Mark Todd Leibowitz, M.D.
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Long Beach, CA 90806

CONTACT INFORMATION:

Site Selection and Information:
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AFFILIATIONS:

Collaborative Neuroscience Network, LLC.
12772 Valley View Street, Suite 3
Garden Grove, CA 92845

Collaborative Neuroscience Network, LLC.
19401 S. Vermont Avenue, Suite F-100
Torrance, CA 90502

Collaborative Neuroscience Network, LLC.
2600 Redondo Avenue, Suites 415 & 500
Long Beach, CA 90806

Ocean View Psychiatric Health Facility
2600 Redondo Avenue, Suite 500
Long Beach, CA 90806

EDUCATION:

1982 Doctor of Medicine
Albert Einstein School of Medicine, Bronx, New York
Alpha Omega Alpha

1978 Bachelor of Arts, Biology
Hofstra University, Hempstead, New York
Phi Beta Kappa
Summa Cum Laude

RESIDENCY & INTERNSHIP:

1983 – 1985 Resident in Internal Medicine
University of Texas, Affiliated Hospitals, Houston, TX

1982 – 1983 Internship in Internal Medicine
University of Texas, Affiliated Hospitals, Houston, TX

CERTIFICATION:

Certified by the American Board of Internal Medicine

LICENSURE:

Licensed Physician and Surgeon, State of California, License No. C41646
Licensed Physician and Surgeon, State of Texas, License No. G6445
Licensed Physician and Surgeon, State of Georgia, License No. 041335

PROFESSIONAL EXPERIENCE:

Investigator/Medical Director, Early Phase Research, February 2013 – Present
Collaborative Neuroscience Network, LLC., Long Beach, California

Internist, February 2013 – Present
Ocean View Psychiatric Health Facility, Long Beach, California

Investigator/Medical Director, January 2008 – December 2012
CEDRA Clinical Research, LLC. / Worldwide Clinical Trials, Drug Development Solutions, Clinical Research Services, Austin/ San Antonio, Texas
San Antonio, TX

Director of Early Drug Development, 2005 – 2007
California Clinical Trials Medical Group, Glendale, California

Assistant Medical Director, 2004 -2005
California Clinical Trials Medical Group, Culver City/ Glendale, California

Research Physician, 2003 – 2007
California Clinical Trials Medical Group, Glendale, California

Internist, 2000 – 2007
Entertainment Industry Physicians, Hollywood, California

Staff Physician, 1998 – 2000
Western Health Services, Ontario, California

PROFESSIONAL EXPERIENCE (*continued*):

Staff Physician, 1996 – 1997
Robert Skversky, M.D., Irvine, California

Research Physician, 1995 – 2003
California Clinical Trials Medical Group, Beverly Hills, California (Facility Relocated)

Staff Physician, 1994 – 1995
Stocker Crenshaw Medical Group, Los Angeles, California

Staff Physician, 1994 – 2007
Heartwatchers, Irvine, California

Internal Medicine Specialist, 1987 – 1993
Orangewood Medical Group, Anaheim, California

Internal Medicine Specialist, 1985 – 1987
Kaiser Permanente, Panorama City, California

INVESTIGATOR EXPERIENCE:

PHASE I: Healthy Normal Subjects (Adult and Elderly) • Bioequivalence • Ethno-Bridging Studies involving CSF Sampling (Lumbar Puncture, Serial/ Continuous Collection via Lumbar Catheter)
Other Indications: Alzheimer's Disease • Anxiety Disorder • Bipolar Disorder • Depression Diabetes • Gastrointestinal Disorders • Hypertension • HIV • Insomnia • Migraine • Mild Cognitive Impairment • Multiple Sclerosis • Obesity • Osteoarthritis • Parkinson's Disease • Pre-and Post-Menopausal Psoriasis • Psychotic Disorders • Schizophrenia and Schizoaffective Disorders
Additional: 200+ Bioequivalence & Ethno Bridging • 70+ Healthy Normal • 40+ First In Man (FIM)

CLINICAL RESEARCH EXPERIENCE:

PHASE I Healthy Normal – Adult (70+ protocols in healthy normal subjects including First-in-Man)

