Paula J. Lane, M.D.
Albuquerque Neuroscience, Inc.
101 Hospital Loop NE, Suite 209
Albuquerque, NM 87109

CONTACT INFORMATION:

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

EDUCATION:

1972 - 1976 Medical College of Georgia Augusta, Georgia
Doctor of Medicine

1969 - 1972 University of Georgia Athens, Georgia
Bachelor of Science

RESIDENCIES:

1980 -1981 Albany Medical College, Family Practice Program
Albany, New York
Family Practice Resident

1976 -1978 Highland Hospital, Division of Duke University Medical Center
Asheville, North Carolina
Psychiatry Resident

CERTIFICATION:

National Board of Medical Examiners

LICENSURE:

New Mexico #81-151

MEMBERSHIPS:

New Mexico Medical Society
Greater Albuquerque Medical Association

PROFESSIONAL EXPERIENCE:

Investigator, 2011- Present
Albuquerque Neuroscience Inc., Albuquerque, New Mexico

Investigator, 2006 - 2011
Lovelace Scientific Resources, Inc., Albuquerque, New Mexico

Investigator and Sub-Investigator, 2001 - 2006
Southwest Clinical Research, Albuquerque, New Mexico

Private Practice, 1991 - 2001
Clinical Research, Albuquerque, New Mexico

Member, 1988 - 1993
Lovelace Medical Foundation Institutional Review Board, Albuquerque, New Mexico

Director, Health Sciences Division, 1987 - 1991
Lovelace Scientific Resources, Inc., Albuquerque, New Mexico

Investigator, Clinical Trials Section, 1986 - 1987
Lovelace Medical Foundation, Albuquerque, New Mexico

Urgent Care Physician, 1984 - 1987
Lovelace Medical Center, Albuquerque, New Mexico

Contract Services, 1981- 1984
Santa Fe PHS Indian Hospital Outpatient Clinics,
New Mexico Health Services Division, Family Planning and Well-Child Clinics,
Women's Health Services Clinics, Santa Fe, New Mexico

Assistant, 1978 - 1979
Asheville Neurosurgical Associates, Asheville, North Carolina

INVESTIGATOR EXPERIENCE:

Acute Lateral Epicondylitis • Acute Low Back Pain • Acute Skeletal Muscle Spasm
Allergic Rhinitis • Alzheimer's Disease • Anxiety • Asthma • Autism Spectrum Disorder
Benign Prostatic Hyperplasia • Bipolar Disorder • Chronic Pain • Constipation • COPD
Depression • Diabetes • Fibromyalgia • Gastroesophageal Reflux Disease (GERD)
Hypercholesterolemia • Hypertension • Influenza • Insomnia • Irritable Bowel Syndrome
Migraine • Multiple Sclerosis • Neuropathic Pain • Obesity • Osteoarthritis
Overactive Bladder (OAB) • Pediculus Humanus Capitis Infestation • Peripheral Artery Disease
Post Herpetic Neuralgia • Restless Legs Syndrome (RLS) • Rheumatoid Arthritis • Schizophrenia
Tinea Pedis • Urinary Tract Infections (UTI) • Vaccines • Women's Health

ADDITIONAL TRIAL EXPERIENCE:

Dermatology • Hot Flushes • Stress Urinary Incontinence

INVESTIGATOR INTEREST:

Cardiology • Dermatology • Geriatrics • Orthopedics • Psychiatry

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 II/III, Randomized, Double-blind, Placebo-controlled, Multicenter Studies to Evaluate the Safety and Efficacy of XXX as a Treatment for Subjects With Mild Alzheimer's Disease and Impaired Glucose Tolerance

A Phase II, Randomized, Double-Blind, Placebo Controlled, parallel group study to evaluate the efficacy and safety of XXX in participants at risk for the onset of clinical symptoms of AD

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 II, 26-Week, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Investigate the Effects of Daily Administration of XXX in Participants with Mild to Moderate Alzheimer's Disease (AD) with an Optional 26-Week Open-label Extension

A 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

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

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 26-Week, Phase III 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, 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, Effect of Passive Immunization on the Progression of Mild Alzheimer's Disease: XXX Versus Placebo

CLINICAL TRIAL EXPERIENCE (*continued*):

Continued Efficacy and Safety Monitoring of XXX, an Anti-Amyloid 13 Antibody in Patients with Alzheimer's Disease

A randomized, multicenter, double-blind, placebo-controlled, 18-month study of the efficacy of the XXX in patients with mild-to-moderate dementia of the Alzheimer's type

