

Diane K. Combs, M.D.
Albuquerque Neuroscience, Inc.
101 Hospital Loop NE, Suite 209
Albuquerque, NM 87109
Tel. 505-848-3773

CONTACT INFORMATION:

Site Selection and Information:
Bobbie Theodore, Alliance Director
Tel. (916) 939-6696
Fax (208) 575-3169
Email: clinicaltrials@alliancesites.com

EDUCATION:

1976-1980 MD Degree
University of Southern California, Los Angeles, CA

1972-1976 BS Degree Cum Laude Biology
University of Southern California College of Letters, Arts and Sciences, Los Angeles, CA

INTERNSHIP & RESIDENCE:

1980-1983 Internship and Residency
Family Practice, Glendale Adventist Medical Center, Glendale, CA

CERTIFICATIONS AND LICENCES:

1993-present	New Mexico Board of Medical Examiners license #93-26
1993-present	California State Board of Medical Examiners, inactive
2008-2015	Recertification ABFP
2001-2009	Recertification ABFP
1995-2002	Recertification ABFP
1989-1996	Recertification ABFP
1983	Board Certification, American Board of Family Practice
1980-1993	California State Board of Medical Examiners, active
1978-1980	National Board of Medical Examiners

INVESTIGATOR EXPERIENCE:

Alzheimer's Disease • Anxiety • Bipolar Disorder • Constipation
Depression • Fibromyalgia • Migraine • Influenza • Insomnia
Post herpetic Neuralgia • Schizophrenia • Type 2 Diabetes Mellitus

PROFESSIONAL EXPERIENCE:

Principal Investigator and Sub-Investigator, July 2010-Present
Albuquerque Neuroscience Inc., Out Patient Research Clinic, Albuquerque, NM

Board of Directors (also served as President and Medical Director), 1993 - Present
Full-time Practicing Physician in Family Practice, 1993 - Oct. 2013
Partner and Board Member, 1993-2012
Southwest Medical Associates Multi-specialty Medical Group, Albuquerque, NM

Medical Consultant, 1988-1993
CPC Hospital Psychiatric Inpatient Facility, Brea, CA

Chairperson, 1987-1988
Medical Records Committee, San Dimas Community Hospital, San Dimas, CA

Partner and Practicing Physician, 1985-1993
President, Vice-President, Secretary at various times, 1985-1993
Family Medical Group of Diamond Bar, Diamond Bar, CA

Physician, 1983-1984
Diamond Bar Medical Group, Diamond Bar, CA

Research Fellow, 1976-1978
LAC-USC Women's Hospital-Sudden Infant Death Research, Los Angeles, CA

MEMBERSHIP:

Member, American Academy of Family Physicians
Member, Greater Albuquerque Medical Association
Member, Society of Teachers of Family Medicine 1991-1993
Member, New Mexico Medical Society

CLINICAL TRIAL EXPERIENCE:

Alzheimer's Disease

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of XXX in Subjects with Alzheimer's Disease

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety study of XXX in Patient's with Prodromal to Mild Alzheimer's Disease

A Phase III, Randomized, Double-Blind, Placebo Controlled, Multi-Center Registration Trial to Evaluate the Efficacy and Safety of XXX in Patients with Mild Alzheimer's Disease Receiving Acetylcholinesterase Inhibitors and/or XXX

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Continued Efficacy and Safety Monitoring of XXX, an Anti-Amyloid β Antibody in Patients with Alzheimer's Disease

A Phase III, Effect of Passive Immunization on the Progression of Mild Alzheimer's Disease: XXX Versus 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 III, Randomized, Double-Blind, Placebo- Controlled, Parallel Group, 26-Week, Study of Two Doses of XXX or Placebo in Subjects With Mild to Moderate Alzheimer's Disease Currently or Previously Receiving an Acetylcholinesterase Inhibitor Medication

A Phase III, 26-Week Extension Study of the Safety and Clinical Effects of XXX in Subjects with Alzheimer's Disease Currently or Previously Receiving an Acetylcholinesterase Inhibitor Medication

Anxiety

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

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

Bipolar Disorder

A Phase III, Randomized, Double- Blind, Placebo-Controlled, Study to Evaluate the Efficacy and Safety of Once a Day, XXX 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 Phase III, Randomized, Double-Blind, Placebo-Controlled, Study to Evaluate the Efficacy and Safety of Once a Day, XXX 0.1, 0.4, and 0.8mg as an Adjunctive Therapy to Treatment as-Usual in the Maintenance Treatment of Bipolar 1 Disorder in Adult Subjects

Constipation

A prospective, multicenter, randomized, double-blind, Sham-controlled study to assess the efficacy and safety of the XXX capsule administered 5 times per week, XXX Chronic Idiopathic Constipation

A Safety & Efficiency Study of the XXX Capsule in Aiding Patients with Functional Constipation

