscular Depot Administered in the Gluteal Muscle in Adult Subjects With Schizophrenia or Bipolar I Disorder

An Open-label, Single- and Multiple-dose, Pharmacokinetic, Safety, and Tolerability Trial of XXX Administered in the Deltoid or Gluteal Muscle in Adult Subjects with Schizophrenia or Bipolar I Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase I, Open Label, Parallel-Design, Single Dose Study to Assess the Relative Bioavailability of XXX Extended-Release Suspension for Subcutaneous Administration XXX, in Vials compared to Prefilled Syringes, in Patients with Schizophrenia or Schizoaffective Disorder

A Phase I Randomized, Open-Label, Pilot Parallel Study To Determine The Relative Pharmacokinetic Characteristics Between XXX Versus Injectable Paliperidone Palmitate Following Different Dosing Regimens In Schizophrenia Alone Or As Use In Schizoaffective Disorders As An Adjunctive Therapy To Antidepressants

A Phase I, Open-label, Sequential Dose Escalation Cohort Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX Long Acting Injectable (LAI) in Subjects with Schizophrenia

A Phase I Randomized, Double-blind, Positive and Placebo-controlled, Four-Arm Crossover Study of the Effects of XXX at Therapeutic and Supra-therapeutic Doses, on the QTc Intervals in Schizophrenic Patients

A Phase Ib, Pivotal, Multiple-Dose, Pharmacokinetic Bioequivalence Trial Comparing Generic to Reference XXX Extended-Release Injectable Suspension (156 mg/1.0 mL) in Patients with Schizophrenia or Schizoaffective Disorder

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

A Phase I, Randomized, Crossover, Open-Label, Multiple Dose, Pivotal Pharmacokinetic Bioequivalence Study Comparing XXX Extended-Release IM 156 mg/1 mL (100 mg eq) with XXX in Subjects with Schizophrenia or Schizoaffective Disorder

A Phase I Study to Evaluate the Effect of Multiple Doses of XXX on QTc Interval in Subjects with Schizophrenia

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

A Phase I, Open-Label Study in Stabilized Schizophrenic Patients to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX and XXX when XXX 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, Placebo-and Positive-controlled Study of the Electrophysiological Effects on the QT Interval after a Supratherapeutic Dose of XXX in Subjects with Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

A Phase I, 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 XXX Following Administration of the Immediate-Release Formulation of XXX® Tablets in Patients With Schizophrenia

A Phase Ib, 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

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

A Phase I, 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

A Phase I, Local-Site Tolerability of Multiple-Dose Treatment with Deltoid Intramuscular Injection of XXX in Subjects with Chronic 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, Comparative 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, Multicenter, Double-Blind, Randomized, Parallel Group, Active-Controlled Tolerability and Safety Study of XXX in Clinically Stable Schizophrenic Outpatients

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

Phase I Other Indications

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

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

A Phase Ib Escalating Dose, Open-Label, Signal-Finding Study to Evaluate the Safety, Tolerability, and Short-Term Efficacy of the Anti-Light Monoclonal Antibody XXX in Adults With Moderate to Severe Active Crohn's Disease Who Previously Failed Treatment With an Anti-TNFα Agent, With and Without Loss of Function Mutations in Decoy Receptor 3 (Anti-LIGHT in Anti-TNFα-Resistant Crohn's Disease [TRaCk LIGHT])

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

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

A Phase I, Randomized, Double-blind, Third-party Open, Placebo-controlled, Dose Escalating Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single and/or Multiple Intravenous and/or Subcutaneous Doses of XXX in Healthy Subjects who may be Mildly Atopic Subjects with Chronic Rhinosinusitis with Nasal Polyps, and Subjects with Moderate Severe Atopic Dermatitis

A Phase I, Open label, Multicenter, Single Dose Study to Evaluate the Pharmacokinetics of XXX in Healthy Subjects with Normal Hepatic Function and Subjects with Impaired Hepatic Function

A Phase I, Open label, Multicenter, Single Dose Study to Evaluate the Pharmacokinetics of XXX in Healthy Subjects with Normal Renal Function and Subjects with Impaired Renal Function

A Phase I, Open-Label, Drug-Drug Interaction Addiction Study Between Methadone and XXX- and Between XXX/XXX and XXX

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase I, Study Comparing the Pharmacokinetics of Intranasal XXX in Subjects with Severe Renal Impairment and Subjects with Normal Renal Function

A Phase I, Systemic Pharmacokinetics of Intranasal XXX in Hepatic-impaired Individuals

A Phase I, 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 I, multi-center, open label, parallel group trial to evaluate the pharmacokinetic interactions between XXX and XXX given in combination with XXX for 24 weeks, and their combined effect on the pharmacokinetics of XXX, XXX, XXX, XXX and XXX in treatment naive patients and prior treatment relapse or partial responder patients with genotype 1 chronic hepatitis C infection

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

A Randomized, Double-Blind, Placebo-Controlled, Ascending Dose Study of Safety and Tolerability of XXX in Adult patients with Parkinsons 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, An Open Label, Single Dose, Cross-over Study to Assess the Effect of XXX in the Fed and Fasted State

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

A Phase I, Two 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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase I, Evaluation of Safety, Tolerability and Pharmacokinetics of 200 µg Single Dose of XXX® XXX XXX Administered Buccally to Opioid-Tolerant Cancer Patients with or without Oral Mucositis

Phase II-IV

Addiction

A Phase IV, Randomized, Double-blind, Double-dummy, Placebo and Active Controlled, Single-dose, Six-way Crossover Study Evaluating the Abuse Potential of XXX Taken Orally Concomitantly with XXX in Healthy Non-Drug Dependent, Recreational Opioid Users

A Phase IV, Open-label, Treatment Extension Study for the Rapid Initiation of Extended-Release XXX Subcutaneous Injection

A Phase IV, Open-label, Rapid Initiation Study for Extended-Release XXX Subcutaneous Injection

A Phase IV, Observational Evaluation of Long-term XXX Plasma Exposure in Subjects Who Received at Least 2 Subcutaneous (SC) Injections of Extended-release XXX in Phase III Studies

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

A Phase II, Multi-Center Trial of XXX in the treatment of Cocaine Use Disorder

ADHD

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

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel-Group Flexible-Dose Study of the Efficacy and Safety of XXX in Adults with Attention-Deficit/ Hyperactivity Disorder (ADHD)

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

A Phase III, Randomized, Double-blind, Multicenter, Placebo-controlled, Parallel-group Trial Evaluating the Efficacy, Safety and Tolerability of XXX Sustained-release Tablets in Adults with Attention-deficit/ Hyperactivity Disorder

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

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

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

A Phase III, Randomized, Double-blind, Multicenter, Parallel-group, Placebo-controlled, Dose-optimization Safety and Efficacy Study of XXX Compared with Placebo in Preschool Children Aged 4-5 Years with Attention-deficit/Hyperactivity Disorder

A Phase II, Multicenter, 3-Part, 6-Week, Double-blind, Randomized, Placebo-controlled, Parallel-design Study to Assess the Efficacy and Safety of XXX in Children and Adolescents (Ages 6-17 Years) with Attention Deficit Hyperactivity Disorder and with or without Copy Number Variants in Specific Genes Implicated in Glutamatergic Signaling and Neuronal Activity

