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Site Selection and Information:
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PROFESSIONAL AFFILIATIONS:

FutureSearch Clinical Trials of Neurology and Sleep Medicine, Austin, TX
Dallas County Medical Society
Depression and Bipolar Support Alliance
National Alliance for the Mentally Ill
Planned Living Assistance Network of North Texas, Board Member
Texas Medical Association
The Meadows Health and Rehabilitation Center

EDUCATION:

1990-1994 Chief Resident (1993-1994), Outstanding Resident Award 1994
University of Texas Southwestern Medical School at Dallas, Department of Psychiatry

1986-1990 Doctor of Medicine, Alpha Omega Alpha - National Medical School Honor Society
University of Texas Medical School At Houston

1982-1986 Pre-Medical Studies, Psi Chi - National Psychology Honor Society
Texas A&M University, College Station

CERTIFICATION:

Diplomate in Psychiatry, American Board of Psychiatry and Neurology

LICENSURE:

Texas Medical License No. J1082

CLINICAL RESEARCH EXPERIENCE:

Addiction • Alcohol Dependence • Alzheimer's Disease • Anxiety Disorders
Attention Deficit Hyperactivity Disorder (ADHD) • Binge Eating Disorder • Bipolar Disorder
Chronic Idiopathic Constipation • Chronic Pain • Dementia • Depression • Fibromyalgia
Migraine • Mild Cognitive Impairment • Neuropathic Pain • Obsessive Compulsive Disorder
Opioid Induced Bowel Dysfunction • Opioid Induced Constipation
Post-Traumatic Stress Disorder (PTSD) • Schizophrenia and Schizoaffective Disorder
Sexual Dysfunction • Sleep Disorders • Smoking Cessation • Stuttering • Tinnitus

PROFESSIONAL EXPERIENCE:

Principal Investigator, 2005 - Present
FutureSearch Trials, Dallas and Austin, TX

Private Practice, 2005- Present
Dallas, TX

Associate Professor, Clinical Researcher, Clinical Supervisor, and Lecturer, 1994-2005
UT Southwestern Department of Psychiatry, Dallas, TX

Assistant Medical Director, 2001-2005
Attending Physician, 1997-2001
Zale Lipshy University Hospital, Psychiatry Unit, Dallas, TX

Attending Physician, 1994 – 2005
Assistant Medical Director, 1994 - 2003
Parkland Hospital Psychiatry Emergency Service, Dallas, TX

Medical Consultant for Managed Care Operations and Utilization Reviewer, 1996-2001
UTSHS Behavioral Care, Dallas/Fort Worth, TX

Psychiatric Physician, March 1992 - June 1994
Dallas County Mental Health and Mental Retardation, Dallas Psychiatric Intensive Care Unit, Dallas, TX

CLINICAL TRIAL EXPERIENCE:

Addiction

A Phase III, Multicenter, Double-blind, Randomized, Placebo-controlled Trial Evaluating the Efficacy and Safety of XXX in Adult Smokers

A Multicenter, Double-blind, Randomized, Placebo-controlled Phase IIb Trial of XXX in Adult Smokers

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Open-label, Flexibly-dosed, 6-month Extension Safety Study of XXX in the Treatment of Adults with Binge-eating Disorder

A Phase II, 12 week, Randomized, Double blind, Parallel group, Placebo-controlled, Flexibly dosed, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in Adults with Moderate to Severe Binge Eating Disorder

A multi-center, multi-region, observational Smoking Cessation study to understand the biological or functional changes related to Smoking Cessation in apparently healthy smokers who are continuously abstinent from smoking for one year

A Phase III, multi center, double blind, placebo controlled, randomized withdrawal study to evaluate the maintenance and efficacy of XXX in adults aged 18 - 55 with moderate to severe binge eating

A Twelve-week, Randomized, Double-blind, Placebo-controlled, Parallel-group, Dose-ranging Study with Follow-up Evaluating the Safety and Efficacy of XXX for Smoking Cessation in Healthy Adolescent Smokers

A Phase III, Multicenter, Open-label, 12-month Extension Safety and Tolerability Study of XXX in the Treatment of Adults with Binge Eating Disorder

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

A Phase II Multi-center, Randomized, Double-Blind, Two-Stage Clinical Trial to Evaluate the Efficacy and Safety of XXX in Patients with Alcohol Dependence

ADHD, Adult

A Phase IV, Open-label Pragmatic Study to Assess the Real-World Effectiveness of XXX XR in Treatment of Adult and Adolescent Patients with ADHD in the United States

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

A Phase III, Randomized, Double-blind, Multicenter, Parallel-group, Placebo-controlled, Forced-dose Titration, Safety and Efficacy Study of XXX in Adults Aged 18-55 Years with Attention-deficit/Hyperactivity Disorder (ADHD)

A Phase III Randomized, Double-blind, Multicenter, Placebo-controlled, Parallel-group, Efficacy and Safety Study of 2 Doses of XXX in Adults with Attention Deficit Hyperactivity Disorder (ADHD)

A Phase III, 12-Month, Multicenter, Open-label, Safety Study of XXX in Adults with Attention Deficit Hyperactivity Disorder (ADHD)

A 6-week Randomized, Multicenter, Double-blind, Parallel, Fixed-dose Study of XXX 1400 mg Compared with Placebo in Adults with Attention Deficit/Hyperactivity Disorder (ADHD)

A Six-Month Open-Label, Multi-Center Study of the Safety and Efficacy of XXX in Adults and Adolescents with ADHD

