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AFFILIATIONS:

Weiss Memorial Hospital
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420 E Superior St
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EDUCATION:

1995 Licensed Clinical Psychologist 071.5109
1994 Doctor of Philosophy
Northwestern University, Chicago, IL
1989 Bachelor of Science
Northwestern University, Evanston, IL

INTERNSHIP:

1993 – 1994 Clinical Psychology Intern
Cook County Hospital, Chicago, IL

LICENSURE:

Licensed Clinical Psychologist

PROFESSIONAL EXPERIENCE:

Founder, President, and Principal Investigator, 2001 – present
Uptown Research Institute, LLC, Chicago, IL

PROFESSIONAL EXPERIENCE (continued):

Founder, President, and Psychologist 2002 – present
Uptown Mental Health, Chicago, IL

Clinical Psychologist, 1996 – 2002
Private Practice, Chicago, IL

Director of Scientific Operations, 2000 – 2001
Forest Foundation, Chicago, IL

Program Director, 1997 – 1999
Geropsychiatry Unit, Forest Hospital, Des Plaines, IL

Clinical Psychologist, 1994 – 1997
Group Practice, Chicago, IL

CLINIAL TRIAL EXPERIENCE:

Phase I • Anxiety • Binge Eating Disorder • Bipolar Disorder • Depression
Obsessive Compulsive Disorder • Post-Traumatic Stress Disorder
Schizophrenia or Schizoaffective Disorder • Tardive Dyskinesia

INVESTIGATOR EXPERIENCE:

Phase I Trial Experience - Schizophrenia

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

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 Phase Ib/II, Multicenter, Randomized, Double-blind, Placebo-controlled, Multiple Ascending Dose Study to determine Efficacy, Pharmacokinetics and Safety of XXX in Agitation associated with Schizophrenia, Schizoaffective Disorder or Schizophreniform Disorder

A Phase I, Randomized, Open-Label, Study Evaluating the Pharmacokinetics of Various Dosing Regimens of XXX in Subjects with Stable Schizophrenia

A Phase I Study of an XXX Initiation Regimen in Adults with Schizophrenia

INVESTIGATOR EXPERIENCE (*continued*):

A Phase I- A Study to Evaluate User Comprehension of Instructions for Use for a Transdermal Patch to Treat Schizophrenia

A Phase I Randomized, Open-Label, Parallel Design, Multiple-Dose, Comparative Bioequivalence Study of XXX Extended-Release Injectable Suspension (156mg/1.0mL) Versus XXX Extended-Release Injectable Suspension (156mg/1.0mL) in Schizophrenia Patients Already Stabilized on XXX

A Randomized, Crossover, Open-Label, Multiple Dose, Pivotal Pharmacokinetic Bioequivalence Study Comparing XXX extended-release IM 156 mg/1.0 mL (100 mg eq) with XXX in Subjects with Schizophrenia or Schizoaffective Disorder

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

Phase II-III Trial Experience

Anxiety

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Fixed-Dose Study Comparing the Efficacy and Safety of 2 Doses of XXX in Acute Treatment of Adults with Generalized Anxiety Disorder

Binge Eating Disorder

The Phase III, Multi-Center, 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 III, Multicenter, Open-Label, 12-Month Extension Safety and Tolerability Study of XXX in the Treatment of Adults with Binge Eating Disorder

Bipolar Disorder

A Phase III Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study to Determine Efficacy and safety of XXX in Agitation Associated with Bipolar Disorder

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

INVESTIGATOR EXPERIENCE (*continued*):

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Study of the Efficacy and Safety of XXX in Subjects Experiencing Acute Manic Episodes Associated with Bipolar I Disorder

A Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXX in Patients with Acute Mania Associated with Bipolar Disorder

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 XXX or XXX in the Treatment of Patients with major Depressive Episodes Associated with Bipolar I or Bipolar II Disorder

A Phase III Study to Assess the Long-Term Safety, Tolerability, and Durability of Treatment Effect of XXX in Subjects with Schizophrenia, Schizophreniform Disorder, or Bipolar I Disorder

A Multi-Center, Randomized, Double-Blind Trial of XXX for the Acute Treatment of Manic Episodes, with or without Mixed Features, in Subjects with a Diagnosis of Bipolar I Disorder

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

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

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

A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX as Adjunctive Therapy to Valproate or Lithium in the Prevention of Recurrent Mood Symptoms Associated with Bipolar I Disorder