Anxiety

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

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

Efficacy and Safety of XXX in Patients with Anxiety Disorder

Arthritis

A Phase IIIb, Multicenter, Open-Label Study to Evaluate the Long-Term Safety and Efficacy of XXX in Patients with Rheumatoid Arthritis (RA)

A Phase IV, Multi-center, Randomized, 52-Week Study to Evaluate the Routine Assessment of Patient Index Data (RAPID3) Compared to the Clinical Disease Activity Index (CDAI) to Prospectively Predict Treatment Success at 52 Weeks Based on a Treatment Decision at Week 12 in Subjects With Moderate to Severe Rheumatoid Arthritis Receiving XXX

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX in Patients with Moderate to Severe Rheumatoid Arthritis (RA) who had an Inadequate Response to one or more TNF-a Inhibitors

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of XXX in Patients with Rheumatoid Arthritis (RA) with or without Background Disease-Modifying Anti-rheumatic Drug (DMARD) Therapy

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX in Patients with Moderate to Severe Rheumatoid Arthritis (RA) who had an Inadequate Response to XXX Therapy

A Double-Blind, Double-Dummy, Randomized, Active-Comparator, Arthritis Non-Inferiority Study of XXX versus XXX for Twelve Weeks in Osteoarthritis Patients to Compare Endoscopic Gastric Ulcer Rates

A Seamless, Phase I/II, Multiple Ascending Dose, Proof of Concept Study of XXX Administered to Subjects with Active Rheumatoid Arthritis on a Background of XXX

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized Double-Blind, Placebo- and Active-Control. Parallel-arm, Phase III Trial with Controlled Adjustment of Dose to Evaluate the Efficacy and Safety of XXX Extended Release (ER) in Subjects with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee

A Randomized, Double-blind, Active Control, Parallel Arm, 90 Day Safety Study of XXX immediate Release (IR) or Oxycodone IR in Subjects With Chronic Pain From Low Back Pain (LBP) or Osteoarthritis (OA) of the Hip or Knee

A Long-Term, Open-Label, Safety Study of the XXX in Patients with Moderate to Severe Chronic Low Back Pain or with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee

An Open-Label, Safety Study with Intermittent Use of the XXX in subjects with Lower Back, Pain from Osteoarthritis of the Knee, Shoulder Pain or Lateral Epicondylitis Pain

A Double Blind, Randomized, Placebo-Controlled, Multi-Dose, Phase III, Parallel Group Study of the XXX for the Management of Moderate to Moderately Severe Chronic Pain of OA of the Hip and Knee in Adults

A Comparison of the Analgesic Efficacy and Safety of XXX Versus Placebo for the Symptomatic Treatment of the Pain and Function of Osteoarthritis

A Randomized, Double-Blind, Active- and Placebo-Controlled, Parallel Group, Dose Response Study of the Safety, Pharmacokinetics, and Effect on Pain and Function, of XXX in Subjects with Osteoarthritis of the Knee

XXX With XXX in the Pain of Osteoarthritis of the Hip or Knee

A Double-Blind Placebo-Controlled Study Comparing the Efficacy and Safety of XXX versus XXX in the Treatment of Osteoarthritis of the Knee

Safety Study of XXX Slow-Release XXX in the Treatment of Osteoarthritis of the Knee AND Open-Label Administration of XXX Slow-Release XXX in the Treatment of Osteoarthritis of the Knee

Dose-Ranging Study of XXX

XXX vs. XXX vs. XXX: A Double-Blind Comparative Study in Patients with Osteoarthritis of the Knee

A Comparison of XXX-SR Tablets with XXX Tablets in the Treatment of Patients with Osteoarthritis of the Knee

CLINICAL TRIAL EXPERIENCE (*continued*):

A Comparison of XXX-SR Tablets with XXX Tablets in the Treatment of Patients with Osteoarthritis of the Hip

A Comparison of XXX-SR Tablets 800 mg and Tablets 600 mg in the Treatment of Rheumatoid Arthritis

Asthma

The Impact of Particle Size of Aerosol Metered Dose Inhalers on the Respiratory Tract Deposition of Asthma Medications

A Phase II Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of XXX in Asthmatic Adults with Symptomatic Human Rhinovirus Infection

Focus Group Study to Gather Patient Perspective of Asthma Symptoms and Asthma Control

A randomized, multi-center, parallel group, double blind, study to assess the safety of XXX (500/400 jig) and XXX (400 lig) in adolescent and adult patients with persistent asthma.