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Arm, Multi-Center Study Measuring the Efficacy and Safety of XXX in Adolescent ADHD Patients

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Arm, Multi-Center Study Measuring the Efficacy and Safety of XXX in Adult ADHD Patients

A Phase IV, Double-Blind, Multi-center, Placebo-Controlled, Randomized Withdrawal, Safety and Efficacy Study of XXX in Adults Aged 18-55 with Attention-Deficit/ Hyperactivity Disorder (ADHD)

A Multi-center, Double-Blind, Placebo-Controlled, Randomized, Parallel-Group Study to Investigate the Safety and Efficacy of XXX in Adults with Attention-Deficit/ Hyperactivity Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

ADHD, Pediatric and Adolescents

A Phase III, 13 week trial to understand the synergistic effects when combining XXX with HealthCare Solutions as adjunctive therapy to stimulant in children with ADHD (8-12 year olds)

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

A Evaluation of XXX ER 100 and 200 mg Efficacy and Safety in Children with ADHD - A Double-Blind, Placebo-Controlled, Pivotal Trial

A Phase III, Evaluation of XXX ER 200 and 400 mg Efficacy and Safety in Adolescents with ADHD - A Double-Blind, Placebo-Controlled, Pivotal Trial

A Phase III, exploratory study to assess the sustained effects of digital therapy in pediatric subjects ages 8 to 12 years old with Attention Deficit Hyperactivity Disorder (ADHD)

A Randomized, Controlled Parallel-group, Intervention Study to Assess Gameplay in Improving Attention in Pediatric Subjects Ages 8 to 12 years old with Attention Deficit Hyperactivity Disorder (ADHD)

A Phase II, Multicenter, 6-Week, Double-blind, Randomized, Placebo-controlled, Parallel-design Study to Assess the Efficacy and Safety of XXX in Adolescents (Ages 12-17 Years) with Genetic Disorders Impacting Metabotropic Glutamate Receptors and Attention Deficit Hyperactivity Disorder

A Phase II, Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of XXX ER for the Treatment of Pediatric Patients with Attention Deficit/Hyperactivity Disorder (ADHD)

A Phase IV, Noninterventional Genotype/Phenotype Study of XXX in Children and Adolescents with Attention Deficit Hyperactivity Disorder (ADHD)

A Phase II,Evaluation of XXX Efficacy and Safety in Children with ADHD - A Double-blind, Placebo-controlled, Dose-ranging Study

A Phase III, Randomized, Double-blind, Multi-center, Placebo-controlled, Dose-Optimization, Safety and Efficacy Study of XXX in Children and Adolescents Aged 6-17 Years with Attention-Deficit Hyperactivity Disorder (ADHD)

A Phase IV, Randomized, Double-Blind, Multicenter, Parallel-Group, Active-Controlled, Forced-Dose Titration, Safety and Efficacy Study of XXX Compared with XXX with a Placebo Reference Arm, in Adolescents Aged 13-17 Years with Attention-deficit/Hyperactivity Disorder (ADHD)

CLINICAL TRIAL EXPERIENCE (*continued*):

Alzheimer's Disease

A Placebo-Controlled, Double-Blind, Parallel-Group, Bayesian Adaptive Randomization Design and Dose Regimen-finding Study with an Open-Label Extension Phase to Evaluate Safety, Tolerability and Efficacy of XXX in Subjects With Early Alzheimer's Disease

A Phase III, Placebo-Controlled, Double-Blind, Parallel-Group, 24-Month Study to Evaluate the Efficacy and Safety of XXX in Subjects with Early Alzheimer's Disease

A Phase III, Open Label Extension Study for Continued Safety and Efficacy Evaluation of XXX in Patients with Mild Alzheimer's Disease

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

A Phase III, Randomized, Placebo-Controlled, Parallel-Group, Double-Blind Clinical Trial to Study the Efficacy and Safety of XXX in Subjects with Amnestic Mild Cognitive Impairment Due to Alzheimer's Disease (Prodromal AD)

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

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

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

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

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

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Placebo-Controlled, Parallel, 24-Week, Adaptive Design Phase II Study of Three Different Doses of XXX or Placebo in Subjects with Mild to Moderate Probable Alzheimer's Disease

A Randomized Controlled Trial to Assess the Efficacy of a Medical Food in Patients with Mild to Moderate Alzheimer's Disease using Alzheimer's Disease Medication

A 24 Week Open-Label Extension to Study XXX: A 24 Week, Prospective, Randomized, Parallel-Group, Double-Blind, Multi-center Study Comparing the Effects of XXX vs. XXX on Activities of Daily Living and Cognition in Patients with Severe Dementia of the Alzheimer's Type (ACTION)

A 24 Week, Prospective, Randomized, Parallel-Group, Double-Blind, Multi-center Study Comparing the Effects of XXX vs. XXX on Activities of Daily Living and Cognition in Patients with Severe Dementia of the Alzheimer's Type

Anxiety Disorders

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

A Phase IIa Randomized, Double-blind, Placebo-Controlled, Parallel-Group, Multi-center Study Investigating the Efficacy, Safety, and Tolerability of XXX in Subjects with Social Anxiety Disorder

An 8-week, Randomized, Phase II, Double-blind, Sequential Parallel-group Comparison Study of Two Dose Levels of XXX Compared to Placebo as an Adjunctive Treatment in Outpatients with Inadequate response to Standard of Care for Generalized Anxiety Disorder