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multinational, Multicenter, Prospective Double-Blind, Sham Controlled, Randomized Study to Assess the Performance, Efficacy and Safety of Vibrating Capsule Medical Device in Aiding Relieving Constipated Individuals

A Phase III, 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 Multinational, Multicenter, Prospective Double-blind, Sham Controlled, Randomized Study to Assess the Performance, Efficacy and Safety of Vibrating Capsule Medical Device in Aiding Relieving Constipated Individuals

An Open-Label Extension (OLE), Long-term Safety' and Tolerability Study of XXX in Patients with Chronic Idiopathic Constipation (CIC)

Depression

A Phase III, Randomized, Double-blind, Placebo-controlled Study of the Efficacy and Safety of XXX with a Fixed, Repeated Treatment Regimen on Relapse Prevention in Adults with Major Depressive Disorder

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

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

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

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

A Phase III, Double-Blind, Placebo-Controlled Study of XXX as Adjunctive Therapy in Major Depressive Disorder

A Phase III, long-term, open-label study of safety and tolerability of XXX as adjunctive therapy in major depressive disorder

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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 IV Freestyle XXX Glucose Monitoring System Post Approval Study for Pediatric Patients

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 Multicenter, Randomized, Open-Label Extension Study to Evaluate Long-Term Safety and Tolerability of Oral XXX in the Acute Treatment of Migraine with Aura

A Multicenter, Randomized, Open-Label, Extension study to evaluate the Long-term Safety and Tolerability of XXX in the Acute Treatment of Migraine with or without Aura

A Phase III, Long term, Open-Label Safety Study of XXX in Patients with Migraine

Pain

A Phase II, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study of the Safety and Efficacy of a Single Treatment of XXX in Patients With Postherpetic Neuralgia

An open-label extension of XXX for 52 weeks in pain associated with Fibromyalgia

A Phase III, Randomized, Double-Blind, Placebo- and Active-Controlled Study of XXX in Subjects with Pain Associated with Fibromyalgia

Schizophrenia

A Phase II, Randomized, Sham-Controlled Study of XXX as an adjunct to standard-of-care treatment for schizophrenia

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

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

A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel, 12 Week, 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 Multicenter 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

Other Indications

A Phase III Multicenter, Open-Label Study to Evaluate the Substitution of XXX with XXX for Monotherapy of Insomnia

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

A Phase II, A Randomized, Double-blind, Parallel Group, Multicenter, Placebo-controlled, Dose-ranging Study to Evaluate the Glycemic Effects, Safety, and Tolerability of XXX Delayed-Release in Subjects with Type 2 Diabetes Mellitus

A Long-Term Multicenter, Randomized, Double-Blind, Controlled, Parallel-Group Study of the Safety and Efficacy of XXX in Subjects With Insomnia Disorder

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to evaluate the efficacy and safety of intravenous XXX in subjects with uncomplicated Influenza

APPOINTMENTS:

Novartis Pharmaceuticals, Regional Consultant--Diovan, Enablex
Staff physician, Presbyterian Hospital, Albuquerque, NM
Staff Physician, Lovelace/Sandia Health System (formerly St. Joseph's Hospital),
Albuquerque, NM
Assistant Clinical Professor, Department of Family Medicine University of Southern California,
Los Angeles, CA
Staff physician, St. Jude's Medical Center, Fullerton, CA
Staff Physician, Brea Community Hospital, Brea, CA
Staff Physician, San Dimas Community Hospital, San Dimas, CA

TEACHING EXPERIENCE:

Teaching and supervising medical students, interns, and residents,
LAC-USC Medical Center, Glendale Adventist Medical Center,
Children's Hospital of Los Angeles, Huntington
Memorial Hospital Pasadena, White Memorial Medical Center,
Kaiser-Permanente Medical Center

PRESENTATIONS:

Eli Lilly and Company, Regional Speaker -- Prozac, Evista
GlaxoSmithKline, Regional Speaker -- Imitrex, Treximet
Novartis, Local Speaker -- Enablex, Reclast

AWARDS:

Fellow, American Academy of Family Practice
Diplomate, American Board of Family Practice
Member, Presbyterian Healthcare Foundation Board
Chief Resident, Glendale Adventist Medical Center
Member, Mortar Board Society, USC
Outstanding Senior Recognition Awards, USC, 1976
Honors program and Honors at entrance, USC 1972-1976

PUBLICATIONS:

"Studies of Maternal-Fetal Interaction During the Last Trimester of Pregnancy. I. Ontogenesis of the Basic Rest - Activity Cycle." - Obstetrics and Gynecology, March 1981

"Maternal, Fetal and Neonatal Heart Rate Periodicities." - Acta. Ped. Scand. Suppl., 1977

"Long-term, Continuous Monitoring of Multiple Psychological Parameters in Newborn and Young Infants." - Acta. Ped. Scand. Suppl., 1977