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, Multiple Ascending Dose Study to Determine the Safety, Tolerability and Pharmacokinetices of XXX Oral Solution in Healthy Adults

A Phase I Open-label, Dose-escalating, Non-randomized, Single-Center Study to Determine the Safety and Pharmacokinetic Profiles of XXX in Healthy Volunteers

CLINICAL RESEARCH EXPERIENCE (*continued*):

A Phase I, Double-blind, Placebo-controlled Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Single Doses of XXX in Healthy Adults and in Adults with ALS

A Phase I, Randomized, Open-label, Single-Dose, Two-Way Crossover Study to Assess the Relative Bioavailability of 5 mg of XXX vs. XXX in Healthy Subjects Followed by a Phase to Study Food Effect on the PK Profile of XXX

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

A Phase I Single Dose Crossover Comparative Bioavailability and Food Effect Study of a New Formulations of XXX vs. the Original Fixed-Dose Combination Formulation of XXX and XXX in Healthy Male Volunteers

A Phase I, Double-Blind, Placebo-Controlled, Randomized, 2 Stage, 2 Way Crossover Study of a Single Oral Dose of XXX in Healthy Adult Subjects

A Phase I Study of the Safety, Tolerability and Pharmacokinetics of XXX in Healthy Normal Volunteers

A Phase I, combined single and multiple rising dose study of the safety and pharmacokinetics of XXX combination

A Phase I, Reliability and validity of an online neurocognitive test battery, the XXX Test, in normal healthy adults

A Phase I uncontrolled, sequential cohort study in healthy subjects to assess the safety and tolerability of multiple-dose administration of XXX , assess the pharmacokinetics (PK) of XXX following multiple-dose administration, and assess the effect of dose titration schedules on the tolerability of XXX in healthy male subjects

A Phase I, prospective, randomized, double-blind, placebo-controlled, sequential-cohort, escalating, single-dose study designed to determine the maximum tolerated oral dose of XXX in healthy, male volunteers

An Exploratory Investigation of Continuous CSF Sampling in Healthy Male Volunteers.

Bioequivalence Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX

A Double-Blind, Placebo-Controlled, Single and Multiple Dose Study to Evaluate the Pharmacokinetics, Safety, Tolerability, and Food Effects of XXX in Healthy Normal Volunteers

A Randomized, Placebo-Controlled, Double-Blind, Single Ascending Dose Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX in Healthy Volunteers

CLINICAL RESEARCH EXPERIENCE (*continued*):

An Open-Label, Single-Dose, Non-Randomized Study of the Mass Balance and Metabolic Disposition of Orally Administered 14C-Labeled XXX in Healthy Male Subjects

An Open-Label, Pharmacokinetic Interaction Study Evaluating the Reciprocal Effect of XXX and Divalproex Sodium (Depakote® ER) in Normal Volunteers

An Open-Label Crossover Study Assessing the Relative Bioavailability and Food Effect of XXX in Healthy Subjects

A Multiple Dose Metabolic Profiling Study of XXX Tablets, USP 200 mg

A Study to Assess XXX Pharmacokinetics Following Single and Multiple-Dose Administration of XXX Tablets in Healthy Male Subjects

An Open-Label, Randomized, 3-way, 6-Sequence, Crossover Study in Healthy Adult Volunteers to Evaluate Pharmacokinetics of XXX 100mg and 200mg (1x100mg and 2x100mg) and Food Effect on the Bioavailability of XXX 200mg

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Intravenous XXX in Healthy Subjects

A Phase I, Single Center, Randomized, Double-Blind, Placebo-Controlled, Ascending, Single and Multiple Dose, Safety, Tolerability, Pharmacokinetic, and Pharmacodynamic Study of Orally Administered XXX in Healthy Adult Volunteers

A Multiple Dose, Steady State Dose Proportionality Study of XXX Injection 50 mg and 100 mg Administered Intravenously and XXX 50 mg and 100 mg (XXX Tablet) Administered Orally in Healthy Volunteers

A Clinical Study to Evaluate a Modified Serial CSF Sampling Method by Indwelling Lumbar Catheter in Healthy Volunteers