A Phase III, Open-Label Extension Study to Evaluate the Safety of XXX Extended-Release Tablets for the Treatment of Impulsive Aggression in Pediatric Subjects with Attention Deficit/Hyperactivity Disorder (ADHD) in Conjunction with Standard ADHD Treatment

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

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 40-week, randomized, double-blind, placebo-controlled, multicenter efficacy and safety of XXX in the treatment of adult patients with childhood-onset ADHD

CLINICAL TRIAL EXPERIENCE (*continued*):

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, 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 Dose-Response Evaluation of the Efficacy and Safety of XXX v. Placebo in the Treatment of Children and Adolescents with Attention Deficit Hyperactivity Disorder

A Phase III Evaluation of the Efficacy and Safety of XXX as add-on to Psychostimulant Medication vs. Psychostimulant Medication Alone in the Treatment of Children and Adolescents with Attention Deficit Hyperactivity Disorder

A Phase III Open-Label, Chronic Exposure Evaluation of the Safety of XXX in the Treatment of Children and Adolescents with Attention Deficit Hyperactivity Disorder

A Phase IV, Double-Blind Study of XXX versus Placebo for the Treatment of ADHD in Young Adults with an Assessment of Associated Functional Outcomes

A Phase II, 9-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Finding Study to Evaluate the Efficacy and Safety of XXX as Treatment for Adults With Attention-Deficit/ Hyperactivity Disorder

A 9-Week, Randomized, Double-Blind, Placebo-Controlled, Flexible-Dosage (up to 425 mg/day), Parallel-Group Study to Evaluate the Efficacy and Safety of XXX (Film-Coated Tablet) in Children and Adolescents with Attention-Deficit/Hyperactivity Disorder and its extension study

A Phase IV, Efficacy and Safety of Once-Daily XXX in Adults with ADHD over an Extended Period of Time (6 months): with a Brief Evaluation of Executive Cognition

A Phase III, Randomized, Double-Blind, Multi-Center, Parallel-Group, Placebo-Controlled Safety and Efficacy Study of XXX in Children and Adolescents Aged 6-17 with Attention Deficit Hyperactivity Disorder (ADHD)

A Phase II, Open-Label Co-Administration Study of XXX and Psychostimulants in Children and Adolescents Aged 6-17 with Attention-Deficit Hyperactivity Disorder (ADHD)

A Phase III, Randomized, Double-blind, Multi-center, Placebo-controlled, Parallel-Group, Safety and Efficacy Study of XXX with an Open-label Extension in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Randomized, Double-Blind, Multi-Center, Parallel-Group, Placebo-Controlled, Dose Optimization Study, Designed to Evaluate the Safety and Efficacy of XXX vs. XXX® in Pediatric patients aged 6-12 with Attention-Deficit/Hyperactivity Disorder (ADHD)

A Phase III, Randomized, Double-blind, Multi-center, Placebo-controlled, Parallel-Group, Safety and Efficacy Study of XXX with an Open-label Extension in Adolescents with Attention-Deficit Hyperactivity Disorder (ADHD)

A Phase III, Multi-Center, Open-label Study of XXX® in Pediatric Patients aged 6-13 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 and Placebo in Adult Outpatients with DSM-IV Attention Deficit/Hyperactivity Disorder

A 5-Week Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Fixed-Dose Study of the Efficacy and Safety of XXX ™ LA (XXX Extended-Release Capsules) Administered Once Daily in Adults with Attention-Deficit/Hyperactivity Disorder and it's extension study

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, Randomized, Multi-Center, Double-Blind, Parallel-Group, Placebo-Controlled Safety and Efficacy Study of XXX ® with an Open-label Extension, in the Treatment of Adolescents Aged 13-17 with Attention Deficit Hyperactivity Disorder (ADHD)

A Phase III, Randomized, Multi-Center, Double-Blind, Parallel-Group, Placebo-Controlled Safety and Efficacy Study of XXX ® with an Open-label Extension, in the Treatment of Adolescents Aged 13-17 with Attention Deficit Hyperactivity Disorder (ADHD) and its extension study

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of XXX in Adults with Attention Deficit Hyperactivity Disorder and its extension study

A Phase III, Open-Label Safety and Efficacy Study of XXX 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, Randomized, Double-Blind Comparison of Placebo and XXX in Adult Outpatients with DSM-IV Attention Deficit Hyperactivity Disorder

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

Alzheimer's Disease

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

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

A Phase II, randomized, double-dummy, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of XXX for the treatment of symptoms of agitation in patients with Alzheimer's disease

A Phase II, 12 Week, Randomized, Double-Blind, Placebo-Controlled, Multi-Center 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

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

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

Anxiety

A Phase III, Randomized, Double-Blind, Parallel Group, 10-Week Placebo-Controlled Fixed Dose Study of XXX and XXX evaluating the Efficacy and Safety of XXX for the Treatment of Generalized Anxiety Disorder

A Phase III, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Study of the Efficacy and Safety of XXX Compared with Placebo as an Adjunct to Treatment in Patients with Generalized Anxiety Disorder Who Demonstrate Partial or No Response to a Selective Seratonin Reuptake Inhibitor or Seratonin-Norepinephrin Reuptake Inhibitor Alone or in Combinator with a Benzodiazapine

A Phase III, 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 12-Month, Open-Label, Flexible-Dosage Study to Evaluate the Efficacy and Safety of XXX® Treatment (up to 16 mg/day in the Treatment of Adults with 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 and its extension study

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

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

XXX Versus Placebo in Patients with Generalized Anxiety Disorder Who Have Responded to Treatment with XXX

A Phase III, 7 Month, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Comparison of 150-300mg/Day of Extended Release XXX and Placebo for the Prevention of Seasonal Affective Disorder in Subjects with a History of Seasonal Affective 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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Placebo-Controlled, Flexible Dosage Trial to Evaluate the Efficacy and Tolerability of XXX in Patients with Generalized 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

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

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

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

A Double-Blind, Fixed-Dose, Multi-Center Study Comparing XXX (4 & 8 Mg. Daily) to XXX (25mg/day) and Placebo in Patients with Generalized Anxiety Disorder

XXX Extended Release in the Treatment of Anxiety

XXX Study, Anxiety Research University of Pennsylvania

XXX and XXX in Outpatients with Generalized Anxiety Disorder

XXX Laboratories, XXX Study, Anxiety Research, University of Pennsylvania

XXX Laboratories, XXX Study, Anxiety Investigational Research, University of Pennsylvania

XXX Anxiety Study with XXX University of Pennsylvania

XXX Anxiety Study XXX

XXX Anxiety Study with XXX

Bipolar Disorder

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

A Phase IIIb, Double-Blind, Placebo-Controlled, Randomized Withdrawal, Multicenter Clinical Trial Evaluating the Efficacy, Safety, and Tolerability of XXX in a Dose-Reduction Paradigm in the Prevention of Relapse in Bipolar I Disorder Patients whose Current or Most Recent Episode is Manic, With or Without Mixed Features

A Multicenter, Open-label Trial to Evaluate the Safety and Tolerability of XXX in the Treatment of Subjects with Bipolar I Disorder