A Randomized, Double-Blind, Placebo-Active Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of XXX Long-Acting Injectable for the Prevention of Mood Episodes in the Treatment of Subjects with Bipolar I Disorder

INVESTIGATOR EXPERIENCE (*continued*):

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, XXX-Referenced, Fixed-Dose Study of XXX in the Treatment of Depression in Subjects with Bipolar I or II Disorder

A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of XXX 750-2000 mg/d Combined with Risperidone in the Treatment of Manic Episodes of Bipolar I Disorder Over 6 Weeks

A 52-Week, Open-Label Extension Study to Evaluate the Safety and Tolerability of XXX 750-2000 mg/d in the Treatment of Manic Episodes of Bipolar I Disorder

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

A Randomized, Double-Blind, Placebo-Controlled, Phase III Study to Evaluate the Efficacy and Safety of Once a Day, XX Tablet for Sublingual Administration XXX 0.1, 0.4, and 0.8 mg as an Adjunctive Therapy in the Treatment of Acute Depressive Episodes Associated with Bipolar 1 Disorder in Adult Subjects

A Randomized, Double-Blind, Placebo-Controlled, Phase III 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 1 Disorder in Adult Subjects

Depression

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

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

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

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

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

INVESTIGATOR EXPERIENCE (*continued*):

A Phase IIa, Randomized, Double-blind, Placebo-controlled Proof of Concept Study to Evaluate the Effects of Oral XXX Versus Placebo in Subjects With Major Depressive Disorder

A Phase III, Multi-Center Study of the Long-Term Safety and Tolerability of XXX for the Adjunctive Treatment of Major Depressive Disorder in Adults Who Have an Inadequate Response to Antidepressant Therapy

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

XXX as a Treatment for Major Depressive Disorder in Adult Females

A Multi-Center, Double-Blind, Randomized-Withdrawal, Parallel-Group, Placebo-Controlled Phase III Study of the Efficacy and Safety of XXX Sustained Release (XXX) as Monotherapy in the Maintenance Treatment of Patients with Major Depressive Disorder Following an Open-Label Stabilization Period (XXX Study)

A Multi-Center, Randomized, Double-Blind, Active-Controlled, Comparative, Fixed-Dose, Dose Response Study of the Efficacy and Safety of XXX in Patients with treatment Resistant Major Depression

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

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 Phase III, Randomized, Double-Blind, Multi-Center, Active-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Fixed Doses of Intranasal XXX Plus and Oral Antidepressant in Adult Subjects with Treatment-Resistant Depression

A Randomized, Double-Blind, Multi-Center, Active-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Fixed Doses of Intranasal XXX Plus Oral Antidepressant in Adult Subjects with Treatment-Resistant Depression

A Double-Blind, Doubly-Randomized, Placebo-Controlled Study of Intranasal XXX in an Adaptive Treatment Protocol to Assess Safety and Efficacy in Treatment-Resistant Depression (XXX)

A Phase III, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy, Safety, and Tolerability of XXX as Adjunct Therapy in the Maintenance Treatment of Adults with Major Depressive Disorder

INVESTIGATOR EXPERIENCE (*continued*):

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

A Double-Blind, Randomized, Multi-Center, Placebo-Controlled Relapse Prevention Study with XXX SR in Patients with Major Depressive Disorder

A Phase IIa Multicenter, Randomized, Double-Blind, Double-Dummy, and Placebo- and Active-Controlled Study to Investigate the Safety and Efficacy of XXX Administered to Patients with Major Depressive Disorder

A Prospective, Longitudinal, Observational Study to Evaluate Potential Predictors of Relapse in Subjects with Major Depressive Disorder Who Have Responded to Antidepressant Treatment

An 8-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study of the Efficacy and Safety of XXX 0.5mg and 1mg Sublingual Tablets Administered Once Daily in Patients with Major Depressive Disorder (MDD)

A 52-Week, Randomized, Double-Blind, Placebo-Controlled, Multi-center, Parallel-group Study of the Long-Term Efficacy, Tolerability and Safety of XXX 25 and 50 mg in the Prevention of Relapse of Major Depressive Disorder (MDD)

An Eight-Week, Multi-National, Multi-Center, Double-Blind, Double-Dummy, Placebo-Controlled Study, with XXX as an Active Control, Evaluating the Efficacy and Tolerability of Two Fixed Doses of XXX in Patients with Major Depressive Disorder