An Open Label Study to Assess the Pharmacokinetic Properties of XXX at Steady State in the Cerebrospinal Fluid of Healthy Volunteers

A Phase I, Single blind, Randomized, Placebo-Controlled, Multiple Ascending Dose, Safety, Tolerability, and Pharmacokinetic Study of XXX with Investigation of Norepinephrine Transporter Blockade

A Multiple-Dose Single-Arm Pharmacokinetics Study of XXX 200 mg Tablets (2 x 100 mg) Following 2-Day Administration in Healthy Adult Volunteers Under Fasting Condition

CLINICAL RESEARCH EXPERIENCE (*continued*):

A Randomised Combination Single and Double Blind Dose Escalation Study to Evaluate the Safety and Dose Response Relationship of XXX in Healthy Volunteers when given by Subcutaneous Injection as a Single Dose

A Single-Dose, Open-Label Pharmacokinetic and Mass Balance Study of XXX Capsules and Microtrace 14c -Labeled XXX Oral Solution in Healthy Subjects

A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single Ascending Doses of XXX in Healthy Male Subjects

A Phase I, Randomized, Open-Label, Two-Way Crossover Study of Two Oral Formulations of XXX in Healthy Human Subjects

An Open-label Study Assessing the Mass Balance of a Single Oral Dose of 14C -XXX

Placebo-Controlled, Single Ascending Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX in Healthy Volunteers

A single 400 mcg (solution) oral dose of XXX and a tracer amount of 14C-XXX (investigational product)

A single 300 mg (solution; 56.3 mL total volume) oral dose of XXX and a single 0.6 mg (1 tablet) oral dose of XXX under fasted conditions

A single oral dose solution containing 80 mg of XXX and 75μCi of 14C- XXX under fasted conditions

A Single-Ascending Dose Study To Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX in Healthy Volunteers

An Open-label, Randomized, Crossover Study to Assess the Pharmacokinetics, Pharmacodynamics and Tolerability of XXX in Healthy Subjects after Switching from XXX or XXX

A Multiple-Dose, Dose Titration Study to Assess the Safety, Tolerability, and Steady State Pharmacokinetics of XXX in Healthy Volunteers

A single active or placebo dose of the study drug XXX by subcutaneous injection under fasted conditions

The Effect of XXX on Sleep Parameters in Healthy Male Volunteers

CLINICAL RESEARCH EXPERIENCE (*continued*):

A Phase I, Open Label Crossover Study to Evaluate the Effect of XXX on XXX Pharmacokinetics in Healthy Adult Subjects

A Double-Blind, Randomized, Active Comparator Study of XXX versus XXX for Seven Days in Healthy Subjects with Endoscopic Evaluation

A Single and Multiple Dose Study of XXX and Interaction Study of XXX and Midazolam

A Phase I, Comparative, Randomized, Single Dose, Crossover Study to Evaluate the Plasma Pharmacokinetics of Four XXX Formulations Followed by a Placebo-Controlled, Double-Blind 7-Day Multi-Dose Safety and Tolerability Assessment in Health Adult (45-65 years) Subjects

A Randomized, Double-Blind, Placebo-Controlled Study to Compare the Pharmacokinetics of 2 Doses and 7 Day Multi-Dose Safety, Tolerability and Pharmacokinetic Assessment of XXX in Healthy Adults (45-65 years**)**

An Evaluation of the Safety, Tolerability, Pharmacokinetics of XXX Following 5 Day Oral Administration

Multiple-Ascending-Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics of XXX Following Intravenous Administration

An Open-Label, Single-Dose, Pilot Study to Determine the Maximum Tolerated Dose, Pharmacokinetics and QTc Effects of XXX

Pharmacokinetics Study of XXX in the Cerebrospinal Fluid

Single Escalating Dose Safety, Pharmacokinetics and Pharmacodynamics Assessment of XXX

Open Label Crossover Study to Evaluate the Effect of XXX on the Pharmacokinetics of XXX in Healthy Normal Volunteers

A Multiple Dose, Open Label Dose-Escalation Study of Transdermal XXX Gel in Healthy Male Volunteers

A Study Evaluating Plasma and CSF XXX and Amyloid-beta Concentrations in Healthy Adult Subjects