A Multicenter, Randomized, Double-blind Trial of XXX versus Placebo for the Acute Treatment of Subjects Manic Episodes, With or Without Mixed Features, Associated With Bipolar I Disorder

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

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

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

A Phase III, Randomized, 6-Week, Double-Blind, Placebo-Controlled, Flexible-Dose, Parallel-Group Study of XXX Adjunctive to Lithium or Divalproex for the treatment of Bipolar I Depression

A Phase III, Randomized, 6-Week, Double-Blind, Placebo-Controlled, Fixed-Flexible Dose, Parallel-Group Study of XXX for the treatment of Bipolar I Depression

A Phase III, 24-Week, Flexible-Dose, Open-Label Extension study of XXX for the treatment of Bipolar I Depression

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Six-Week, Double-Blind, Multicenter, Placebo-Controlled Study Evaluating the Efficacy and Safety of Flexible Doses of XXX as Add-on, Adjunctive therapy with Lithium, Valproate or Lamotrigine in Bipolar I Depression

Controlled Trial of Safety and Efficacy of XXX Versus Placebo in Patients with Bipolar Depression

Controlled Trial of XXX versus Placebo in Patients with Bipolar Disorder in Manic or Mixed States

A Phase III, Six-Week, Randomized, Double-Blind, Multicenter, Fixed-Flexible Dose, Placebo-Controlled Study Evaluating the Efficacy and Safety of Oral XXX in Outpatients with Bipolar I Depression

A Phase IV, double-blind placebo-controlled trial of XXX and XXX in bipolar I disorder, mixed episode

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

A Phase III, 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

An International, Multi-centre, Double-blind, Randomized, Parallel-group, Placebo-controlled, Phase III Study of the Efficacy and Safety of XXX and XXX as Monotherapy in Adult Patients with Bipolar Depression for 8 weeks and XXX in Continuation Treatment for 26 up to 52 weeks

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

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

A Phase III, Multi-Center, Randomized, Parallel-group, Double-blind, Phase Ill Comparison of the Efficacy and Safety of 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 Phase III, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of XXX in the Treatment of Patients with Bipolar I Disorder with a Major Depressive Episode

A Phase III, Multi-Center, Double-Blind, Placebo-Controlled, Fixed-Dose, 8-Week Evaluation of the Efficacy and Safety of XXX in the Treatment of Major Depression in Patients with Type II Bipolar Disorder

A Phase III, 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

A Phase IV, 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

A Phase III, Multi-Center, Double-blind, Randomized, Placebo-controlled, Double-Dummy Trial of the Use of XXX in the Treatment of Patients with Bipolar Depression

XXX versus Placebo as Add-On Treatement 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

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

Depression

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

A Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study Evaluating the Efficacy of XXX in the Treatment of Adult Subjects with Major Depressive Disorder

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

A Phase III, Randomized, Double-Blind Study Comparing the Efficacy and Safety of XXX Plus Sertraline Versus Placebo Plus Sertraline in Adults With Major Depressive Disorder

A Phase III Randomized, Double-Blind, Placebo-controlled Study Evaluating the Efficacy and Safety of XXX in the Treatment of Adults with Severe Postpartum Depression

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

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

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multicenter, Double-blind, Randomized, Placebo-controlled Study Evaluating the Efficacy of XXX in the Treatment of Adult Subjects with Major Depressive Disorder

A Phase III, Double-blind, Placebo-controlled Study of XXX as an Adjunct to Antidepressants in the Treatment of Patients with Major Depressive Disorder who have had an Inadequate Response to Antidepressants Alone

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy, Safety, and Tolerability of XXX as Adjunctive Therapy in the Maintenance Treatment of Adults With Major Depressive Disorder.

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

A Phase IIa, Multicenter, Randomized, Double-Blind, Placebo-Controlled, 3-Arm Trial to Assess the Safety and Tolerability of a 7-Day Dosing with XXX 25 mg QD and 50 mg QD as Adjunctive Therapy in the Treatment of Patients Diagnosed with Major Depressive Disorder

A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter Study of XXX as Monotherapy in Patients with Major Depressive Disorder

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

A Phase IIb, Randomized, Double-Blind, Parallel-Group, Placebo Controlled Study to Evaluate the Efficacy and Safety of 2 Fixed Doses (5.0 mg or 2.5 mg) of XXX in Adult Patients with Major Depressive Disorder

A Phase IIIb, Efficacy and Safety Study of Adjunctive XXX in Treatment Refractory Major Depressive Disorder

A Phase II, Two-Part (Open-Label Followed by Double-Blind) Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of XXX in the Treatment of Adult Subjects With Moderate to Severe Major Depressive Disorder

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

A Phase II Randomized, Double-Blind, Placebo-Controlled Study of Intermittent Doses of XXX in the Treatment of Subjects with Severe Depression despite Antidepressant Treatment

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Placebo-Controlled, Phase IV, Relapse Prevention Study Evaluating the Efficacy and Safety of XXX (5, 10 and 20 mg) in Adults With Major Depressive Disorder

A Phase II, Multicenter, Randomized, Double-blind, Placebo controlled, Study to Evaluate the Efficacy and Safety of Adjunctive XXX in Major Depressive Disorder

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

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

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

A Phase III, Randomized, Double-blind, Active-controlled Trial to Assess the Efficacy and Safety of XXX Administered Orally to Subjects with Treatment Resistant Major Depressive Disorder

A Phase III, Interventional, Randomised, Double-blind, Parallel-group, Placebo-controlled, Fixed-dose Study to Evaluate the Efficacy and Safety of (1 and 3mg/day) as Adjunctive Treatment in Elderly Patients with Major Depressive Disorder with an Inadequate Response to Antidepressant Treatment

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

A Phase III, 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 Phase II, 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 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 Phase III, double-blind, efficacy and safety study of XXX versus placebo in the treatment of children and adolescents with Major Depressive Disorder

A Phase III, Long-Term, Open-label Extension Study of XXX in Adult Patients with Major Depressive Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

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

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

A Phase III, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Active-Referenced, Fixed- Dose Study Comparing the Efficacy and Safety of 2 Doses of XXX in Acute Treatment of Adults With Major Depressive Disorder with an extension study

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

A Double-Blind, Placebo-Controlled Study of XXX in Combination with XXX in 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 III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, XXX-Referenced, Parallel-Group Study to Evaluate the Efficacy and Safety of 2 Fixed Doses of XXX In Adult Outpatients with Major Depressive Disorder

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

A Phase III, 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 Phase III, Multi-Center, Randomized, 24-52-Week, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety and Tolerability of X100 mg 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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

A Phase III, Eight Week, Double-Blind, Placebo controlled, Multicenter study with XXX as positive control, evaluating the efficacy, safety, tolerability of a fixed dose of XXX in outpatients with Major Depressive Disorder

XXX as an Antidepressant Augmentation Agent in Treatment Refractory Unipolar Depression

A Phase III, 10-Month Open-Label Evaluation of the Long-Term Safety of XXX in Outpatients with Major Depressive Disorder

A Phase III, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Study of a Flexible Dose of XXX in Adult Outpatients with Major Depressive Disorder

A Phase IV, Comparison of XXX Dosing Strategies in the Treatment of Patients with Major Depression