A Double-Blind, Randomized, Placebo-Controlled Extension to the Study of XXX in Adult Patients with Chronic Asthma (Extension)

Evaluating the Psychometric Properties of Multiple Administration Modes of the Adult Asthma Control Test

A Two-week, Randomised, Double-Blind Study Assessing the Onset of Effect Questionnaire (OEQ) Administered Daily Versus Weekly in Adult Subjects (> 18 years of age) with Mild to Moderate Asthma, Receiving) XXX x 2 Actuations Twice Daily or XXX x 2 Actuations Twice Daily

A Double-Blind, Randomized, Placebo-Controlled, Multicenter, Parallel Group, Dose-Ranging Study of XXX in Adult Patients with Chronic Asthma

Autism Spectrum Disorder

A Phase II, Open-Label Extension Study Of The Safety And Tolerability Of XXX In Pediatric Patients With Autism, Asperger's Disorder Or Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS)

A Phase II, Open-Label Study Of The Safety And Tolerability Of XXX In Pediatric Patients With Autism, Asperger's Disorder, Or Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS)

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Double-Blind Placebo-Controlled, Randomized Withdrawal Study Of The Safety And Efficacy Of XXX In Pediatric Patients With Autism, Asperger's Disorder, Or Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS) Previously Treated With XXX

Bipolar Disorders

A Randomized, Double-Blind, Placebo-Controlled, Phase 3 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

A Randomized, Double-Blind, Placebo-Controlled, Phase III Study to Evaluate the Efficacy and Safety of Once a Day, XXX Table 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

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

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)

A 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 confirmatory, placebo-controlled, randomised, double-blind, single-dummy, parallel group, ratio-finding study in constipated pain patients to establish an optimal XXX-XXX ratio with an improved bowel function and a comparable analgesic efficacy compared to XXX alone

A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of XXX for the Treatment of Constipation-Predominant Irritable Bowel Syndrome (IBS-C)

An Open-Label 52-week Study to Assess the Long-Term Safety of XXX in Opioid-Induced Constipation (OIC) in patients with Non-Cancer-Related Pain

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IIb, Double-blind, Randomised, Placebo-controlled, Multi-centre, Dose-finding Efficacy and Safety Study of a Range of Doses of XXX in Patients with Chronic Idiopathic Constipation

A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel-group Trial of XXX Administered Orally for 26 Weeks in Patients with Irritable Bowel Syndrome with Constipation

Open Label Extension Study to Assess the Safety of a Fixed Dose of Subcutaneous XXX in Subjects with Advanced Illness and Opioid-Induced Constipation

A Randomized, Double-Blind, Placebo-Controlled Study of a Fixed Dose of Subcutaneous XXX in Adults With Advanced Illness and Opioid-Induced Constipation: Efficacy, Safety, and Additional Health Outcomes

A Phase II, Double-Blind, Randomized, Placebo-Controlled, Multiple-Dose, Dose Escalation Study to Evaluate the Efficacy, Safety and Tolerability of XXX in Patients with Opioid-Induced Constipation (OIC)

An Open-label, Long-term Safety Study of Oral XXX Administered to Patients with Chronic Constipation or Irritable Bowel Syndrome with Constipation

A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel-group Trial of XXX Administered Orally for 12 Weeks Followed by a 4-Week Randomized Withdrawal Period in Patients with Chronic Constipation

COPD

A 24-Week, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX Inhalation Powder and the Individual Components Delivered Once-Daily via a Novel Dry Powder Inhaler in Subjects with Chronic Obstructive Pulmonary Disease

A randomized, double-blind, parallel group study to assess the efficacy and safety of 52 weeks of once daily treatment of orally inhaled XXX fixed dose combination (2.5 µg/5 lig; 5 µg/5 ilg) (delivered by the XXX Inhaler) compared with the individual components (2.5 lig and 5µg XXX, 5 1.tg XXX) (delivered by the XXX Inhaler) in patients with Chronic Obstructive Pulmonary Disease (COPD)

A Clinical Outcomes Study to compare the effect of XXX Inhalation Powder 100/25mcg with placebo on Survival in Subjects with moderate Chronic Obstructive Pulmonary Disease (COPD) and a history of or at increased risk for cardiovascular disease.