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

A Phase III, Double-Blind, Placebo-Controlled, Flexible-Dose Study of XXX in Patients with Generalized Anxiety Disorder

A Multi-center, Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Phase II Study of Two Oral Dose Groups of XXX, with a XXX Arm, in Subjects with Generalized Anxiety Disorder (GAD)

An Efficacy and Safety of Three Doses of XXX in Acute Treatment of Adults with Generalized Anxiety Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

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 GAD

A Multi-center, Randomized, Double-Blind, Placebo and XXX Controlled Trial of the Safety and Efficacy of XXX in the Treatment of Outpatients with GAD

A Multi-center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study of the Efficacy and Safety of XXX Extended-Release (XXX) Compared with Placebo as an Adjunct to Treatment in Patients with Generalized Anxiety Disorder Who Demonstrate Partial or No Response to a Selective Serotonin Reuptake Inhibitor or Serotonin-Norepinephrine Reuptake Inhibitor Alone or in Combination with a Benzodiazepine

An Eight-Week, Multi-center, Randomized, Double-Blind, Placebo-Controlled Study, with XXX as an Active Control, to Evaluate the Efficacy, Safety and Tolerability of a XXX Dose Once Daily, in Patients with Generalized Anxiety Disorder.

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

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multi-center Study to Evaluate the Efficacy, Safety and Tolerability of XXX in Patients with Generalized Anxiety Disorder

A 10-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of XXX in the Treatment of Adults with Generalized Anxiety Disorder

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

Bipolar Disorders

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

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

A Phase 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

CLINICAL TRIAL EXPERIENCE (*continued*):

A 52-week, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of an Intramuscular Depot Formulation of XXX as Maintenance Treatment in Patients with Bipolar I Disorder

A Multicenter, Double-Blind, Fixed-Dose, Long-Term Extension Trial of the Safety of XXX in Subjects Diagnosed with Bipolar 1 Disorder who Completed Protocol XXX

A Phase IIIb, Multicenter, Double-Blind, Fixed-Dose, Parallel-Group, Three Week Placebo Controlled Trial Evaluating the Safety and Efficacy of XXX in Subjects With Bipolar I Disorder Experiencing an Acute Manic or Mixed Episode

A Randomized, Double-Blind, Placebo-Controlled, Proof-of-Concept, Phase II Study to Evaluate the Efficacy and Safety of Once a Day XXX 0.1, 0.4, and 0.8 mg as an Adjunctive Therapy to Treatment-as-Usual in the Maintenance Treatment of Bipolar I Disorder in Adult Patients

A Randomized, Double-Blind, Placebo-Controlled, Proof-of-Concept, Phase II Study to Evaluate the Efficacy and Safety of Once a Day XXX Tablet for Sublingual Administration XXX 0.1 mg, 0.4 mg, and 0.8 mg In the Treatment of Acute Depressive Episodes Associated with Bipolar I Disorder in Adult Patients who are on Lithium and/or Valproate

A Phase III, Randomized, 6-Week, Double-blind, Placebo-controlled, Flexible-dose, Parallel-group Study of XXX for the Treatment of Bipolar I Depression in Subjects Demonstrating non-response to Treatment with XXX alone AND A 24-Week, Flexible-Dose, Open-Label Extension Study of XXX for the Treatment of Bipolar I Depression

A 6-Month, Open-Label, Flexible-Dosage (150-200 mg/day) Extension Study of the Safety and Efficacy of XXX Treatment as Adjunctive Therapy in Adults With Major Depression Associated With Bipolar I Disorder

A Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dosage Study to Evaluate the Efficacy and Safety of XXX Treatment (150 and 200 mg/day) as Adjunctive Therapy in Adults with Major Depression Associated with Bipolar I Disorder

A Six-Week, Double-Blind, Multi-center, Placebo-Controlled Study Evaluating the Efficacy and Safety of Flexible Doses of Oral XXX as Add-On, Adjunctive Therapy with XXX, XXX, or XXX in Bipolar I Depression

A Multi-center, Randomized Eight Week, Double-blind, Placebo-Controlled, Flexible Dose Study to Assess the Safety, Tolerability, and Efficacy of XXX in the Treatment of Bipolar I Depression

A Multi-center, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled, Phase III Study of the Efficacy and Safety of XXX Sustained Release as Monotherapy in Adult Patients with Acute Bipolar Depression

CLINICAL TRIAL EXPERIENCE (*continued*):

A Dose-Escalating, Phase II Study to Assess the Safety and Tolerability of XXX in the Treatment of Bipolar I Depression

An International, Multi-center, 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 Eight Weeks and XXX in Continuation Treatment for 25 Up to 52 Weeks

An International, Multi-center, 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

A Phase III, Randomized, Six-Month, Double-Blind Trial in Subjects with Bipolar I Disorder to Evaluate the Continued Safety and Maintenance of Effect of XXX Plus a Mood Stabilizer (vs. Placebo Plus a Mood Stabilizer) Following a Minimum of Two Months of Response to Open-Label Treatment with Both Agents

A Phase III, Randomized, Six-Month, Double-Blind Trial in Subjects with Bipolar 1 Disorder to Evaluate the Continued Safety and Maintenance of Effect of XXX Plus a Mood Stabilizer (vs. Placebo Plus a Mood Stabilizer) Following a Minimum of Four Months of Response to Open-Label Treatment with Both Agents

A Double-Blind Placebo-Controlled Trials of XXX and XXX in Bipolar I Disorder, Mixed Episode