An Open Label Pilot Study to Evaluate the Safety and Efficacy of XXX Titrated to 8mg Nightly, in Conjunction with XXX 20mg or XXX 10mg, in Patients with Insomnia Associated with Mild to Moderate Depression

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

A Phase III, XXX Versus Placebo in the Treatment of Elderly Patients with Major Depressive Disorder

A Phase IV, XXX Versus XXX Extended Release in the Treatment of Major Depressive Disorder

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

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

A Phase III, Depression Response to XXX in Adults With Major Depressive Disorder: 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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multi-Center, 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 and its extension study

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

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of 8 weeks of Oral XXX I° (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 Phase III, Double-Blind, Multi-Center 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

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

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

An Open-Label Pilot Study to Evaluate the Safety and Efficacy of XXX Titrated to 200mg, in Patients with Mild to Moderate Depression with Attendant Symptoms of Fatigue within a Primary Care Setting

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

A Phase III, XXX Once-Daily Dosing Versus Placebo in Patients with Major Depression and Pain

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, 8-Week, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Multi-Center, 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 Flexible Dose Comparison of the Safety and Efficacy of XXX and Placebo in the Treatment of Major Depressive Disorder and its extension study

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

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

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

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

Continuation Treatment with Once-Weekly Modified-Release XXX in Major Depressive Disorder

A Double-Blind, Randomized, Placebo and XXX-Controlled, Multi-Center, Dose-Finding Trial with XXX in Out-Patients with Moderate to Severe 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

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

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

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

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

XXX plus XXX Combination Therapy in Treatment Resistant Depression: A Dose-Ranging Study

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

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

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

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

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

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

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

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

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

Elderly Extension XXX Open-Label Treatment of Depression

XXX Study, Depression Research University of Pennsylvania

XXX Extended Release, Depression Study University of Pennsylvania

XXX Study, Depression in the Elderly Research University of Pennsylvania

XXX Study, Depression Research University of Pennsylvania

XXX Depression Study University of Pennsylvania

CLINICAL TRIAL EXPERIENCE (*continued*):

Fibromyalgia

A Phase IIa, Randomized, Double-Blind Placebo-controlled, Parallel-group Study to Assess the Analgesic Efficacy and Safety of XXX in Patients with Fibromyalgia

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

Migraine

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

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

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

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

A Phase II/III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy, Safety, and Tolerability of Multiple Dosing Regimens of Oral XXX in Episodic Migraine Prevention

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

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

A Phase III, Parallel Group, Double-Blind, Randomized, Placebo Controlled, Phase 3 Trial to Evaluate the Efficacy, and Safety, of XXX Administered Intravenously in Patients with Chronic Migraine

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Efficacy, Tolerability and Safety Study of XXX in Episodic Migraine with or Without Aura

CLINICAL TRIAL EXPERIENCE (*continued*):

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 Generalized Anxiety Disorder

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

A Randomized, Double-blind, Placebo-controlled Phase II Study of XXX in Adults with Post-Traumatic Stress Disorder (PTSD)

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

A Phase II, Multicenter, Randomized, Double-blind, Placebo- and Active-controlled Trial of XXX (1 - 3 mg/day) as Monotherapy or as Combination Therapy in the Treatment of Adults with Post Traumatic Stress Disorder (PTSD)

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

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose Study Evaluating the Efficacy and Safety of the Neurokinin-1 Receptor Antagonist XXX in Post-traumatic Stress Disorder (PTSD)

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 (PTSD) in Adults and its extension study

CLINICAL TRIAL EXPERIENCE (*continued*):

Schizophrenia

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

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

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

A Phase IIIb Multi-Center, Open-Label, Mirror-Image, Trial in Adult Subjects with Schizophrenia Treated Prospectively for 6-months with XXX

A Phase II/III, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-arm Study to Assess the Efficacy, Safety, and Tolerability of XXX for the Treatment of Negative Symptoms of Schizophrenia

A Phase II, Randomized, Double-blind, Multiple-dose, Placebo-controlled Study to Evaluate the Safety and Efficacy of XXX in Subjects with Cognitive Impairment Associated with Schizophrenia (CAIS)

A Phase IIIb Double-blind, Placebo-controlled, Randomized Withdrawal Multicenter Clinical Trial Evaluating the Efficacy, Safety, and Tolerability of XXX in a Dose Reduction Paradigm in the Prevention of Relapse in Patients with Schizophrenia

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

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

A Phase IIb, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled Study, to Evaluate the Efficacy, Safety, and Tolerability of XXX as Adjunctive Treatment in Patients with Cognitive Impairment Associated with Schizophrenia Treated with Antipsychotics

A Phase III, Multicenter, Randomized, Double-blind, Parallel Group, Placebo-Controlled, Mono-Therapy, 12-Week Study to Evaluate the Efficacy and Safety of 2 Fixed Doses of XXX in Adult Patients with Negative Symptoms of Schizophrenia, Followed by 36-Week Open-Label Extension

A Phase IIIb, Multicenter, Randomized, Double-blind Study to Evaluate the Efficacy and Safety of XXX or XXX for the treatment of schizophrenia in subjects hospitalized for acute exacerbation

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

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

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

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

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

An Multi-center, Prospective, Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of XXX as an Add-on Treatment for Schizophrenia in Adults

A Phase IIa, prospective, randomized, double-blind, placebo-controlled, multiple-dose study designed to determine the safety, tolerability and preliminary efficacy of an oral dose range of XXX in patients with chronic schizophrenia not responding adequately to their current antipsychotic medication

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

A Randomized, Double-blind placebo-controlled study to evaluate the efficacy and safety of a low dose XXX in acutely psychotic subject with acute schizophrenia

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

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

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

A Phase III, 26 Week, Multicenter, Open Label, Extension Study of XXX in patients with Schizophrenia

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

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

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

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

A Phase II, Multi-center, Randomized, 4-week, Double-blind, Parallel Group, Placebo and Active-controlled Trial of the Safety and Efficacy of XXX vs. Placebo in Patients with an Acute Exacerbation of Schizophrenia

A Phase III, Multi-center, Randomized, 12-week, Double-blind, Parallel-group, Placebo-controlled Study to Evaluate Efficacy and Safety of XXX in Patients with Sub-optimally Controlled Symptoms of Schizophrenia Treated with Antipsychotics Followed by a 40-week Double-blind, Parallel-group, Placebo-controlled Treatment Period

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

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

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

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

A Phase III, Multi-center, Randomized, 24 Week, Double-blind, Parallel-group, Placebo-controlled Study to Evaluate Efficacy and Safety of XXX in Stable Patients With Persistent, Predominant Negative Symptoms of Schizophrenia Treated With Antipsychotics Followed by a 28 Week, Double-blind Treatment Period

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multi-center, Randomized, 12-week, Double-blind, Parallel-group, Placebo-controlled Study to Evaluate the Efficacy and Safety of XXX in Patients With Sub-optimally Controlled Symptoms of Schizophrenia Treated With Antipsychotics Followed by a 40-week Double-blind, Parallel-group, Placebo-controlled Treatment Period

A Phase II, Randomised Double-blind, Placebo Controlled, Parallel Group Study to Evaluate the Cognitive Enhancing Effects of XXX in Stable Patients with Schizophrenia