An Open-Label, Single-Sequence Crossover, Pharmacokinetic Interaction Study of Repeated Oral 900-mg Daily Doses of St. John's Wort on the Pharmacokinetics of a 20-mg Single Oral Dose of XXX in Healthy Subjects

CLINICAL RESEARCH EXPERIENCE (*continued*):

An Investigator-and Subject Blinded Randomized Placebo-Controlled, Two-Period Crossover Study in Healthy Subjects to Evaluate the Pharmacodynamic Effects of Single Oral Doses of XXX on Aß Concentrations in Cerebrospinal Fluid Using Serial Sampling Methodology

Placebo-Controlled, Multiple-Dose Study to Evaluate the Pharmacodynamics, Pharmacokinetics, and Safety of XXX in Healthy, Right-Handed Female Subjects Using Electrophysiological Methodologies

A Study to Evaluate the Effects of a Single Oral Dose Administration of XXX in the Cerebrospinal Fluid of Healthy Young Males

Effect of 2-week Administration of XXX, a Selective Glucocorticoid Antagonist, on CSF and Peripheral Stress-System Peptides and Hormones in Healthy Male Subjects

Pharmacokinetic Interaction of Repeated Oral 240-mg Doses of Diltiazem on Pharmacokinetics of XXX 20-mg Single Oral Dose in Healthy Subjects

A Single-Center, Multiple Ascending Dose, Open-Label, Parallel Group Study to Investigate the Pharmacodynamics, Pharmacokinetics, Safety and Tolerability of XXX in Healthy Male Volunteers

A Methodology Study to Evaluate the Variability of Aß Peptide Levels in the Cerebrospinal Fluid (CSF) of Healthy Human Subjects When Collected Serially over Two Study Sessions Separated by 10 Days

An Open-Label, Randomized, Two Treatment by Two-Sequence Crossover Pharmacokinetic Interaction Study to Assess the Effect of 10-day Repeated Oral Doses of XXX 100 mg OD on the Steady-State Serum Concentrations of Lithium (300 mg BID) in Young Healthy Male and Female Subjects

A Pharmacodynamic Study to Assess the Glycinergic Responses in Cerebrospinal Fluid and Plasma after Single Oral Doses of XXX in Healthy Male Volunteers

A Two Part, Double-Blind, Randomized, Two Period Crossover Study to Evaluate the Ability of Single and Multiple Doses of XXX to Reduce Levels of the Aβ Peptide in Cerebrospinal Fluid Collected by Lumbar Puncture in Healthy Subjects

A Study to Evaluate the Effect of Single and Multiple Doses of Rifampin on the Pharmacokinetics of XXX

A Study to Evaluate the Ability of Single Oral Doses of XXX to Reduce Cerebrospinal Fluid Levels of the Aβ Peptide Over a 12-30-Hour Period in Healthy Male Subjects

CLINICAL RESEARCH EXPERIENCE (*continued*):

A Multiple-Dose, Dose-Escalation Study with XXX to Evaluate the Safety and the Pharmacokinetics of XXX and XXX in the Plasma and Cerebrospinal Fluid in Healthy Subjects

Protein Profiling of Plasma and Cerebrospinal Fluid in Healthy Subjects

Pharmacokinetic Evaluation of XXX in Healthy Volunteers

A Placebo-Controlled Study of the Electrophysiological Effects of Female Supratherapeutic Doses of XXX on the QT Interval

An Exploratory Study of XXX Effects on Plasma and CNS Biomarkers of Norepinephrine Transporters (NET) Inhibition

Cerebrospinal Fluid Penetration of XXX Compared with XXX and Assessment of the ABC Drug Transporter Protein MDR1

A Two Part Study to Characterize the Histology and Clinical Features of Rash Associated with XXX and to Assess the Potential for Cross-Sensitization to Another Quinolone in Healthy Female Volunteers

XXX Cerebrospinal Fluid Pharmacokinetics in Healthy Human Subjects

Single Dose Escalation Safety Study of XXX

A Double-Blind, Escalating Single-Dose, Safety, Tolerability, and Pharmacokinetic Study of XXX in Healthy Male Volunteers