An XXX vs. XXX and Placebo in the Treatment of Mild to Moderate Mania Associated with Bipolar I Disease

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

A Multi-center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of XXX in the Treatment of Depression in Outpatients with Bipolar Disorder

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

A Cognitive Behavioral Therapy for Bipolar Maintenance

Depression

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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 of the Efficacy and Safety of XXX with a Fixed, Repeated Treatment Regimen on Relapse Prevention in Adults with Major Depressive Disorder

A 52-Week Open-Label Extension Study of XXX in Subjects With Major Depressive Disorder and Inadequate Response to Antidepressant Treatment

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Adjunctive XXX in Subjects With Major Depressive Disorder and Inadequate Response to Antidepressant Treatment

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

A 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 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 II, Depression Diagnostic Aid Confirmatory Performance Study - An Abbreviated Investigational Device Exemption Study

A Phase III, Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Fixed Doses of Intranasal XXX Plus an Oral Antidepressant in Adult Subjects with Treatment-resistant Depression

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

A Phase III, Open-label Long-term Extension Safety Study of Intranasal XXX in Treatment-resistant Depression

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

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

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

A Phase III, Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Fixed Doses of Intranasal XXX Plus an Oral Antidepressant in Adult Subjects with Treatment-resistant Depression

A Phase III, Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Flexible Doses of Intranasal XXX Plus an Oral Antidepressant in Adult Subjects with Treatment-resistant Depression - Trial of Rapid-acting Intranasal XXX for Treatment-resistant Major Depressive Disorder

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

A Phase II, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of XXX as an adjunctive therapy in patients with major depressive disorder with an inadequate response to antidepressant treatment

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IIIb, Multicenter, Open-label Exploratory Trial to Evaluate the Efficacy, Safety, and Subject Satisfaction of XXX as Adjunctive Therapy in the Treatment of Adults with Major Depressive Disorder and an Inadequate Response to Previous Adjunctive Therapy

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

A Phase III, Open-Label Extension Study to Assess the Safety and Tolerability of Treatment With XXX in Patients Who Have Completed Study XXX

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Sequential Parallel Study of XXX in the Adjunctive Treatment of Subjects with Severe Depression and Recent Active Suicidal Ideation Despite Antidepressant Treatment

A Phase III Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of XXX vs. Placebo in the Treatment of Psychotic Symptoms in Patients with Major Depressive Disorder with Psychotic Features

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

A Phase II, Randomized, Double-blind, Placebo-controlled Study to Evaluate XXX in Subjects with Major Depressive Disorder and Inadequate Response to Antidepressant

A Multicenter, Randomized, Double-blind, Parallel group, Placebo-controlled, Phase II Study of 2 Dose Groups of XXX Adjunct to Current Antidepressant Therapy in Patients with Major Depressive Disorder who exhibit an Inadequate Response to Antidepressants

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

A Phase III, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of XXX in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant

Antidepressant-Induced Sleepiness, Cognitive Symptoms and/or Fatigue, during SSRI Treatment of MDD

A Randomized, 6-week, Double-Blind, Placebo-Controlled, Flexible-Dose, Parallel-Group Study of XXX For the Treatment of Major Depressive Disorder with Mixed Features

CLINICAL TRIAL EXPERIENCE (*continued*):

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

A Phase III, Open-label, Multicenter, 12-month Extension Safety and Tolerability Study of XXX in Combination With an Antidepressant in the Treatment of Adults With Major Depressive Disorder With Residual Symptoms or Inadequate Response Following Treatment With an Antidepressant

A 12-week, Open-Label Extension Study For the Treatment of Major Depressive Disorder with Mixed Features

A Phase IV,Multicenter, Randomized, 8-week, Double-blind, Placebo-controlled, Parallel-group, Study to Evaluate the Efficacy of Two Fixed Doses (50 and 100 MG/Day) of XXX in Adult Outpatients with Major Depressive Disorder (MDD)

A Phase III Randomized, Double-blind 10-week Clinical trial of XXX versus XXX and versus XXX in moderate to severe Major Depressive Disorder (MDD)

A Long-term, Phase III, Multicenter, Open-label Trial to Evaluate the Safety and Tolerability of Oral XXX as Adjunctive Therapy in Adults with Major Depressive Disorder

A Phase IIb, Randomized, Double-Blind, Placebo-Controlled, Active Controlled, Parallel Group, Multicenter Study to Assess the Safety and Efficacy of 2 Fixed Dose Groups of XXX as Monotherapy Treatment in Patients with Major Depressive Disorder with an Inadequate Response to Antidepressant Therapy

A Multicenter, Randomized, Double-blind, Active-Controlled, Comparative, Fixed-Dose, Dose Response Study of the Efficacy and Safety of XXXin Patients with Treatment Resistant Major Depression

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

XXX Compared to Placebo as Adjunctive Therapy to SSRI in the Prevention of Symptom Re-emergence in Major Depressive Disorder

A Multicenter, Double-Blind, 58 Week Rollover Study to Assess the Safety and Tolerability of XXX in Patients With Treatment Resistant Major Depression

A Randomized, Double-Blind, Parallel-Group, Active-Controlled, Flexible-Dose Study Evaluating the Effect of XXX vs. XXX on Sexual Functioning in Adults With Well-Treated Major Depressive Disorder Experiencing Selective Serotonin Reuptake Inhibitor–Induced Sexual Dysfunction