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

A Phase II, 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 XXX as an active control, in the treatment of Acute Exacerbation of Schizophrenia

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 52-week, Multicenter, Open-label Study to Evaluate the Effectiveness of XXX as Maintenance Treatment in Patients with Schizophrenia

A Phase II, 6-Week, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Oral XXX Once Daily and XXX Once Daily for Treatment of Hospitalized Adult Patients with Acute Schizophrenia

A Phase II, Long-Term, Phase II, Multicenter, Randomized, Open-Label, Comparative Safety Study of XXX versus Atypical Antipsychotic Standard of Care in Patients with DSM-IV-TR Schizophrenia

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

A Phase II, Randomized, Double-blind, Placebo-controlled add-on Trial of the Safety and Efficacy of XXX in Outpatients on Select Atypical Antipsychotics With Prominent Negative or Disorganized Thought Symptoms

CLINICAL TRIAL EXPERIENCE (*continued*):

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

A Phase III, Randomized, Double-Blind, Parallel-group, Flexible-dose Study Exploring the Neurocognitive effect of XXX versus XXX in patients with schizophrenia using the MATRICS Consensus Cognitive Battery (MCCB).

A Phase II, 24-Week, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dosage Study to Evaluate the Efficacy and Safety of (150, 200, and 250 mg/ Day) XXX as Adjunctive Therapy in Adults With Schizophrenia

A Multi-Center Cardiac Safety Study Of Subjects Who Participated In XXX Sponsored Phase I And Phase II Completed And Discontinued Trials With XXX (Protocols: XXX)

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 Phase II, 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 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

Comparison of the Test-Retest Reliabilities in the CDR versus MATRICS Cognitive Batteries in Patients with Schizophrenia

A Phase IV, 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 XXX or XXX Monotherapy

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

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 Phase II, 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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Randomized, Double-blind, Placebo- and Active-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 Phase III, Randomized, Open-Label Study Comparing the Effects of XXX Depot with Oral XXX on Treatment Outcomes in Outpatients with Schizophrenia

A Multicenter, Randomized, Double-blind, Fixed-dose, Efficacy and Safety Trial of XXX vs. Placebo as Augmentation Therapy in Schizophrenic Subjects Currently Receiving XXX (2 or 3 mg b.i.d.)

A Phase III, 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 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 Phase IV, Randomized Double-Blind Study of XXX versus XXX in the Treatment of Schizophrenia

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

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

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multi-Center, Double–Bind, Placebo-Cntrolled, 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-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 Phase III, 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 Phase III, 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 Study of Two Doses of XXX as an Adjunctive Treatment to XXX in Male Outpatients with Schizophrenia and Associated Cognitive Deficits

A Phase II, 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, Dose-Response Study of XXX in Subjects with Schizophrenia who have Predominantly Negative Symptoms

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

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

A Phase II, 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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

An Outpatient Open-Label Comparison of the Neurocognitive effects of XXX or XXX 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

Other Indications

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

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

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

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

A Phase IV, Randomized, Double-blind, Placebo-controlled, Clinical trial of Structured Opioid Discontinuation versus Continued Opioid Therapy in Suboptimal and Optimal Responders to High-dose Long-term Opioid Analgesic Therapy for Chronic Pain

A Randomized, Double-blind, Dose-finding Study to Evaluate the Change in Weight After 24 Weeks Treatment With 8 Doses of XXX Compared to Placebo in Obese or Overweight Adults, Followed by 24 Weeks Treatment With 2 Doses of XXX and Placebo

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

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Single Dose, 52-week study to evaluate the safety and efficacy of intra-articular injections of study medication in subjects with chronic, moderate to severe osteoarthritis knee pain

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Intravaginal XXX Against Sexual Dysfunction which Study is described in the Protocol XXX

XXX device study to evaluate new oral fluid collection device to be used in drug screen tests

A Phase II, Two-Part Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Efficacy of XXX Oral Solution in Patients with Parkinson's Disease (PD) of Moderate Severity Responding to immediate release oral Levodopa/Carbidopa and Withdrawn from Levodopa/ Carbidopa

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

A Phase II, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multiple-Dose Study to Assess the Efficacy and Safety of XXX in Subjects with Neuropathic Pain Associated with Diabetic Peripheral Neuropathy

A Phase IIa, Randomized, Open-label, Parallel, Study to Determine the Tolerability, Pharmacokinetics, and Efficacy of XXX in Subjects with Crohn's disease experiencing Abdominal Pain

A Phase IIa, Multicenter, Randomized, Double-blind, Placebo-controlled and Active-controlled, Parallel-group Study Evaluating the Analgesic Efficacy and Safety of XXX in Subjects with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee

A One-Month, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Active Comparator, Parallel-Group Study of the Efficacy and Safety of XXX in Subjects 55 Years and Older with Insomnia Disorder

A Phase IIa, Double-Blind, Randomized, Placebo-controlled, Exploratory Study to Evaluate the Safety, Biological Activity and Pharmacokinetics of XXX in Adult Patients With Moderate-to-Severe Atopic Dermatitis

A Phase III, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Dose-optimization Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in Adults Aged 18-55 Years With Moderate to Severe Binge Eating Disorder

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 Phase IV, non-treatment follow-up for a cardiac assessment following use of smoking cessation treatment in subjects with and without a history of psychiatric disorders

CLINICAL TRIAL EXPERIENCE (*continued*):

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

A Phase IIa, 12 week multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group study to assess the safety and tolerability of Oral XXXX in Patients with Parkinson's Disease

A Phase II, Randomized, Multi-Center, Double-Blind, Parallel-group Trial To Assess the Analgesic Efficacy and Safety of a New Analgesic Compared with Placebo in Subjects with Painful Diabetic Peripheral Neuropathy

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

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

An Open-Label Study To Evaluate The Safety Of Topically Applied XXX Ointment For The Treatment Of Atopic Dermatitis

A Randomized, Double-Blind, Multi-Center Comparison of the Efficacy and Safety of XXX 400mg or 600mg once daily and XXX 500mg twice daily in the Treatment of Patients with Acute Bacterial Exacerbations of Treatment of Patients with Acute Bronchitis

Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial Consisting of a Double-Blinded First-Line Anti-Hypertensive Drug with XXX, XXX, XXX, or XXX and an Open-Labeled Second- and Third-Line Anti-Hypertensive Drug with XXX, XXX, XXX, or XXX along with a Lipid Lowering Component of Pravastatin vs. Usual Care

A Randomized, Double-Blind, Double-Dummy, Multi-Center, Parallel-Group Study to Asses the Efficacy and Safety of XXX, 320mg Oral Dose Once a Day for 7 or 14 Days Compared with XXX, 200mg Oral Dose Once a Day for 7 or 14 Days in the Treatment of Bacterial Community Acquired Pneumonia

A Phase III, Randomized, Double-Blind Comparative Safety and Efficacy of XXX and XXX in the Treatment of Patients with Uncomplicated Skin or Skin Structure infection

A Randomized Investigator-Blinded Active-Controlled, Parallel-Group Phase III Study Comparative Safety and Efficacy of XXX and XXX in the treatment of Patients with Acute Bacterial Sinusitis

