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AFFILIATIONS:

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

Heartland Hospice Network Office/Heartland Hospice In-Patient Unit
750 Prides Crossing, Suite 110
Newark, DE 19713-6104

EDUCATION:

1985 College of Osteopathic Medicine and Surgery D.O.
Des Moines University, Des Moines, IA

1981 B.S.
Temple University School of Pharmacy, Philadelphia, PA

RESIDENCY:

1988 Internal Medicine Residency Program
Mercy Catholic Medical Center – Darby, PA

LICENSURE:

DEA, 2013 – Present
State of Delaware, 2013 – Present
State of New Jersey, 1990 – Present
State of Pennsylvania, 1986 – Present

CERTIFICATION:

Board Eligible, Internal Medicine

GCP Training – CITI Collaborative Institutional Training Initiative, Human Research Curriculum, 12/2014

GCP Training – NIH-Web based training Course “Protecting Human Research Subject” 8/2014

PROFESSIONAL EXPERIENCE:

Medical Director of Inpatient Services, 04-2018 – Present
Hassman Research Institute, LLC., Berlin, NJ

Investigator/Sub-Investigator/Rater, 04-2018 – Present
Hassman Research Institute, LLC., Berlin, NJ

Investigator/Sub-Investigator/Rater, 2014 – 4-2018
PRA Healthsciences (Formerly CRI Lifetree) - Marlton, NJ

Medical Director, 2009 – Present
Heartland Hospice Network Office/Heartland Hospice In-Patient Unit – Newark, DE

Team Physician, 2008 – 2009
Heartland Hospice – Newark, DE

Medical Director, 2008 – Present
Heartland Homecare – Newark, DE

Medical Director, 2007 – Present
Heartland Hospice Philadelphia Office – Blue Bell, PA

Medical Director, Multiple Nursing Homes, 2006 – 2008
Genesis Health Care – Kennett Square, PA

Principal and Sub-Investigator, 2000 – 2002
Southern New Jersey Medical Institute – Stratford, NJ

Physician, 1991 – Present
Larry Shusterman, DO – Philadelphia, PA

Physician, 1988 – 1996
DeKalb Medical Center – Bridgeport, PA

INVESTIGATOR EXPERIENCE:

Phase I • ADHD • Age Associated Memory Impairment • Alzheimer's Disease • Anxiety Disorder • Bipolar Disorder • Chronic Hepatitis C • Healthy • Depression • Diabetes • Opioid Induced Constipation • Pain • Panic Disorder • Parkinson's Disease • Schizophrenia • Tourette's Disorder • Men's and Women's Health (Erectile Dysfunction, Postpartum Depression)

CLINICAL TRIAL EXPERIENCE:

Phase I Depression

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

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

Phase I Healthy

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

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

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

A Phase I, randomized, placebo-controlled, double-blind, Multiple Ascending Dose Study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics in Healthy Volunteers

A randomized, double-blind, placebo-controlled, multiple ascending dose (MAD) study in healthy subjects to evaluate the safety, tolerability and pharmacokinetics of XXX

A Randomized, double-blind, active-controlled, single-dose crossover study to evaluate the pharmacokinetics, pharmacodynamics, and safety of increasing doses of XXX compared with Percocet (10mg/325mg) following intranasal insufflation by healthy, nondependent, recreational opioid users

An open-label, randomized, two-way, crossover trial of the bioequivalence of 3 mg oral doses of XXX commercial and clinical trial tablets in healthy subjects

CLINICAL TRIAL EXPERIENCE (continued):

Phase I Schizophrenia or Schizoaffective Disorder

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

A Phase I, Multicenter, Open-Label, Dose-Escalation trial to assess the safety, tolerability and pharmacokinetics of XXX in adolescents with schizophrenia or other related psychiatric disorders

A Phase I, placebo-controlled, single ascending-dose study to evaluate the safety, tolerability and pharmacokinetics of XXX in adults with schizophrenia

A Phase I, randomized, open-label, study evaluating the pharmacokinetics of various dosing regimens of XXX in subjects with stable schizophrenia

Phase I Other Indications

A Phase I Randomized multi-center, open-label, crossover pharmacokinetic study of XXX and an oral dose of XXX under fed conditions in patients with Parkinson's Disease

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

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

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

A Phase I, randomized, double-blind, placebo-controlled, safety, tolerability, pharmacokinetic study of multiple rising doses of XXX in adult subjects with Attention-Deficit/Hyperactivity Disorder

A Phase I, randomized, double-blind, placebo-controlled, safety, tolerability, and pharmacokinetic study of multiple rising doses of XXX in adult subjects with Attention-Deficit/Hyperactivity Disorder

CLINICAL TRIAL EXPERIENCE (continued):

Phase II – IV

Alzheimer's Disease

The safety and efficacy of XXX for the prevention of Alzheimer's Disease in patients at risk

Safety and efficacy of XXX in slowing progression of symptoms of Alzheimer's Disease

An open-label, six-month extension of XXX studies XXX and XXX to prospectively evaluate the long-term safety, tolerability, and efficacy of 1 through 6 mg BID (2-12 mg/day) XXX in outpatients with probably Alzheimer's Disease

Anxiety Disorder

An open-label study of the safety, tolerability, and efficacy of medication in patients with generalized anxiety disorder

A double-blind, randomized, placebo-controlled, parallel-group, fixed-dose, study of efficacy, safety and tolerability of 30mg and 90 mg XXX extended release compared to placebo in patients with generalized anxiety disorder