An Eight-Week, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety and Tolerability of XXX 100mg Once Daily in Combination with XXX 10mg Once Daily in Patients with Major Depressive Disorder

An Eight-Week, Double-Blind, Placebo-Controlled, Multicenter Study with XXX (10mg qd) as Positive Control, Evaluating the Efficacy, Safety and Tolerability of a Fixed Dose of XXX (350mg q12) in Outpatients with Major Depressive Disorder (MDD)

A 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, 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

INVESTIGATOR EXPERIENCE (*continued*):

A Multi-Center, 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

Obsessive Compulsive Disorder

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

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

Post-Traumatic Stress Disorder

A Phase III, Double-Blind, Randomized, Multi-Center, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX Taken Daily at Bedtime in Patients with Military-Related PTSD

Schizophrenia or Schizoaffective Disorder

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety, Efficacy, and Pharmacokinetics of XXX in Obese Adult Patients with Schizophrenia Taking Antipsychotic Medications XXX Study

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

A Phase II Randomized, Double-blinded, Placebo-controlled Parallel Group Trial to Examine the Efficacy and Safety of XXX Once Daily With Adjunctive Computerized Cognitive Training Over 12 Week Treatment Period in Patients With Schizophrenia

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 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, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XXX as an Adjunctive Treatment in Adult Patients with Schizophrenia

INVESTIGATOR EXPERIENCE (continued):

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

A Phase II randomised, double-blinded, placebo-controlled parallel group trial to examine the efficacy and safety of 4 once daily oral doses of XXX over 12-week treatment period in patients with Schizophrenia.

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase II Study of the Safety and Efficacy of XXX in the Treatment of Cognitive Deficits in Schizophrenia

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 Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase II Study of the Safety and Efficacy of XXX in the Treatment of Cognitive Deficits in Schizophrenia (CDS) in Smokers

Long-Term Safety and Efficacy of XXX in Subjects with Schizophrenia: A Double-Blind Extension Study for Subjects Completing Study XXX

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 II Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of 10 mg, 25 mg, 50 mg, and 100 mg Once Daily Oral Administration of XXX During a 12-Week Treatment Period in Patients with Schizophrenia on Stable Antipsychotic Treatment.

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, Extension of Study XXX to Assess the Long-Term Safety and Durability of Effect of XXX in Subjects with Stable Schizophrenia

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

Safety and Tolerability of Initiating XXX in Subjects with Schizophrenia who are Inadequately Treated with XXX or XXX Long Acting Injection

A Phase II, Efficacy, Safety, and Tolerability Study of XXX in Schizophrenia with Alcohol Use Disorder

INVESTIGATOR EXPERIENCE (*continued*):

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

A Phase III, Multicenter Study to Assess the Long-Term Safety and Tolerability of XXX in Subjects with Schizophrenia

A Phase III Study to Determine the Antipsychotic Efficacy and Safety of XXX in Adult Subjects with Acute Exacerbation of Schizophrenia

A Phase III, Multicenter Study to Assess the Long-Term Safety and Tolerability of XXX in Subjects with Schizophrenia

A 24-Week, Double-Blind, Placebo-Controlled, Parallel-Arm, Fixed-Dose Study to Evaluate the Efficacy and Safety of XXX as Adjunctive Therapy in Adults with Schizophrenia

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

A Randomized, Double-Blind, Placebo-Controlled, Parallel, 12-Week, Phase II Study of Two Different Doses of an Alpha-7 Nicotinic Acetylcholine Receptor Agonist XXX or Placebo in Schizophrenia Subjects on Chronic Stable Antipsychotic Therapy

A Randomized, Double-Blind, Placebo-Controlled, Parallel, 26 Week, Phase III Study of 2 Doses of an Alpha-7 Nicotinic Acetylcholine Receptor Agonist XXX or Placebo as an Adjunctive Pro-Cognitive Treatment in Schizophrenia Subjects on Chronic Stable Atypical Antipsychotic Therapy

A Multi-Center 26-Week Extension Study to Evaluate the Safety and Clinical Effects of Prolonged Exposure to 1 and 2 mg Doses of XXX, an Alpha-7 Nicotinic Acetylcholine Receptor Agonist, as an Adjunctive Pro-Cognitive Treatment in Subjects with Schizophrenia on Chronic Stable Atypical Antipsychotic Therapy

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of XXX in the Prevention of Relapse in Patients with Schizophrenia.