A multicenter trial comparing the efficacy and safety of XXX and with XXX over 24 weeks in subjects with COPD

CLINICAL TRIAL EXPERIENCE (*continued*):

A randomized, active-controlled, double-blind, double-dummy, parallel group design, multi-center trial to compare the efficacy and safety of 2.5 lig and 5 lig XXX Inhalation Solution delivered by the XXX Inhaler with XXX inhalation capsules 18 1.tg delivered by the XXX

A 12-week treatment, multi-center, randomized, double-blind, placebo-controlled, parallel-group study to assess the efficacy and safety of once daily XXX in patients with chronic obstructive pulmonary disease

A Randomized, Double-Bind, Placebo-Controlled Study Evaluating the Efficacy, Safety, and Tolerability of 2 Doses of XXX Compared With Placebo for 12 Weeks in Patients With Moderate to Severe, Stable Chronic Obstructive Pulmonary Disease Followed by a 40-Week Evaluation of the 2 XXX Doses

A Phase III, one-year, randomized, open-label safety and patient acceptability study of XXX (20/100 mcg) Inhalation Spray in comparison to XXX Inhalation Aerosol (36/206 mcg) and the free combination of XXX Inhalation Aerosol (34 mcg) and XXX inhalation aerosol (180 mcg) in adults with chronic obstructive pulmonary disease (COPD)

Randomized, double-blind, double-dummy, placebo-controlled, 4-way cross-over study to determine the 24-hour FEV1-time profiles of orally inhaled XXX (5 iig [2 actuations of 2.5 lig] and 10 lig [2 actuations of 5 110), administered once daily with the XXX and orally inhaled XXX (12 lig), administered twice daily with the XXX after 6 weeks of treatment in patients with Chronic Obstructive Pulmonary Disease (COPD)

Randomized, double-blind, placebo-controlled, parallel group study to assess the efficacy and safety of 48 weeks of once daily treatment of orally inhaled XXX (5 .tg [2 actuations of 2.5 lig] and 10 1.ig [2 actuations of 5 [tg]) delivered by the XXX, in patients with Chronic Obstructive Pulmonary Disease (COPD)

A multinational, randomized, double-blind, placebo- and active-controlled, parallel group efficacy and safety comparison over 24 weeks of three doses (50 jig , 100 pg, 200 pg) of XXX to XXX 5 pg and placebo delivered by the XXX inhaler in patients with chronic obstructive pulmonary disease (COPD)

A 24-week (+ 24 week extension), randomised, placebo-controlled (only 1st 12-week period), double-blind, parallel-group, efficacy and safety comparison of XXX Inhalation Powder in the morning , XXX Inhalation Powder in the morning, XXX Powder in the morning and evening and XXX Inhalation Powder in the morning plus XXX Inhalation Powder in the evening in patients with COPD

A 24 Week Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of 18 MCG of XXX Inhalation Capsules Administered by XXX Once-Daily Plus XXX vs. Placebo Plus XXX in Chronic Obstructive Pulmonary Disease (COPD) Subjects Naive to Maintenance Therapy

CLINICAL TRIAL EXPERIENCE (*continued*):

A comparison of XXX delivered by the XXX inhaler to XXX Inhalation Aerosol and XXX delivered by the XXX in a 12-week, double-blind, safety and efficacy study in adults with chronic obstructive pulmonary disease

A comparison of XXX delivered by the XXX Inhalation Aerosol and XXX delivered by the XXX in a 12-week, double-blind, safety and efficacy study in adults with chronic obstructive pulmonary disease

A Trial to Evaluate the Safety and Efficacy of XXX Combined With XXX in Patients With Chronic Obstructive Pulmonary Disease

A 52-week randomized, double-blind, parallel group, placebo controlled, multicenter clinical trial, to assess the efficacy and safety of 200 [tg of the anti-cholinergic XXX compared to placebo, both administered once-daily by inhalation, in the maintenance treatment of patients with moderate to severe, stable chronic obstructive pulmonary disease

Psychometric validation of a subject-administered questionnaire to assess cough and sputum in patients with COPD associated with chronic bronchitis and chronic bronchitis (not obstructed)

A Multicenter, Double-Blind, Double-Dummy, Randomized,
Active-Controlled, Parallel Group Long-Term Safety Study of the XXX in the Treatment of Subjects with Chronic Obstructive Pulmonary Disease

A Double-Blind, randomized, parallel-group, multicenter clinical study to compare the efficacy and tolerability of the XXX in subjects with COPD

A 6-Month Double-blind, Double-dummy, Randomized, Parallel group, Multi-center Safety and Efficacy Study of the XXX and Placebo in COPD Patients