CLINICAL TRIAL EXPERIENCE (*continued*):

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

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of the Safety and Efficacy of Two Fixed Doses of XXX as Adjunctive Therapy in the Treatment of Adults With Major Depressive Disorder

A Phase II, Double-Blind, XXX and Placebo-Controlled Study of XXX among Outpatients with Major Depressive Disorder Who have Responded Inadequately to Prior Selective Serotonin Reuptake Inhibitors (SSRIs) (Triple Reuptake Inhibitor Anti-Depressant Effects – TRIADE Study)

A Randomized, Double-blind, Placebo-controlled, Parallel Group, Phase II Study of XXX in Subjects with Major Depressive Disorder

A Phase II, Randomized, Double-Blinded, Placebo-Controlled, Parallel-Group, Assessment of the Efficacy, Safety and Tolerability of XXX Modified Release Table, 125 mg Twice Per Day in Subjects with Treatment Resistant Depression

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

A Long-Term, Open Label Safety Study of XXX Once Daily as Adjunctive Treatment for Patients with Major Depressive Disorder Who Are Partial Responders to XXX Treatment

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

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

A Phase III, Long-Term, Open-Label, Flexible-Dose, Extension Study Evaluating the Safety and Tolerability of XXX in Subjects with Major Depressive Disorder

A Randomized, Double-Blind, Parallel Group, Active- and Placebo-Controlled Study to Assess the Efficacy and Safety of XXX in Adult Subjects With Treatment-Resistant Major Depressive Disorder

An 8-week, Randomized, Double- Blind, Placebo-Controlled, Parallel-Group, Multi-center Study of the Efficacy and Safety of XXX Sublingual Tablets Administered Once Daily in Patients with Major Depressive Disorder (MDD)

CLINICAL TRIAL EXPERIENCE (*continued*):

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

A Multi-center, Long-Term, Open-Label Study to Assess the Safety and Tolerability of XXX as Adjunctive Therapy in the Treatment of Outpatients with Major Depressive Disorder

A Long-Term, Open-Label, Flexible-Dose, Extension Study Evaluating the Safety and Tolerability of XXXin Subjects with Major Depressive Disorder

A Double-Blind, Randomized, Multi-center, Placebo-Controlled, Relapse Prevention Study with XXX in Out-Patient Adults with Major Depressive Disorder

A Randomized, Double-Blind Assessment Comparing Discontinuation Symptoms in Abrupt Discontinuation vs. a One Week Tapering Regimen in MDD Patients Treated for 6 Months Open Label with 50 mg XXX Sustained Release

A Multi-center, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study of the Safety and Efficacy of XXX as Adjunctive Therapy in the Treatment of Adults with Major Depressive Disorder

Hypo-Sexual Dysfunction in Patients with Depression

A Phase II, Multi-center, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in Adults with Clinically Significant, Persistent Executive Function Impairments (EFI) and Partial or Full Remission of Recurrent Major Depressive Disorder

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

A Double-Blind, Placebo-Controlled and Comparator-Controlled Study of XXX in Combination with XXX in Patients with Major Depressive Disorder

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

A Multi-center, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate Functional Outcome in Outpatients with Major Depressive Disorder Treated with XXX

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IIb, Multi-center, Randomized, Double-Controlled Efficacy and Safety Study of Adjunctive XXX in Patients with Severe Major Depressive Disorder (MDD) and a History of Poor Response or Tolerability to Antidepressants

A 12-Week Randomized Open-Label Trial of XXX vs. Generic SSRIs in the Treatment of a Severe Depressive Episode

A One-Year Open Label Study Assessing the Safety of XXX in Patients with Major Depressive Disorder

A Double-Blind, Randomized, Placebo-Controlled, Double-Dummy, Multi-center Study Examining the Safety, Efficacy and Tolerability of XXX in Subjects with SSRI Resistant Major Depressive Disorder

A Double-Blind, Randomized, Placebo-Controlled Study Examining, the Safety, Efficacy, and Tolerability of XXX in Subjects with Major Depressive Disorder (Including Atypical and Melancholic Features).

A Multi-center, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled Phase III Study of the Efficacy and Safety of XXX Sustained Release XXX as Mono-Therapy in the Treatment of Elderly Patients with Major Depressive Disorder

An Eight-Week, Multinational, Multi-center, Randomized, Double-Blind, Placebo-Controlled Study, with XXX as an Active Control, to Evaluate the Efficacy, Safety and Tolerability of XXX, in Elderly Patients with MDD

An Eight-Week, Randomized, Fixed-Dosage, Placebo-Controlled, Parallel-Group, Multi-center Study of the Efficacy, Safety and Tolerability of XXX in the Treatment of Major Depressive Disorder

A Multi-center, Randomized, 24-52-Week, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of XXX Once Daily in the Prevention of Relapse of Depressive Symptoms in Outpatients with Major Depressive Disorder Who Achieved an Initial Response to 12 Weeks of Open-Label Treatment with XXX Once Daily

A One-Year Open Label Study Assessing the Safety of XXX in Patients with Major Depressive Disorder

A Multi-center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Phase III Study of the Efficacy and Safety of Sustained-Release XXX and Sustained Release XXX as Monotherapy in the Treatment of Patients with Major Depressive Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

An Eight-Week, Double-Blind Placebo-Controlled, Multi-center Study with XXX as Positive Control, Evaluating the Efficacy, Safety and Tolerability of a Fixed Dose of XXX in Outpatients with Major Depressive Disorder (MDD)