CLINICAL TRIAL EXPERIENCE (*continued*):

A Double-Blind, Randomized, Placebo-Controlled Trial of XXX in the Treatment of Picornavirus Respiratory Tract Disease

A Multi-Center, Double-Blind, Placebo-Controlled Trial for Safety and Efficacy Evaluation of XXX in the Treatment of Viral Syndrome

Oral XXX Compared with XXX, XXX, and Benign Gastric Ulcer

XXX vs. XXX Uncomplicated Urinary Tract Infection

XXX vs. XXX in Uncomplicated Urinary Tract Infections

Open Multi-Center Trial of XXX in the Treatment of Elderly Patients with Mood Disorders

Double-Blind Active-Controlled Efficacy Study of XXX in patients with Acute Bacterial Exacerbations of Chronic Bronchitis

Randomized Parallel Comparative Study of the Clinical Effectiveness of Two Nit Combs after Treatment with a XXX-Based Pediculicide

XXX Extend Tabs vs. XXX , Allergic Rhinitis Study

Insomnia Treatment Study Comparing XXX and XXX

Safety and Efficacy of XXX Vaginal Cream (SB) Compared with XXX Vaginal Cream (Monistat 7) and Placebo in the Treatment of Vulvovaginal Candidiasis

Double-Blind Active-Controlled Efficacy Study of XXX- Inpatients with Community Acquired Pneumonia

Cheviak Bigasdh Syndrome Study Independently conducted

POST GRADUATE TRAINING:

1982 - 1994 Ongoing Clinical Research Training Instructor (5 years)
Collaborated with Karl Rickels, M.D. Chairman of the Department of Psychiatry and President of the Private Practice Research Group
Department of Psychiatry, University of Pennsylvania

1981 - 1984 W. George Case, M.D., Director
1240 Hours of Training in the Conduct of Clinical Research
University of Pennsylvania

AWARDS AND HONORS:

2007	Howard Hassman, DO & Cheryl Hassman Devereux Leadership Award
1996	Entrepreneur of the Year Award, Ernst & Young
1996	Outstanding Efforts in the Healthcare Community The City of San Diego, Susan Golding, Mayor
1995	San Diego Press Club, Headliner
1982	American College of General Practitioners - Osteopathic Medicine and Surgery Preceptor Program
1980 - 1983	Philadelphia College of Osteopathic Medicine Lambda Omicron Gamma, National Medical Fraternity Award for Outstanding Leadership (three-time recipient)

ADVISORY BOARDS:

2007 - Present	Our Lady of Lourdes Hospital Institutional Review Board
2006 - Present	AstraZeneca Seroquel Global Advisory Board
2003 - Present	DOV Pharmaceuticals Advisory Board for General Anxiety Disorder and Depression
2003 - Present	Cephalon Inc. Advisory Committee for General Anxiety Disorder
2002 - 2003	Novartis Clinical Expert Advisory Board for Adult ADHD Study
2001 - 2003	Scientific Advisory Group of Organon, Inc. for The New Treatment Option for the Mature Depressed Patient, presenter of Patient Trial Program The Plaza Hotel, New York, NY March 24, 2001
2001 - 2002	Scientific Advisory Group of Organon, Inc. for The New Treatment Option for the Mature Depressed Patient, presenter of Patient Trial Program New York Hilton, New York, NY March 25, 2001
2000 - 2003	Eli Lilly and Company Advisory Board on Tomoxetine for ADD and ADHD Pediatrics, Adolescents, and Adults
1999 - Present	Forest Laboratories Advisory Board for Geriatric Study
1999 - 2000	Eli Lilly and Company Advisory Board on Tomoxetine for ADD and ADHD Pediatrics, Adolescents, and Adults
1999 - Present	Eli Lilly and Company Advisory Board for Pediatric, Adolescent, and Adult ADHD

PROFESSIONAL AFFILIATIONS, SOCIETIES AND MEMBERSHIPS:

2007 - 2014	CRI Worldwide, LLC. Board of Directors
2007 - Present	The International Society for CNS Clinical Trials and Methodology (ISCTM)
2007 - Present	American Society for Clinical Pharmacology and Therapeutics
2007 - Present	International Congress on Schizophrenia Research
2006 - Present	American College of Clinical Pharmacology
2004 - 2009	Gerson Lehrman Group's Council of Healthcare Advisors
2003 - Present	American Medical Association Carol Stream, IL

PROFESSIONAL AFFILIATIONS, SOCIETIES AND MEMBERSHIPS:

2003 - Present	American Academy of Sleep Medicine Westchester, IL
2003 - Present	Associated Professional Sleep Society Westchester, IL
2000 - 2001	Advisory Board for Eli Lilly on Tomoxetine for ADD and ADHD Pediatrics, Adolescence, and Adults
1999 - Present	Forest Laboratories Advisory Board for Geriatric Study
1999 - Present	Member, Lilly Advisory Board on ADHD
1997 - 1998	California Board for Devereux California
1994 - 1997	Fellow, American Academy of Disability Evaluative Physicians
1993 - 1998	Qualified Medical Evaluator by Department of Industrial Relations Industrial Medical Council
1991 - 1997	Appointed Instructor of Department of Psychiatry University of Pennsylvania
1991	Appointed Member of San Diego Advisory Committee for State Insurance Commissioner, John Garamendi
1989 - 1997	Alvarado Hospital Medical Center, San Diego, California Supervisor of Surgery Committee
1987 - 1996	College of Osteopathic Medicine Faculty Council Member
1986 - 1987	Alvarado Hospital Medical Center, San Diego, California Family Practice Supervisory Committee Supervisor of Orthopedic Committee
1986 - 1987	The Prudential Insurance Company, La Jolla, California Assistant Medical Director
1986 - 1987	Alvarado Medical Center Utilization Review Committee
1986 - 1987	Alvarado Medical Center, Family Practice Sub-Supervisory Committee (1987-1988)
1986 - 1987	Alvarado Medical Center Orthopedics Committee (also appointed 1987-88)
1985 - 1987	Associate Medical Director Pru-Care Plus, San Diego, CA
1984 - 1995	Philadelphia College of Osteopathic Medicine Faculty Council Member
1984 - 1995	Pacific College of Osteopathic Medicine Faculty Council Member
1984 - Present	American Osteopathic Association of Osteopathic Physicians and Surgeons of CA
1983	American Heart Association
1983	New Jersey Association of Osteopathic Physicians and Surgeons
1982 - Present	Osteopathic Physicians and Surgeons of New Jersey
1979	American College of General Practitioners in Osteopathic Medicine and Surgery
1979	Philadelphia College of Osteopathic Medicine, Alumni Association

PROFESSIONAL AFFILIATIONS, SOCIETIES AND MEMBERSHIPS:

1979	Lambda Omicron Gamma National Osteopathic Medical Fraternity
1979 - Present	Pennsylvania Osteopathic Association

PUBLISHED BOOKS:

1999 *Alternative Treatments for Common Conditions,* St. Louis: Quality Medical Publishing, Inc. 1999 Copyright by Quality Medical Publishing, printed in the USA.