Exploratory Genotyping of Ethnic Koreans to Ascertain Polymorphic Traits in Drug Transporter Proteins and Metabolic Enzymes

An Open Label, Repeat Dose Study to Determine the Concentration Profile of XXX in the Cerebrospinal Fluid of Healthy Subjects Following 300 mg Oral Dose of XXX Administered Once Daily for 7 Days

Penetration of XXX into Cerebrospinal Fluid in Man Following the Intravenous Infusion of XXX

PHASE I Healthy Normal - Elderly

A Phase I / II, randomized, double-blind, placebo-controlled study to assess the effect of 3 month multiple oral doses of XXX on safety, tolerability, pharmacokinetics and pharmacodynamics in healthy elderly subjects

CLINICAL RESEARCH EXPERIENCE (*continued*):

A Randomized, Placebo-Controlled, Double-Blind, Multiple Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX in Healthy Elderly Subjects

A Single-blind Study to Assess the Effect of XXX on the Electrocardiogram (ECG) in Elderly Subjects

A Double-blind, Placebo-controlled, Single, Escalating Dose Study to Evaluate the Preliminary Pharmacokinetics, Safety, and Tolerability, of XXX in Healthy Elderly Volunteers

A Single-Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX in Healthy Elderly Subjects

A Multiple- Ascending-Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics of XXX following Intravenous Administration

A Double Masked Placebo-Controlled Study Evaluating the Safety Tolerability, Pharmacokinetics and Pharmacodynamics and Immunogenicity of Single Escalating Doses of XXX in Patients with AMD

A Study to Evaluate the Effect of Multiple Doses of XXX on the Single Dose Pharmacokinetics of XXX

A Single and Multiple Dose Study of XXX and Interaction Study of XXX and XXX

A Multiple Dose Study of XXX in Healthy Elderly Subjects

Placebo-Controlled, Ascending Multiple Dose Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of XXX

Placebo-Controlled, Ascending Multiple-Dose Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of XXX in Healthy Young and Elderly Subjects

PHASE I and Early Phase - Special Patient Populations

Alzheimer's Disease /Mild Cognitive Impairment

An Open-Label, Multiple-Dose Study to Assess the Safety and Tolerability of Twice Weekly Plasma Infusions from Young Male Donors in Subjects with Mild to Moderate Alzheimer's Disease

A Prospective, Randomized, Double-Blind, Dose-Comparison Concurrent Control Study to Assess the Safety and Tolerability of XXX Infusions in Subjects with Mild to Moderate Alzheimer's Disease

CLINICAL RESEARCH EXPERIENCE (*continued*):

Experimental Medicine Study to Evaluate the Kinetics of Cerebrospinal Fluid Biomarkers in Subjects with Alzheimer's Disease and Progressive Supranuclear Palsy Compared to Healthy Subjects Using a XXX Labeling Method

An Open-Label, Two-Stage Study to Evaluate the Pharmacokinetics and Pharmacodynamics of XXX in Plasma and Cerebrospinal Fluid (CSF) after a 10-Day Treatment Period in Subjects with Amnestic Mild Cognitive Impairment (MCI)

Crossover Study of XXX and Immediate-release XXX in Healthy Adult Subjects to Compare Pharmacokinetics and Pharmacodynamic Effects on Cognition

A Single Dose Study of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX in Blood and Cerebrospinal Fluid, when Administered Orally to Healthy Young Subjects and Patients with Alzheimer's Disease

Assessment of Alzheimer's Disease Bio-Markers in Healthy Male Subjects

Comparison of Serum and Cerebrospinal Fluid Pyruvate Concentrations in Subjects with Alzheimer's Disease (AD), Subjects with Mild Cognitive Impairment (MCI) and Healthy Elderly Subjects

Over 25 Early Phase Protocols which Examined Cognitive Efficacy and PK/PD Measures in a Wide Variety of Study Designs Including Inpatient Bridging (MTD) Studies, Proof-Of-Concept, Early Stage Methodological and Long Term Maintenance Studies. Extensive experience in the use of Single and Serial/Continuous CSF Sampling for PK and Biomarkers in AD and MCI Patients as well as healthy volunteers (young and elderly) Wide Spectrum of Compounds Studied Including Cholinesterase Inhibitors, Muscarinic Agonists, Nicotinic Agonists, Beta and Gamma Secretase Inhibitors, Vaccines (Active and Passive Immunization Trials) and Other Disease-Modifying Agents. Also conducted many studies in MCI.