An Eight-Week, Double-Blind Placebo-Controlled, Multi-center Study with XXX as Positive Control, Evaluating the Efficacy, Safety and Tolerability of a Fixed Dose XXX in Outpatients with Major Depressive Disorder (MDD)

An Eight-Week, Multi-center, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy, Safety and Tolerability of One Fixed Dose of XXX in Patients with Major Depressive Disorder

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

A Randomized, Parallel-Group, Sham-Controlled, Multi-center Study to Evaluate the Efficacy and Safety of XXX CRS Repetitive Transcranial Magnetic Stimulation (RTMS) System in Patients with Major Depression

A Nine-Week, Uncontrolled, Open Label, Multi-center Study to Evaluate the Efficacy and Safety of the XXX CPS Repetitive Transcranial Stimulation (RTMS) System in the Treatment of Patients with Major Depression Previously Nonresponsive to Active or Sham RTMS

The Sequenced Treatment Alternatives to Relieve Depression

A Six-Month Open Label Maintenance Study of Patients with Major Depression Previously Responsive to RTMS Treatment with XXX CRS Repetitive Transcranial Stimulation (RTMS) System

A Pilot Safety and Efficacy Study of the Vagus Nerve Stimulation (VNS) Using the Neurocybernetic Prosthesis (NEP) System in Patients with Depression

Fibromyalgia

A Phase IIb, Double-Blinded, Randomized, Placebo-Controlled, Trial of XXX for the Treatment of Fibromyalgia

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 Fibromyalgia

A Phase III, Double-Blind, Randomized, Multicenter, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX SL Taken Daily At Bedtime In Patients with Fibromyalgia

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, 3-Month, Multicenter, Open-Label Extension Study to Evaluate the Safety and Efficacy XXX SL Tablets Taken Daily at Bedtime in Patients with Fibromyalgia

A Phase III, Double-Blind, Randomized, Multicenter, Placebo-Controlled Study to Evaluate the Efficacy and Safety of an Investigational Product Taken Daily at Bedtime in Patients with Fibromyalgia

An Open-label Extension Study of XXX for 52 weeks in Pain Associated with Fibromyalgia

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

A Phase II, Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled Study of XXX in Subjects with Fibromyalgia

Qualitative Study to Develop a Patient Reported Outcome (PRO) Measure to Assess Cognitive Function in Chronic Pain

A Multi-center, Multiple Dose, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study of the Safety and Efficacy of XXX in Female Patients with Fibromyalgia Syndrome

A Phase II Randomized Double-Blind, Placebo-Controlled Crossover Study Assessing the Ability of XXX to Improve Cognitive Function in Fibromyalgia Patients

A Multi-center, Randomized, Double-Blind, XXX-Referenced, Placebo-Controlled, Parallel-Group, Adaptive Design Study of XXX in Adult Female Outpatients with Fibromyalgia Syndrome

A Parallel, Randomized, Double-Blind, Placebo-Controlled, Multi-center Proof of Concept Trial to Assess the Efficacy and Safety of Two Different Transdermal Doses of XXX in Subjects with Signs and Symptoms Associated with Fibromyalgia Syndrome

A Flexible Dosed XXX vs. Placebo in the Treatment of Fibromyalgia

A Six-Month Open Label Extension Study of the Long-Term Safety of the XXX in Outpatient with Fibromyalgia Syndrome

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

CLINICAL TRIAL EXPERIENCE (*continued*):

Migraine

A Phase III, Multicenter, Randomized, Double-blind, Group Sequential, Placebo-controlled Study to Assess Efficacy and Safety of XXX or the Treatment of Migraine (With or Without Aura) in Children and Adolescents ≥ 6 to <18 Years of Age

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

A Phase III: Double-Blind, Randomized, Placebo Controlled, Safety and Efficacy Trial of XXX intranasal (IN) for the Acute Treatment of Migraine

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled, Crossover Study to Evaluate the Efficacy, Safety, and Tolerability of Oral XXX in the Treatment of Migraine When Administered During the Prodrome

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

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

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

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

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

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

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

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

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

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

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of XXX in Patients with Episodic Migraine – the XXX 2 Study

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

An Open Label Trial to Evaluate the Safety of XXX Administered Intravenously in Patients with Migraine

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

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

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Safety, Tolerability, and Efficacy Study of XXX in the Treatment of Acute Migraine Headache

Pain

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Enriched-Enrollment Withdrawal, Multicenter Study to Evaluate the Efficacy and Safety of a Long-Acting Subcutaneous Injectable Depot of XXX in Subjects with Moderate to Severe Chronic Low Back Pain Currently Treated with Daily Opioids

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

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

An Open-label Phase III Trial to Evaluate the Safety and Tolerability of XXX Tablet, in Patients with Moderate-to-Severe Chronic Noncancer Pain

A National, Randomized, 12-Week, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of XXX (3.0 and 6.0 mg) in Patients with Chronic Idiopathic Constipation

A Randomized Double-Blind Placebo Controlled Parallel Group Study of the Efficacy and Safety of XXX In Subjects with Post-Traumatic Peripheral Neuropathic Pain

A Randomized, 4-Week, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Assess the Safety and Efficacy of XXX for the Treatment of Opioid-induced Constipation (OIC) in Patients with Non-malignant Chronic Pain Receiving Opioid Therapy

An Phase III open-label extension study of up to 52 weeks to assess the safety, tolerability, and analgesic efficacy of XXX in the management of moderate to severe chronic pain requiring ATC opioid analgesia for an extended period of time

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Double-blind, Placebo-controlled, Multicenter, Randomized Withdrawal Study to Evaluate the Analgesic Efficacy, Safety, and Tolerability of XXX in Opioid-Experienced Subjects with Moderate to Severe Chronic Low Back Pain Requiring Around-the-clock Opioid Analgesia for an extended period of time.