A Randomized, Double-Blind, Parallel-Group, 52-week Study to Compare the Effect of the XXX on the annual Rate of Moderate/Severe Exacerbations in subjects with Chronic Obstructive Pulmonary Disease (COPD)

Depression

Phase IV Concept Elicitation and Cognitive Debriefing Interviews in Adults with Major Depressive Disorder and Sleep Disturbance

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 Evaluating the Efficacy and Safety of XXX in the Treatment of Adults with Severe Postpartum Depression

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

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 Phase II, Multicenter, Double-blind, Parallel-group, Randomized, Placebo-controlled, Forced-dose Titration, Dose-ranging 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

8-week, Randomized, Double blind, Placebo -controlled, Parallel-group, Multi-center Study of the Efficacy and Safety of XXX Administered Once Daily in Patients with Major Depressive Disorder

An Open-Label Study to Evaluate the Prevalence of Phenotypic Poor Metabolizers at XXX Among XXX -Treated Outpatients With Depression

CLINICAL TRIAL EXPERIENCE (*continued*):

Diabetes

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

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 52-Week, Phase III, Double-Blind, Active-Controlled, Multicenter Extension Study to Evaluate Safety and Efficacy of XXX in Patients with Type 2 Diabetes Mellitus on Background Treatment with XXX Alone or in Combination with XXX or with XXX Alone

A trial comparing efficacy and safety of XXX with XXX in insulin naïve subjects with type 2 diabetes. A 26-week randomized, controlled, open label, multicentre, multinational trial comparing efficacy and safety of XXX with XXX as add on to current oral anti-diabetic treatment in insulin-naïve subjects with type 2 diabetes mellitus inadequately controlled with 1-2 oral anti-diabetic drugs

A Phase III, Randomized, Double-Blind, Active-Controlled, Multi-Center Extension Study to Evaluate Safety and Efficacy of XXX in Subjects With Type 2 Diabetes Mellitus on a Background Medication of XXX

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Dose-Ranging Clinical Study to Evaluate the Efficacy and Safety of XXX Nasal Spray Solution in Diabetic Subjects with Gastroparesis

A Non-invasive Photonic Device for Diabetes Screening

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Safety and Efficacy of XXX in Patients with Type 2 Diabetes Mellitus on Background Treatment with XXX with or without XXX

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate Safety and Efficacy of XXX in Subjects With Type 2 Diabetes Mellitus on a Background Medication of Metformin

A Randomized Trial Comparing XXX with Placebo in Subjects with Type 2 Diabetes on Insulin Glargine With or Without Oral Antihyperglycemic Medications

A Prospective, Multi-Center, Paired Data, Cohort Screening Trial Comparing XXX to the Fasting Plasma Glucose Test in Subjects at Risk for Diabetes

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Placebo-Controlled, Double-Dummy, Parallel-Group, Multicenter, Dose-Ranging Study in Subjects With Type 2 Diabetes Mellitus to Evaluate the Efficacy, Safety, and Tolerability of Orally-Administered XXX With XXX as a Reference Arm IND

A 2-Month Safety Follow-up Trial of Subjects from XXX Protocols

A Multicenter, Randomized, Double Blind, Placebo Controlled Study Comparing the Safety and Efficacy of Multiple Doses of XXX Sustained Release (SR)/XXX Sustained Release (SR) and Placebo in Obese Subjects with Type 2 Diabetes Mellitus

A Phase III, Open-Label, Crossover Study to Evaluate the Efficacy and Safety of XXX (HIIP) Compared with Once-Daily Insulin Glargine in Insulin-Naive Patients with Type 2 Diabetes Mellitus on Oral Agents

A 1-Year, Randomized, Double-Blind, Placebo-Controlled Phase III Study to Evaluate the Efficacy and Safety of XXX in the Treatment of Overweight, Oral Agent-Treated Subjects with Type 2 Diabetes Mellitus

A multi-center, randomized, open-label, active controlled, parallel arm study to compare the efficacy of 12 weeks of treatment with XXX 100 mg, qd to XXX as add-on therapy in patients with type 2 diabetes inadequately controlled with metformin monotherapy in a community-based practice setting

A Phase III, 24-Week, Multi-Center, Open-Label, Randomized, Controlled Trial Comparing the Efficacy and Safety of Prandial Inhalation of XXX in Combination with Metformin or XXX Alone Versus 2 Oral Anti-Diabetic Agents (Metformin and a Secretagogue) in Subjects With Type 2 Diabetes Mellitus Sub-Optimally Controlled on Combination Metformin and a Secretagogue