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

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

A Phase III, 6-Month, Open-Label, Single-Arm Safety Study of Flexibly-Dosed XXX Extended Release (1.5-12 mg/day) in the Treatment of Adolescents 9-17 Years of Age) with Schizophrenia

INVESTIGATOR EXPERIENCE (*continued*):

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (50 mg eq, 100 mg eq and 150 mg eq) of XXX in Subjects with Schizophrenia

A Blinded-Initiation Study of Medication Satisfaction in Subjects with Schizophrenia Treated with XXX ER After Suboptimal Response to Oral Risperidone

A Single-Arm Study to Evaluate Adherence to Treatment with, and Safety and Tolerability of, the XXX Device System in Subjects with Schizophrenia or Bipolar I Disorder Who are Currently on Maintenance Therapy with XXX

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

A Phase II, Multi-Center, Double-Blind, Placebo-Controlled Comparator Study of 2 Doses of XXX Versus Placebo in Patients with DSM-IV-TR Schizophrenia

A Long-Term, Open-Label, Multi-Center Study of XXX Compared to Atypical Antipsychotic Standard of Care in Patients with DSM-IV-TR Schizophrenia

Long-Term, Open-Label, Safety Study of XXX in Patients with Schizophrenia

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

A Phase III, Multi-Center, Double-Blind Comparison of XXX and XXX in Patients with DSM-IV-TR Schizophrenia Followed by Open-Label Treatment with XXX

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

A Phase III, Multi-Center, Double-Blind, Placebo-Controlled Study of 3 Doses of XXX Monohydrate in the Acute Treatment of Patients with DSM-IV-TR Schizophrenia

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

XXX versus XXX in the Treatment of Acutely Ill Patients with Schizophrenia

An Open-Label Study of Intramuscular XXX Depot in Patients with Schizophrenia or Schizoaffective Disorder

INVESTIGATOR EXPERIENCE (*continued*):

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

A Phase II, 6-Week, Double-Blind, Placebo-Controlled, Multicenter Trial of XXX for Cognitive Impairment in Subjects with Schizophrenia

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, 16-Week Study of the Safety and Efficacy of XXX Used as an Augmentation Therapy in the Treatment of Patients with Chronic Schizophrenia Demonstrating an Inadequate Response to Quetiapine or Risperidone Monotherapy

A Randomized, Double-Blind, Comparison of the Efficacy and Safety of XXX, XXX, or Placebo in the Treatment of Acutely Agitated Patients with a Diagnosis of Schizophrenia or Schizoaffective Disorder

A One-Year, Open-Label, Study to Evaluate the Safety and Tolerability of XXX Implants as a Maintenance Treatment in Patients with Schizophrenia

Interventional, Randomized, Double-Blind, Active-Controlled, Fixed-Dose Study of XXX in Patients with Schizophrenia

Interventional, Open-Label, Flexible-Dose, Long-Term Safety Study of XXX in Adult Patients with Schizophrenia

A Randomized, Double-Blind, Parallel-Group, Flexible-Dose Study Exploring the Neurocognitive Effect of XXX vs XXX in Patients with Schizophrenia Using the MATRICS Consensus Cognitive Battery

A Phase IIIb, Prospective, Matched-Control, Randomized, Open-Label, Flexible-Dose, Study in Subjects with Recent-Onset Schizophrenia or Schizophreniform Disorder to Compare Disease Progression and Disease Modification Following Treatment with XXX Long-Acting Injection or Oral Antipsychotics

A Randomized Open-Label Active Controlled Comparison of XXX 1 Month/3Month Formulations versus Oral Atypical Antipsychotics in Subjects with Recent Onset of Schizophrenia

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

A Randomized, Multicenter, Double-blind, Relapse Prevention Study of XXX 3-Month Formulation for the Treatment of Subjects with Schizophrenia

INVESTIGATOR EXPERIENCE (*continued*):

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Two Doses of XXX in the Treatment of Subjects with Schizoaffective Disorder

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

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses of XXX injected at 4-week intervals in Subjects with Symptomatic Schizophrenia