A Phase III, Double-blind, Placebo-controlled, Multicenter, Randomized withdrawal Study to Evaluate the Analgesic Efficacy, Safety, and Tolerability of XXX in Opioid-naïve Subjects with Moderate to Severe Chronic Low Back Pain Requiring around-the-clock Opioid Analgesia for an Extended Period of Time

A Multi-center, 12-week, Double-blind, Placebo-controlled, Randomized Withdrawal Study to Determine the Efficacy and Safety of XXX Extended-release Capsules in Subjects with Moderate to Severe Chronic Low Back Pain

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

A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of XXX controlled-release Tablets to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to XXX Controlled-release Tablets) in Opioid-experienced Subjects with Controlled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy

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

A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of XXX controlled-release Tablets to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to XXX) in Opioid-experienced Subjects with Uncontrolled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy

A Randomized, Double-blind, Placebo-controlled, Multicenter Trial with an Enriched Study Design to Assess the Efficacy and Safety of XXX Controlled-release Tablets Compared to Placebo in Opioid-experienced Subjects with Moderate to Severe Pain due to Chronic Low Back Pain who Require Around-the-clock Opioid Therapy

A Phase IV Multi-center, Primary Care-Based, Open-Label Study to Assess the Success of Converting Opioid-Experienced Patients, with Chronic, Moderate to Severe Pain, to XXX Using a Standardized Conversion Guide, and to Identify Behaviors Related to Prescription Opioid Abuse, Misuse, and Diversion

CLINICAL TRIAL EXPERIENCE (*continued*):

A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of the Efficacy and Safety of XXX in Patients with Chronic Low Back Pain

Post-Traumatic Stress Disorder

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

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

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

A 12-Week Open-Label Extension Study to Evaluate XXX SL Taken Daily at Bedtime in Patients 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 Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed Dose Study Evaluating the Efficacy and Safety of the XXX in Post-Traumatic Stress Disorder (PTSD)

Schizophrenia

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

A Phase 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 Double-blind, Randomized, Active-controlled, Parallel-group Study of XXX 6-Month Formulation

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Parallel-group, 6-week Study to Evaluate the Efficacy and Safety of XXX in Subjects with an Acute Exacerbation of Schizophrenia

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

A Phase III Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of XXX (90-mg and 120 mg) as a Treatment in Subjects with Acute Schizophrenia Over 8 Weeks (2 Subcutaneous Doses) and Long term safety, and tolerability of XXX in stable schizophrenia subjects

An Exploratory, Multicenter, Open-label, Flexible-dose XXX Trial in the Treatment of Adults with Early-Episode Schizophrenia

A 12-Week, Randomized, Phase II, Double-blind, Parallel-group, Study of Two Dose Levels of XXX Compared to Placebo in the Adjunctive Treatment of Outpatients with Sub-Optimally Controlled Symptoms of Schizophrenia

A Phase II, partial-blind, multi-center extension study to evaluate the long-term safety and health outcomes of XXX in subjects who completed Study XXX

A Phase II, Randomized, Multicenter Study to Evaluate the Efficacy and Safety of XXX for the Treatment of Schizophrenia to Mitigate or Prevent XXX -Induced Weight Gain

A Phase III, Open Label, Multicenter, Extension of Study XXX to Assess the Long-term Safety and Durability of Effect of XXX in Subjects with Stable Schizophrenia

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

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

A Phase III, Interventional, randomized, double-blind, parallel-group, placebo-controlled, active-reference, flexible-dose study of XXX in patients with acute schizophrenia

A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel-group Study of XXX in the Prevention of Relapse in Patients with Schizophrenia

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Three Fixed Doses of XXX in the Treatment of Adults With Acute Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

A 12-week, Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of XXX in the Acute Treatment of Adults With Schizophrenia

A Phase III Multicenter, Double-Blind, Fixed-Dose, Long-Term Extension Trial of the Safety of XXX using XXX as an Active Control in Subjects Diagnosed with Schizophrenia who completed Protocol XXX

A Phase IIIb Multicenter, Randomized, Double-Blind, Fixed-Dose, 6-Week Trial of the Efficacy and Safety of XXX Compared With Placebo Using XXX A 12-week, Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of XXX in the Acute Treatment of Adults With Schizophrenia

A Randomized, Double-blind, Placebo-controlled, Parallel, 12‑Week, Phase III Study of 2 Doses of XXX or Placebo as an Adjunctive Pro-cognitive Treatment in Schizophrenia Subjects on Chronic Stable Atypical Antipsychotic Therapy

A Phase III Multicenter 40-Week Extension Study to Evaluate the Safety and Clinical Effects of Prolonged Exposure to 1 and 2 mg Doses of XXX as an Adjunctive Pro cognitive Treatment in Subjects with Schizophrenia on Chronic Stable Atypical Antipsychotic Therapy

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy, Safety, and Tolerability of XXX as Maintenance Treatment in Adults with Schizophrenia

A Phase II, Double-Blind, Placebo-Controlled, Multicenter, Parallel Group Study to Assess Efficacy, Safety, and Tolerability of XXX as Augmentation Therapy to Improve Negative Symptoms and Cognition in Outpatients with Schizophrenia