PUBLISHED ARTICLES:

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

2017 *Press Release* Milan, Italy and Morristown, NJ, USA, March 25, 2017 "Evenamide met study objectives of good tolerability, safety, and preliminary evidence of efficacy as an add-on therapy for the treatment of schizophrenia Unique mechanism: glutamate modulation and voltage-gated sodium channel blockade"

2013 Coauthor for article: "Development of a clinical global impression scale for fatigue" *Journal of Psychiatric Research*, January 2012, Steven D. Targum, Howard Hassman, Maria Pinho, Maurizio Fava

2012 *Journal of Psychiatric Research* "Development of a clinical global impression scale for fatigue" Steven D. Targum, Howard Hassman, Maria Pinho, Maurizio Fava

2007 *The Journal of Clinical Psychiatry,* "Cognitive Functioning and Acute Sedative Effects of Risperidone and Quetiapine in Patients with Stable Bipolar I Disorder: A Randomized, Double-Blind, Crossover Study"

PUBLISHED ARTICLES (*continued*):

2005 *American Journal of Psychiatry,* Vol.162, No.7, pp.1351-1360, July 2005 "A Randomized, Double-Blind, Placebo-Controlled Trial of Quetiapine in the Treatment of Bipolar I or II Depression," The BOLDER Study Group including Howard A. Hassman, D.O.; along with Joseph R. Calabrese, M.D.; Paul E. Keck Jr., M.D.; Wayne MacFadden, M.D.; Margaret Minkwitz, Ph.D.; Terrence A. Ketter, M.D.; Richard H. Weisler, M.D.; Andrew J. Cutler, M.D.; Robin McCoy, R.N.; Willis Wilson, M.S.; Jamie Mullen, M.D.

2004 *The Journal of Clinical Psychiatry*, Vol. 65, No.3, pp. 414-420, 2004 "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," Howard A. Hassman, D.O.; Philip T. Ninan, M.D.; Steven J. Glass, M.D.; Frank C. McManus, Ph.D.

2002 "Multi-site, Open Label, Observational Study of the Effectiveness and Safety of Remeron® SolTabTM (mirtazapine orally disintegrating tablets in depressed patients who are at Least 50 Years of Age," Howard A. Hassman, D.O.; Steven P. Roose, M.D.; Peter J. Holland, M.D.; Murray Rosenthal, D.O.; Heidi E. Rodrigues.

2000 "Comparative Study of the Clinical Effectiveness of a Pyrethrin-Based Pediculicide with Combining versus a Permethrin-Based Pediculide with Combing"

2000 "Pleconaril Treatment Shortens Duration of Picornavirus Respiratory Illness in Adults," H.A. Hassman; F.G. Hayden; T. Coats; R. Menedez; T. Bock; The Pleconaril Respiratory Infection Study Group

1998 Clinical Pediatrics "Comparative Study of the Clinical Effectiveness of a Pyrethrin-Based Pediculicide with Combining Versus a Permethrin-Based Pediculicide," H. A. Hassman, D.O.; Bainbridge, Ph.D.; G.L. Klein, M.D.; S.I. Neibart, M.D.; K. Ellis, D.O.; D. Manring, M.D.; R. Goodyear, R.N.C.; J. Newman, M.D.; S. Micik, M.D.; F. Hoehler, Ph.D.; P. Walicke, M.D.

1998 *The Journal of Clinical Psychiatry,* "Buspirone and Imipramine for Treatment of Major Depression in the Elderly," Howard A. Hassman, D.O.; Edward Schweizer, M.D.; Karl Rickels, M.D.; Felipe Garcia-Espana, Ph.D.

1993 *Archives of General Psychiatry,* "Antidepressants for the Treatment of Generalized Anxiety Disorder: A Placebo-Controlled Comparison of Imipramine, Trazodone and Diazepam," Howard A. Hassman D.O.; Karl Rickels, M.D.; Robert Downing, Ph.D.; Schwizer, M.D.

PUBLISHED ARTICLES (*continued*):

1991 *European Journal Pharmacopsychiatry,* "Adinazolam, Diazepam, Imipramine and Placebo in Major Depressive Disorder, a Controlled Study," H. Hassman; K. Rickels; J. London; Ira Fox; Irma Csanalosi; Ch. Weise; The Psychopharmacology Research and Treatment of Unit and the Private Practice Research Group, Department of Psychiatry and The University of Pennsylvania.

2015 Data Compilation of A New Depression Rating Scale, the Rosenberg-Hassman Mood Scale (RHMS); A Patient-Reported Outcome (PRO) Presented: American Psychiatric Association, Philadelphia, PA, 2012

CLINICAL ABSTRACTS:

2012 A New Depression Rating Scale, the Rosenberg-Hassman Mood Scale (RHMS); A Patient-Reported Outcome (PRO)
Presented: American Psychiatric Association, Philadelphia, PA, 2012

2012 The Effect of Pharmacokinetic Parameters on Euphoria, Drug Liking Following Different Oral Hydromorphone Formulations in Opioid-Experienced, Non-dependent, Recreational Drug Users
Presented at: European Congress of Psychiatry (EPA) , Prague, Czech Republic

2012 Validation of a Global Assessment Measure for Fatigue
Abstract accepted: European Congress of Psychiatry (EPA), Prague, Czech Republic

2012 The Effect of Pharmacokinetic Parameters on Euphoria, Drug Liking Following Different Oral Hydromorphone Formulations in Opioid-Experienced, Non-dependent, Recreational Drug Users
Abstract Accepted: Society of Biological Psychiatry, Philadelphia, PA, May 3, 2012

2012 Validation of a Global Assessment Measure for Fatigue
Abstract Accepted: Society of Biological Psychiatry, Philadelphia, PA, May 3, 2012

2012 The Effect of Pharmacokinetic Parameters on Euphoria, Drug Liking Following Different Oral Hydromorphone Formulations in Opioid-Experienced, Non-dependent, Recreational Drug Users
Abstract Accepted: ISCTM, Washington DC, February 2012

2010 Patient Acceptance of Remote Rating Strategies in CNS Trials

CLINICAL ABSTRACTS (*continued*):

2010 Implications of the Cognitive Deficit Profile in Schizophrenia for Therapeutic Strategies

2009 Examining Patient Validity for Clinical Trials- A Post-hoc Analysis of Placebo Responders.

2005 Cognitive Function and Acute Sedative Effects of Risperidone and Quetiapine in Patients with Stable Bipolar I Disorder: A Randomized, Double-blind, Crossover Study

2004 Quetiapine Reduces Persistent Anxiety in Patients with Major Depressive Disorder

2004 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

2003 Modafinil Combined with Selective Serotonin Reuptake Inhibitor at Treatment Initiation Enhances the Rate and Degree of Benefit in Major Depressive Disorder

2001 American Rosuvastatin Trialists Group — Long-Term Efficacy and Safety of Rosuvastatin: Results of a 52-Week Comparator-Controlled Trial Versus Pravastatin and Simvastatin

1998 Hoechst Marion Roussel — A Double-Blind, Multi-Center, Randomized, Active-Controlled, Two-Arm, Parallel-Group Comparative Study of the Efficacy and Safety of Oral HMR3647 Versus Oral Clarithromycin in the Treatment of Community Acquired Pneumonia in Adults

POSTERS:

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

POSTERS (*continued*):

2020 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.

2020 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.