A 52 week extension to a Multicenter, Randomized, Double-Blind, Active Controlled Study to Compare the Effect of 52 Weeks Treatment with the XXX in Drug Naive Patients with Type 2 Diabetes

A 52 Week, Randomized, Double-Blind, Parallel-Group, Multi-Center, Active-Controlled study to Evaluate the Efficacy, Safety and Tolerability of the XXX therapy when Administered to Patients with Type 2 Diabetes

Pulmonary Outcomes within a 2-year Period in Subjects with Diabetes Mellitus Treated with Treatment and in Subjects without Abnormalities in Glucose Control

An Open-Label, Multi-Center, Long-Term Extension study to Evaluate the Safety and Tolerability of the XXX when Added to Insulin Therapy in Patients with Type 2 Diabetes Mellitus

CLINICAL TRIAL EXPERIENCE (*continued*):

A 24- Week, Randomized, Double-Blind, Multicenter, Placebo-Controlled Study to Evaluate the Efficacy, Safety and Tolerability of the XXX therapy when added to the therapy of Patients with Type 2 Diabetes Poorly Controlled on Insulin

Evaluation of the effect of Transdermal Testosterone Supplementation on Glycemic Control, Body Composition, and Lipid Concentrations in Hypogonadal Men with Non-Insulin-Dependent Diabetes Mellitus

A Multicenter, Double-Blind, Evaluation of Recombinant Human Basic Fibroblast Growth Factor in the Treatment of Diabetic Ulcers

A Long-Term, Multi-Center, Glycemic Control Study in Outpatients with Insulin Independent (Non-Insulin Dependent —Type II) Diabetes Mellitus. A Randomized, Double-Blind Safety and Efficacy Comparison of XXX, XXX, Versus XXX

A Comparison of XXX with XXX in the Treatment of Patients with Type II Diabetes Mellitus

A Multi-Center, Double-Blind, Placebo Controlled Study of the Efficacy and Safety of XXX in the Treatment of Obese Patients with Non-Insulin Dependent (Type II) Diabetes Mellitus

Fibromyalgia

A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Proof of Concept Study of the Efficacy and Safety of XXX for Treatment of Patients with 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

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

A Phase III, Effect of XXX 30/60 mg Once Daily versus Placebo in Adolescents with Juvenile Primary Fibromyalgia Syndrome

A Multicenter, Open-label, 52-Week Extension Study to Evaluate the Safety and Efficacy of XXX in Pediatric Patients With Primary Fibromyalgia

A Multicenter, Randomized, Double-blind, Placebo-Controlled Withdrawal Study to Evaluate the Safety, Tolerability, and Efficacy of XXX in Pediatric Patients With Primary Fibromyalgia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Discontinuation Study to Evaluate the Durability of Effect of XXX for the Treatment of Fibromyalgia in Patients With Long Term XXX Treatment

A Multicenter, Randomized, Open-Label, Controlled Study to Evaluate the Safety, Tolerability, and Efficacy of XXX When Added to XXX in Patients Unable to Tolerate Full Therapeutic Doses of XXX in the Treatment of Fibromyalgia

A Multicenter, Randomized, Open-Label, Controlled Study to Evaluate the Safety, Tolerability, and Efficacy of XXX When Added to XXX in the Treatment of Fibromyalgia

A Randomized, Double-Blind, Placebo-Controlled, Dose Titration, Efficacy and Safety Study of XXX ER (0.75mg to 4.5mg) Administered Orally Once Daily Versus Placebo Over a 16-Week Maintenance Phase in Patients Diagnosed with Fibromyalgia as Assessed by the American College of Rheumatology (ACR) Criteria, Followed by a 24-Week Open-Label Extension Phase

A Randomized, Double-Blind Placebo-Controlled Dose Escalation Study of XXX100 and 200 MG Daily in Patients with Fibromyalgia: Effects on 24-Hour Ambulatory Blood Pressure Monitoring

A Parallel, Randomized, Double-Blind, Placebo-Controlled, Multicenter Proof of Concept Trial to Assess the Efficacy and Safety of 2 Different Transdermal Doses of XXX in Subjects with Signs and Symptoms Associated with Fibromyalgia Syndrome

A multicenter, 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 III, Multi-center, Open-Label, Extension Study of XXX for the Treatment of Fibromyalgia