A six-month, double-blind, placebo-controlled, parallel-group comparison of XXX capsules and placebo in outpatients with generalized social anxiety Disorder

Associated Memory Impairment

A Phase II, randomized, multicenter, double-blind, placebo-controlled, parallel-group study comparing XXX with placebo in subjects with age associated memory impairment (AAMI)

Attention Deficit Hyperactivity Disorder

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

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

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

CLINICAL TRIAL EXPERIENCE (continued):

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

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

A 6 -week, Randomized, Double Blind, Multicenter, Placebo-controlled, parallel-group efficacy and safety study of XXX versus placebo in subjects 6 to 12 years of age with Attention Deficit Hyperactivity Disorder

Bipolar Disorder

A Phase III, multicenter, 3-week, randomized, double-blind, placebo-controlled, parallel-group trial to evaluate the efficacy, safety and tolerability of flexibly dosed XXX compared with placebo for the treatment of Bipolar I Disorder (current or most recent episode manic)

Chronic Hepatitis C

A Phase Ib, randomized, double-blind, multiple-dose ranging study evaluating the safety, tolerability, pharmacokinetics and antiviral activity of XXX in subjects with chronic hepatitis C Virus infection

A Phase Ib, randomized, double-blind, multiple-dose ranging study evaluating the safety, tolerability, pharmacokinetics and antiviral activity of XXX in subjects with Chronic Hepatitis C Virus infection

Depression

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

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A 2015 Phase III, Multicenter study of the long-term safety and tolerability of XXX for the adjunctive treatment of major depressive disorder in adults who have an inadequate response to antidepressant therapy

A Phase III efficacy and safety study of XXX for the adjunctive treatment of major depressive disorder

A double-blind, placebo-controlled comparative efficacy study of two medications in producing remission in outpatients with major depressive disorder

A Phase II multi-center, randomized comparison of XXX versus placebo in the treatment of subjects with major depressive disorder

Safety of Open-label standard antidepressant therapy in the treatment of major depressive disorder: A 1-month follow-up after termination of Study XXX

Safety and efficacy of long-term administration of XXX in the treatment of major depressive disorder: A 4-month double-blind extension to Study XXX

A double-blind, placebo-controlled, dose-finding study evaluating the safety and efficacy of XXX and 24 mg/day (0.5, 2, 8 mg TID) in the treatment of major depressive disorder

Placebo-controlled evaluation of the safety and efficacy of XXX in the prevention of depression relapse

Fixed dose comparison of the safety and efficacy of XXX, XXX, and placebo in the treatment of major depressive disorder

A multicenter, double-blind, placebo controlled, randomized, fixed dose study of XXX in the treatment of depressed patients

Diabetes

A Phase II, randomized, double-blind, placebo-controlled, parallel group trial to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of multiple oral doses of XXX given as monotherapy to adults with Type 2 Diabetes Mellitus

A multicenter, randomized, double-blind, placebo-controlled trial of XXX in subject with Type 2 Diabetes and Diabetic Peripheral Neuropathy

Reliable inhibition of thrombocyte activity: comparison of XXX capsules, 325mg and Enteric-coated aspirin

CLINICAL TRIAL EXPERIENCE (continued):

A multiple dose clinical trial to study the safety, tolerability, pharmacodynamics, and pharmacokinetics of XXX in Type 2 Diabetes Mellitus patients

Men's & Women's Health

An Open-label proof-of-concept study evaluating the safety, tolerability, pharmacokinetics, and efficacy of XXX injection in the treatment of adult female patients with severe postpartum depression

An open, non-comparative extension study of XXX in patients with erectile dysfunction

Migraine

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

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

Pain

A randomized, double-blind, placebo-controlled, single-dose, parallel group study to evaluate the clinical efficacy and safety of XXX tablet in subjects with Chronic Non-Cancer Pain and Opioid-Induced Constipation

A randomized, double-blind, placebo-controlled, single dose, parallel group study to evaluate the clinical efficacy and safety of XXX tablets in subject with chronic non-cancer and opioid constipation who responded initially to subcutaneous methyl naltrexone injection

Panic Disorder

Flexible dose comparison of the safety and efficacy of XXX, XXX, and placebo in the treatment of panic disorder

Parkinson's Disease

A Phase Ib, 2 period, open label, multicenter, dose escalation study to evaluate the safety, tolerability, pharmacodynamics of XXX in subjects with Parkinson's Disease and motor fluctuations

A randomized, double-blinded, multiple ascending dose study in patients with early-stage Parkinson's disease to evaluate the safety, tolerability and pharmacokinetics of XXX

CLINICAL TRIAL EXPERIENCE (*continued*):

Schizophrenia

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

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

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

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

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

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

A Randomized, open-label, parallel-group study to assess the relative bioavailability of XXX and Risperdal® Consta® at 25 mg following multiple intramuscular injections in stable patients with schizophrenia and/or schizoaffective disorder

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 single-arm study to evaluate adherence to treatment with, and safety and tolerability of, the XXX system in subjects with schizophrenia or bipolar I disorder who are currently treated with oral aripiprazole

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)

CLINICAL TRIAL EXPERIENCE (*continued*):

Tourette's Disorder

An open-label, multicenter study evaluating the safety and tolerability of once daily XXX in children and adolescents with Tourette's Disorder