2020 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.

2019 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.

2018 Cohen, E. A., Hassman, H. H., Walling, D. P., Hoover, S., Wyka, K., Ball, R. R., Joseph, A. V., Lobb, J. M., Hazzard-Randolph, D., Ereshefsky, L. (2018, November). A first-time investigation of a subject intervention to reduce the placebo and nocebo effects: A multicenter, randomized, single-blind, all placebo study of a Placebo-Control Reminder Script for subjects with Major Depression. Poster presented at the Annual Meeting of the CNS Summit Conference, Boca Raton, FL.

2018 Hassman, H., Cohen, E.A., Ball, R.R., Joseph, A.V., Wyka K., Lobb, J.M., & Ereshefsky, L., (2018, February). Can subjects with Major Depression learn about key placebo response factors? The effect of an educational placebo response video. Poster presented at the Annual Meeting of the International Society for CNS Clinical Trials and Methodology Conference, Washington, DC.

POSTERS (*continued*):

2017 Hassman, H., Cohen, E. A., Myers, K. A., Hossain, S. I, Joseph, A. V., & Lobb, J. M. (2017, November). The Power of an Educational Placebo Response Video: Strengthening Subject Placebo Response Awareness Across Demographic Variables and Diagnoses. Poster presented at the Annual Meeting of the CNS Summit, Boca Raton, FL.

2017 Hassman, H., Cohen, E., Hossain, S., Amerman, P.M., Joseph, A.V., & Myers, K.A., (2017, May). Enhancing subjects' awareness of key placebo response factors: The importance of implementing a brief educational placebo response video. Poster presented at the Annual American Society of Clinical Pharmacology, Miami, FL.

2013 Further Development of the Rosenberg Hassman Mood Scale (RHMS), a Patient-Reported Outcome (PRO) 2013 San Francisco

2012 Validation of a Global Assessment Measure for Fatigue Abstract Accepted: Society of Biological Psychiatry, Philadelphia, PA, May 3, 2012

2012 The Effect of Pharmacokinetic Parameters on Euphoria, Drug Liking Following Different Oral Hydromorphone Formulations in Opioid-Experienced, Non-dependent, Recreational Drug Users Abstract Accepted: Society of Biological Psychiatry, Philadelphia, PA, May 3, 2012

2012 Validation of a Global Assessment Measure for Fatigue Abstract accepted: European Congress of Psychiatry (EPA), Prague, Czech Republic, March 3, 2012

2012 The Effect of Pharmacokinetic Parameters on Euphoria, Drug Liking Following Different Oral Hydromorphone Formulations in Opioid-Experienced, Non-dependent, Recreational Drug Users Presented at: European Congress of Psychiatry (EPA) , Prague, Czech Republic, March 3, 2012

2011 Validation of a Global Assessment Measure for Fatigue Presented at: CNS Summit, November 18, 2011, Boca Raton, FL

2011 Validation of a Global Assessment Measure for Fatigue Presented at: NCDEU, June 2011, Boca Raton, FL

2011 The profile of cognitive impairment in schizophrenia: Implications for therapeutic strategies Presented at: Advancing Drug Discovery for Schizophrenia, March 9, 2011, NY, NY

2011 The Profile of Attentional Deficits in Schizophrenia: Implications for Pharmacotherapy Presented at: ISCTM, Washington DC, February 21, 2011

POSTERS (*continued*):

2010 The Profile of Attentional Deficits in Schizophrenia: Implications for Pharmacotherapy CNS Summit, Boca Raton, FL, November 2010

2010 The Implications of Cognitive Deficit Profile in Schizophrenia for Therapeutic Strategies Presented at ISCTM, Baltimore, MD, October 2010

2010 The Profile of Attentional Deficits in Schizophrenia: Implications for Pharmacotherapy Presented at ECNP, Amsterdam, The Netherlands, August 2010

2010 The Implications of Cognitive Deficit Profile in Schizophrenia for Therapeutic Strategies NCDEU, Boca Raton, FL, June 2010

2010 The Profile of Cognitive Impairment in Schizophrenia: Implications for Therapeutic Treatment Strategies Presented at the Schizophrenia International Research Society Congress (SIRS), April 10-14, 2010 in Florence, Italy

2010 Examining Patient Validity for Clinical Trials: A Post-hoc Analysis of Placebo Responders Presented at the Schizophrenia International Research Society Congress (SIRS), April 10-14, 2010 in Florence, Italy

2010 Pharmacokinetics and Pharmacodynamics of 18F-AV-45 (florbetapir F 18) PET Imaging in Alzheimer's Disease and Healthy Control Subjects: Results of a Phase II Trial: 18F-AV-45-A03 Presented at: Human Amyloid Imaging, Toronto, Canada, April 9

2010 Implications of the Cognitive Deficit Profile in Schizophrenia for Therapeutic Strategies

2009 Examining Patient Validity for Clinical Trials- A Post-hoc Analysis of Placebo Responders.

2008 A Comparison of the MATRICS consensus Cognitive Battery (MCCB) with Cognitive Drug Research (CDR) Presented at NCDEU 2008

2007 The Use of the CDR Computerized Schizophrenia Battery to Measure Cognitive Function in Schizophrenia Clinical Trials Hassman H, Krefetz DG, Kelly B, Satek S, Wesnes K, Ferguson J, Presented at NCDEU June 6, 2007

2006 Cognitive Function and Acute Sedative Effects of Risperidone and Quetiapine in Patients with Stable Bipolar I Disorder: A Randomized, Double-blind, Crossover Study presented at NCDEU, Boca Raton, Florida June 15

POSTERS (*continued*):

2005 Cognitive Function and Acute Sedative Effects of Risperidone and Quetiapine in Patients with Stable Bipolar I Disorder: A Randomized, Double-blind, Crossover Study Presented at NCDEU, Waikoloa, Hawaii, December 15

2005 An Open Label Pilot Study to Evaluate the Safety of GabitriltM (tiagabine hydrochloride) Titrated to 8mg Nightly, in Conjunction with Fluoxetine 20mg or Escitalopram 10mg, in Patients with Insomnia Associated with Mild to Moderate Depression Presented at NCDEU, Boca Raton, Florida June 4

2004 Quetiapine Reduces Persistent Anxiety in Patients With Major Depressive Disorder Presented at NCDEU, Phoenix, Arizona June 4

2004 Modafinil Combined With Selective Serotonin Reuptake Inhibitor at Treatment Initiation Enhances the Rate and Degree of Benefit in Major Depressive Disorder Presented at ECNP, Stockholm, Sweden, October 13

2000 Mirtazapine vs. Sertraline after SSRI Non-Response Presented at ECNP, Munich, Germany, September 13

PATENTS:

Hassman, "Compositions and methods for the treatment of depressive disorders through the administration of modafinil with antidepressants." *Abstract: Compositions and methods for treatment of depressive disorders through the administration of modafinil with antidepressants.* European Patent EP1628652, Publication Date: 01, Mar 2006

Hassman, "Analeptic and antidepressant combinations." *Abstract: Compositions and methods for the treatment of depressive disorders through the administration of modafinil with antidepressants.* United States Applications 20040229940, 20040229941, 20040229942, Publication Date: 18, Nov 2004