A Phase III, Randomized, Double Blind, Double-Dummy Parallel-Group Study to Evaluate the Efficacy and Safety of XXX (50mg eq.) Administered Every 4 Weeks and XXX (25 mg) Administered Every 2 Weeks in Subjects with Schizophrenia

A Randomized, Double-Blind, Parallel-Group, Comparative Study of XXX (50mg-EQ) and Risperidone Long-Acting Intramuscular Injection (25mg) in Subjects with Schizophrenia

A Fifteen-Month, Prospective, Randomized, Active-Controlled, Open-Label, Flexible-Dose Study of the Prevention of Significant Treatment Events with XXX Compared with Oral Antipsychotic Treatment in Adults with Schizophrenia Recently Discharged from Jail

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

A Prospective, Randomized, Active-Controlled, Rater-Blind, International Study of the Prevention of Relapse Comparing XXX in Adults with Recently-Diagnosed Schizophrenia Who Are at High Risk of Relapse

A Phase IIb/III, Multi-center, Prospective, Randomized, Placebo-controlled, Sequential Parallel Comparison Design (SPCD) Study of the Safety and Efficacy of XXX , a D-Amino Acid Oxidase Inhibitor, as an Add-on Treatment for Schizophrenia in Adults

An adaptive Phase II/III, Double-blind, Randomized, Placebo-controlled, Two-Part, Dose-Finding, Multi-center Study of the Safety and Efficacy of XXX , a D-Amino Acid Oxidase Inhibitor, as an Add-on Therapy with XXX, for Residual Symptoms of Refractory Schizophrenia in Adults

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

INVESTIGATOR EXPERIENCE (*continued*):

A Sixteen-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

A 12 Week, Phase II, Randomized, Double-Blind, Placebo Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of XXX in Subjects with Cognitive Impairment Associated with 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 (90mg and 120mg) as a Treatment in Subjects with Acute Schizophrenia Over 8 Weeks (2 Subcutaneous Doses)

A Multi-Center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Monotherapy, 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 40-Week Open-Label Extension

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Trial to Examine the Efficacy and Safety of 4 Oral Doses of XXX Once Daily Over a 12-Week Treatment Period in Patients with Schizophrenia

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

A 24 Week Multi-Center, Double-Blind, Randomized, Parallel-Group, Dose Ranging Study of the Efficacy and Safety of Oral Doses of XXX 5, 10, and 30mg 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 Multi-Center, Open-Label, Parallel-Group, Randomized, Flexible Dose Study to Evaluate the Safety and Tolerability of Switching from Existing Atypical Antipsychotics to XXX in Subjects with Schizophrenia or Schizoaffective Disorder

A Randomized, Multicenter, Double-Blind, Parallel Group Study to Compare the Effects of XXX and XXX on Weight Changes in Stable Schizophrenic Patients

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

INVESTIGATOR EXPERIENCE (continued):

Validation of Intermediate Measures (VIM) Study for Clinical Trials of Cognition in Schizophrenia Treatment Units for Research on Neurocognition and Schizophrenia (TURNS)

Tardive Dyskinesia

A Phase III, Open-Label, Safety and Tolerability Study of XXX for the Treatment of Tardive Dyskinesia

An Open-Label, Rollover Study for Continuing XXX Administration for the Treatment of Tardive Dyskinesia

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Dose Titration Study to Assess the Safety, Tolerability, and Efficacy of XXX For the Treatment of Tardive Dyskinesia

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX for the Treatment of Tardive Dyskinesia in Subjects with Schizophrenia or Schizoaffective Disorder

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel, Fixed-Dose, Titration Study to Assess the Efficacy, Safety, and Tolerability of XXX for the Treatment of Tardive Dyskinesia

MEMBERSHIP:

American Society of Clinical Pharmacology (ASCP)
Schizophrenia International Research Society (SIRS)
International Society for CNS Clinical Trials and Methodology (ISCTM)
CNS Summit (Founding Member)

PRESENTATIONS AND PUBLICATIONS:

Hard M, Wehr A, von Moltke L, Du Y, Farwick S, Walling DP, Sonnenberg JG. *Pharmacokinetics and Safety of Deltoid or Gluteal Injection of Aripiprazole Lauroxil NanoCrystal Dispersion Used for Initiation of the Long-Acting Antipsychotic Aripiprazole Lauroxil*. Therapeutic Advances in Psychopharmacology 2019; Vol. 9: 1-9.

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