Anxiety / Depression

A Phase IIa Study to Compare the Safety, Tolerability and Initial Efficacy of XXX IR, given with XXX in Patients with Major Depressive Disorder

APhase I, Single-center, Randomized, Investigator/ Subject-blind, Placebo-controlled, Multiple--ascending Dose, Semi-sequential Adaptive Study to Investigate the Safety, Tolerability and Pharmacokinetics of XXX Following Oral Administration in Healthy Subjects and in Patients with Major Depressive Disorder

Single Blind, Placebo Controlled, Multiple Ascending Dose Study of XXX Administered Orally for 14 Days to Evaluate its Safety and Tolerability

CLINICAL RESEARCH EXPERIENCE (*continued*):

An Exploratory Cerebrospinal Fluid Collection Study in Healthy Normal Subjects and Patients with Major Depressive Disorder and Generalized Anxiety Disorder

Over 20 Protocols, from Early Phase (MTD) and Proof-Of-Concept Studies to Late Stage Efficacy and Maintenance Trials in MDD, Mixed Depression and Anxiety, Elderly Depression and Dysphoric Disorder. Additionally, Over 20 Protocols Involving Generalized Anxiety Disorder, Obsessive Compulsive Disorder, Panic and Social Anxiety Patients.

Ethno-Bridging

A Phase I, Randomized, Double-blind, Placebo-controlled Trial to Assess the Tolerability, Safety, and Pharmacokinetics of Ascending Single Oral Tablet Doses of XXX in Healthy Subjects and in Healthy Japanese Subjects and the Effect of a High-Fat Meal.

A Phase Ib, Randomized, Controlled, Double-blind Trial to Evaluate the Safety and Immunogenicity of Multivalent Pneumococcal Conjugate Vaccines in Healthy Japanese Adults Aged 18 to 49 Years

A Phase I Investigator/Subject Blind, Randomized, Placebo-controlled Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single Doses of XXX in Healthy Japanese Subjects

A Phase I Rising Single and Multiple Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX in Healthy Adult Japanese Subjects

A Randomized, Double-blind, Placebo-Controlled Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics Following Ascending Single Doses of a Prolonged Release Tablet of XXX in Healthy Male Japanese Subjects

A Single-center, Open-Label, Single Dose, Exploratory Study in Caucasian and Japanese Healthy Subjects to Investigate the Pharmacokinetics of XXX and its Metabolite in Plasma and Cerebrospinal Fluid

A Randomized, Open-Label, Cross-Over Study to Characterize the Pharmacokinetics of XXX From Single Doses of Noncolored Buccal Tablets Over the Dose Range of 100 through 800 mcg in Healthy Japanese Subjects Residing in the United States

Safety, Tolerance, and Pharmacokinetic Evaluation of Multiple Doses of XXX in Healthy Caucasian and Japanese Adults

A Double-Blind, Placebo-Controlled, Ascending Single Dose Study of XXX in Caucasian and Japanese Healthy Subjects

CLINICAL RESEARCH EXPERIENCE (*continued*):

Double-Blind, Placebo-Controlled, Ascending Single-Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX in Healthy Japanese and Non-Japanese Subjects

A Single Dose, Open Label Study in Healthy Subjects Comparing the Pharmacokinetics of XXX Between Caucasian and Japanese Subjects

A Single-Blind, Randomized, Placebo-Controlled Ascending Repeat Dose Study in Japanese Male Subjects

Safety, Tolerability, Pharmacokinetic and Pharmacodynamic Evaluation of Multiple Oral Doses of XXX in Healthy Japanese and Caucasian and Adults

Single- and Multiple-Dose Study to Evaluate and Compare the Pharmacokinetics of XXX Between Healthy Japanese and Caucasian Men

Ascending Single Dose Study of the Safety, Tolerability, and Pharmacokinetics of XXX Administered Orally to Healthy Japanese Men