A Phase III Pivotal, Multi-center, Double-blind, Randomized, Placebo-Controlled Monotherapy Study of the XXX for the Treatment of Fibromyalgia

Hypercholesterolemia

A Randomized, Double-Blind, Active-Controlled, Multicenter, Crossover Study to Evaluate the Efficacy and Safety of XXX 10 mg/20 mg Fixed-Dose Combination Tablet Compared to Co-administration of Marketed XXX 10 mg and XXX 20 mg in Patients with Primary Hypercholesterolemia

An 8-Week, Multicenter, Randomized, Double-blind, Four-arm, Parallel-group Study Comparing the Safety and Efficacy of XXX to XXX in Subjects with Hypercholesterolemia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multicenter Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Efficacy of XXX in Moderately Obese Hyperlipidemic Patients With or Without Concomitant XXX

A 12-Week, Multicenter, Randomized, Double-Blind, Parallel-Group Study of the Combination of XXX and XXX Compared to XXX and XXX Monotherapy in Subjects with Type IIa and IIb Dyslipidemia

A Multi-center, Randomized, Double-Blind, "Factorial" Design Study to Evaluate the Lipid-Altering Efficacy and Safety of the XXX Combination Tablet in Patients With Primary Hypercholesterolemia or Mixed Hyperlipidemia

A randomized, double-blind, parallel-group, placebo-controlled, multicenter study evaluating the efficacy and safety of three doses of XXX in abdominally obese patients with atherogenic dyslipidemia

A Randomized, Double-Blind, Multi-Center Study Comparing the Effects of XXX Phosphate Modified Release Formulation XXX with XXX on the Lipid Profile in Normolipidemic, or Mildly Dyslipidemic Hypertensive Patients

A Long-Term, Open-Label, Safety Extension Study of the Combination of the XXX and XXX therapy for Subjects with Mixed Dyslipidemia

A Double-Blind, Multi-Center, Parallel, Randomized, Active, Controlled Study of XXX Compared to XXX in Patients with Hypercholesterolemia

Hypertension

A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group, Phase III Trial to Evaluate the Safety and Efficacy of XXX in subjects with Type 2 Diabetes with inadequately controlled hypertension on an Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB)

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of XXX in Subjects with Type 2 Diabetes with inadequately controlled hypertension treated with an XXX) or XXX and an additional Antihypertensive medication

An 8 week Randomized, Double-Blind, Parallel Group, Multi-Center, Active Controlled Study to Evaluate the Antihypertensive Efficacy and Safety of XXX Administered in Combination with XXX versus XXX alone in Hypertensive Patients with Type 2 Diabetes Mellitus

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IIIb, Double-Blind, Randomized, 12-Week Efficacy and Safety Study Comparing the XXX Plus XXX Fixed-Dose Combination vs XXX in Subjects With Moderate to Severe Hypertension

A Randomized, Double-Blind, Active-Comparator, 8-Week Forced-Titration Study of the Efficacy and Safety of the XXX Versus XXX in Hypertensive Subjects

A 12-week multicenter, randomized, double-blind, parallel-group, active-control study to evaluate the antihypertensive efficacy and safety of XXX-based regimen versus a XXX based regimen in patients with Stage 2 systolic hypertension

A Phase III, Double-Blind, Randomized, Factorial, Efficacy and Safety Study of XXX Plus Chlorthalidone Fixed-Dose Combination in Subjects with Moderate to Severe Hypertension

XXX 80 mg plus XXX 10 mg fixed-dose combination tablet Study versus XXX 10 mg over encapsulated tablets or XXX 80 mg tablets as first line therapy in patients with severe HyperTeNsion: A Phase III, 8-week, randomized, double-blind, double-dummy, forced-titration comparison XXX

A Prospective, Open-Label, Titration Study to Evaluate the Efficacy and Safety of XXX in Multiple Subgroups of Hypertensive Subjects Who Are Non-Responders to Anti-Hypertensive Monotherapy

An 8-week randomized, double-blind, parallel-group, multi-center, active-controlled dose escalation study to evaluate the efficacy and safety of XXX (300/25 mg) compared to XXX (25 mg) in older patients with stage 2 systolic hypertension

An 8-week double-blind, multicenter, randomized, multifactorial, placebo-controlled, parallel-group study to evaluate the efficacy and safety of XXX administered alone and in combination with XXX in patients with essential hypertension