A Randomized, Double-blind, Placebo-controlled, Dose-ranging, Parallel-group, Phase II Study of the Safety and Efficacy of XXX in the Treatment of Cognitive Deficits in Schizophrenia (CDS) in Non-smokers

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study of the Efficacy and Safety of XXX in Subjects with Acute Exacerbation of Schizophrenia

A Randomized, Multicenter, Double-Blind, Relapse Prevention Study of XXX for the Treatment of Subjects with Schizophrenia

A Phase III, Randomized, Multicenter, Double-Blind, Non-inferiority Study of XXX 3 Month and 1 Month Formulations for the Treatment of Subjects with Schizophrenia

A Phase III, 12-Week, Multicenter, Open-Label Extension Study In Subjects with Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study of the Efficacy and Safety of XXX in Subjects with Acute Exacerbation of Schizophrenia

A Phase III, Multicenter, Open-label Study to Assess Hospitalization Rates in Adult Subjects with Schizophrenia Treated Prospectively for 6 Months with XXX Compared with 6-month Retrospective Treatment with Oral Antipsychotics in a Naturalistic Community Setting in the United States

A Double-blind, Placebo-controlled, Randomized Withdrawal Study of XXX for the Maintenance Treatment of Subjects with Schizophrenia

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

A Phase III, multi-center, randomized, 6-month, 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 6-month double-blind extension period

A Phase III, multi-center, randomized, 3 month, double-blind, parallel-group placebo-controlled study to evaluate efficacy and safety of XXX in stable patients with sub-optimally controlled symptoms of schizophrenia treated with antipsychotics, followed by a 9 months double blind extension period

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of XXX Evaluating Time to Relapse in Subjects With Schizoaffective Disorder

A 12-week, Randomized, Multicenter, Open-label, XXX Flexible Dose Study Assessing Efficacy, Safety and Tolerability of Two Switch Approaches in Schizophrenia Patients Currently Receiving XXX or XXX

A 24-Week Multi-center, Double-Blind, Randomized, Parallel-Group, Dose Ranging Study of the Efficacy and Safety of Oral Doses of XXX and Placebo on Top of an Established Treatment Regimen of Either XXX, XXX, or XXX Monotherapy in the Treatment of Cognitive Impairment in Schizophrenia

A Randomized, 6-week, Open-Label Study Evaluating the Safety, Tolerability, and Efficacy of XXX for the Treatment of Schizophrenia or Schizoaffective Disorder in Subjects SWITCHED From Other Antipsychotic Agents and A 24-Week, Flexible-Dose, Open-Label Extension Study of Subjects Switched to XXX for the Treatment of Schizophrenia or Schizoaffective Disorder

A 16-Week, Multi-center, Open-Label Study Evaluating the Safety, Tolerability, and Efficacy of Switching from XXX to XXX in Subjects Diagnosed with Schizophrenia or Schizoaffective Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multi-center, Open-Label, Flexible-Dose, Parallel-Group Evaluation of the Cataractogenic Potential of XXX and XXX in the Long-Term Treatment of Patients with Schizophrenia or Schizoaffective Disorder

XXX vs. XXX in the Treatment of Schizophrenia and Other Psychotic Disorders

The Comparative Efficacy of XXX, XXX, and XXX for Cognition in Schizophrenia

Sleep Disorders

A Randomized, Double-Blind, Placebo-Controlled Subjective Study to Assess the Efficacy of XXX in Patients with Primary Insomnia characterized by Difficulty in Maintaining Sleep

An Efficacy and Safety of XXX on Sleep Maintenance Insomnia with a Sub-Study of the Effect of XXX on Stable Type II Diabetes Mellitus: A One-Year, Multi-center, Randomized, Double-Blind, Placebo-Controlled Study

The Efficacy of XXX as Adjunctive Therapy in Subjects with Insomnia Related to Generalized Anxiety Disorder (GAD)

Other Indications

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

A Phase II/III Randomized, Double-blind, Placebo-controlled Trial of XXX in Subjects with Obsessive Compulsive Disorder

A Phase IV, Randomized, Double-Blind, Parallel Group, Placebo- and Active-Controlled, Study Evaluating the Effect of XXX 10 and 20 mg/day vs XXX 20 mg/day on Sexual Functioning in Healthy Subjects

A Multicenter, Randomized, Placebo-controlled, Double-blinded Study of the Efficacy and Safety of XXX in Subjects with Opioid-Induced Bowel Dysfunction

A Three-Arm, Double-Blind, Placebo-Controlled Clinical Trial to Assess the Efficacy, Safety and Tolerability of XXX for the Treatment of Adults with Stuttering Comparing Three Electrode Placement to Optimize ECT

A Randomized, Double-Blind, Placebo-Controlled, Clinical Evaluation of the Efficacy, Safety and Tolerability of XXX in Patients with Subjective Tinnitus and An Open-Label, Long-Term Treatment Study to Assess the Long-Term Safety and Tolerability and Efficacy of XXX in Patients with Subjective Tinnitus

CLINICAL TRIAL EXPERIENCE (*continued*):

Continuation ECT vs. Pharmacotherapy: Safety and Efficacy

PROFESSIONAL INTERESTS

Psychopharmacology
Psychodynamic Psychotherapy
Short-Term Psychotherapy
Clinical Research
Cognitive Rehabilitation in Schizophrenia