A Comparison of XXX Repeating Single-Dose Pharmacokinetics in Healthy Japanese and Caucasian Subjects

Safety, Pharmacodynamic and Pharmacokinetic Study of Oral Multiple Doses of XXX in Healthy Young Male Japanese Volunteers and Their Matching Healthy Caucasian Male Volunteers. Double-Blind, Randomized, Placebo Controlled, Escalating Doses Study

A Randomized, Open-Label, Crossover Study to Evaluate the Effect of Food on the Pharmacokinetics of XXX in Healthy Japanese Subjects

Safety, Pharmacodynamic and Pharmacokinetic Study of Oral Single Doses of XXX in Healthy Young Male Japanese Volunteers and Their Matching Healthy Caucasian Male Volunteers (Double-Blind, Randomized, Placebo Controlled, Escalating Doses Study)

An Open-Label Study to Compare the Cytochrome P450-Mediated Metabolizing Ability Among First and Third Generation Japanese Residing Outside of Asia and Caucasians

Influence of XXX Genotype and Race on the Pharmacokinetics of XXX in Healthy Male Subjects Following Oral Dosing

XXX in Healthy Japanese-American and Caucasian Subjects: An Open-Label Comparison of the Pharmacokinetics of Ascending Doses

CLINICAL RESEARCH EXPERIENCE (*continued*):

An Open-Label, Non-Randomized, Parallel-Group Study to Assess the Influence of Smoking and Ethnicity on XXX Pharmacokinetics Following a Single XXX mg Oral Dose in Healthy Male and Female Volunteers from Four Ethnic Groups

Bipolar/ Schizophrenia/ Schizoaffective/Psychotic Disorders

A Phase I, Interventional, randomized, double-blind, parallel-group, active-control, multiple-dose study investigating the effect of XXX on cardiac repolarization in men and women with schizophrenia and schizoaffective disorder

The Effect of XXX on Blood Glucose Levels in Stable Schizophrenia Patients with Impaired Glucose Tolerance

Randomized, Double-Blind, Placebo-Controlled, Ascending Multiple Dose Study of the Safety, Pharmacokinetics, and Pharmacodynamics of XXX Administered Orally to Healthy Subjects and Subjects with Schizophrenia and Schizoaffective Disorder

An Open Label, Parallel Group, Randomized, Single Sequence Study to Characterize the Pharmacokinetics of XXX (200 mg twice daily and 400mg once daily) Administered as Single and Repeat Doses for 14 days in Patients With Schizophrenia and Healthy Volunteers

XXX: Effect of Single Oral Dose on Sensory Gating in Healthy Relatives of Schizophrenics with Abnormal P50 Gating

Over 50 Protocols in Schizophrenia (Stable, Acutely Agitated, Negative Symptoms), Schizoaffective Disorder, and Bipolar Disorder

Other Indications

Over 50 Specialized Patient Population Studies including Diabetes, Gastrointestinal Disorders, Hypertension, HIV, Insomnia, Migraine, Multiple Sclerosis, Obesity, Osteoarthritis, Parkinson's Disease, Psoriasis, Pre- and Post-Menopausal.

An Experimental Medicine, Randomized, Double-Blind Study Assessing Neuropsychiatric Symptoms in Quitting Smokers treated with XXX or Placebo

A Study to Assess Estradiol Bioavailability and the Safety and Tolerability of XXX in Healthy Postmenopausal Women

A Phase I, Open Label, Drug Interaction Study Evaluating the Effect of XXX Fixed-Dosed Combination Tablet on the Pharmacokinetics of a Representative Hormonal Contraceptive Medication, Norgestimate/Ethinyl Estradiol

CLINICAL RESEARCH EXPERIENCE (*continued*):

A Single-blind, Placebo-controlled, Multiple Ascending Dose Study with XXX Administered Orally to Healthy Obese Subjects for 14 Days to Evaluate its Safety, Tolerability, and Pharmacokinetics

Additional Experience

Have Conducted Numerous Specialty Studies such as Bridging (MTD) Studies (up to 44 days inpatient), PK/PD, Bioequivalence, Drug-Drug Interaction (DDI) and QTc Studies.