A 16-Week , Phase I, Multicenter, Double-Blind, Randomized, XXX controlled, Parallel-Group Pharmacological study, to Assess the Effect of XXX (375 mg and 750 mg, bid) compared to equimolar doses of XXX (250mg and 500mg, bid) and to XXX (600mg, tid) on Arterial Blood Pressure as Measured by Ambulatory Blood Pressure Monitoring in Osteoarthritis Patients with Controlled Essential Hypertension

A Phase III, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX in Subjects with Essential Hypertension

A 54-week, open-label, multicenter study to assess the long-term safety and tolerability of the combination of XXX 300 mg/ XXX 10 mg in patients with essential hypertension

CLINICAL TRIAL EXPERIENCE (*continued*):

A randomized, double-blind, double-dummy, placebo-controlled, 3x4 factorial design trial to evaluate the XXX after eight weeks of treatment in patients with Stage I or II hypertension with an ABPM sub-study

A Prospective, Randomised, Open-Label, Blinded-Endpoint, Parallel Group Multi-centre, Forced Titration, 14-week Treatment Study Comparing XXX and XXX in Patients with Mild-to-Moderate Hypertension using Ambulatory Blood Pressure Monitoring

XXX Cardiovascular Treatment Assessment Versus XXX

A Prospective, Randomized, Double-Blind, Double-Dummy, Titration-to-Response Trial Comparing XXX and XXX in Patients with Mild-to-Moderate Hypertension using Ambulatory Blood Pressure Monitoring

A Prospective Randomized Open-Label Blinded-Endpoint Trial Comparing XXX and XXX in Patients with Mild to Moderate Hypertension Using Ambulatory Blood Pressure Monitoring

Long Term Trial of the Efficacy and Safety of XXX Compared with XXX in Patients with Mild-to-Moderate Hypertension

Randomized, Double-Blind, Multicenter Dose-Ranging Trial of Once Daily XXX vs. Placebo vs. XXX in Essential Hypertension

A Prospective, Double-Blind, Randomized Comparison of Two Treatment Regimens: XXX and XXX vs. XXX and XXX plus 25 mg XXX (equivalent to the combination drug XXX 10/25) in the Treatment of Patients with Mild to Moderate Hypertension

A Double-Blind Randomized Parallel Group Comparative Study of the Safety and Efficacy of Switching from XXX (30 and 60 mg Daily) to XXX (30 and 60 mg Daily) Administered Without Food in Patients with Mild to Moderate Hypertension

A Multicenter Dose Response Study of XXX in Patients with Mild-to-Moderate Essential Hypertension

A Randomized, Placebo-Controlled Double-Blind, Parallel Study of the Safety and Antihypertensive Efficacy of XXX Monotherapy as Compared to XXX Monotherapy and to the Combination of XXX and XXX in Patients with Mild to Moderate Hypertension AND Open-Label Extension

A Study of the Safety and Antihypertensive Efficacy of XXX Extended Release (ER) 360 mg in Combination with XXX Compared to XXX ER Alone AND Open-Label Extension

Controlled Clinical Trial Comparing XXX and XXX to Each of the Monocomponents and Placebo in the Treatment of Mild to Moderate Essential Hypertension

CLINICAL TRIAL EXPERIENCE (*continued*):

Open Label Study of the Long-Term Safety of Oral XXX in Combination with XXX

A Multicenter, Double-Blind Study of the Safety and Efficacy of Once-Daily XXX with Once-Daily XXX for the Treatment of Mild to Moderate Uncomplicated Hypertension in Non-Insulin Dependent (Type II) Diabetic Outpatients

A Double-Blind, Randomized, Multicenter Trial of XXX vs XXX in Patients with Mild to Moderate Hypertension

Double-Blind, Randomized, Placebo-Controlled, Factorial Study to Evaluate the Safety and Efficacy of Oral XXX in Combination with XXX

Open-Label Study of the Long-Term Safety of Oral XXX Therapy in Patients with Mild to Moderate Essential Hypertension

A Sixteen-Week, Double-Blind, Placebo-Controlled, Dose-Response Study Using XXX Tablets for the Treatment of Benign Prostatic Hyperplasia in Patients with Mild to Moderate Essential Hypertension AND Extension

A Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging Antihypertensive Safety and Efficacy Study of Once-Daily XXX and XXX

Double-Blind, Randomized, Placebo-Controlled, Six-Week, Parallel, Dose-Ranging Study to Evaluate the Safety and Efficacy of Oral XXX Therapy (0.25, 0.5, 1, 2 and 4 mg/day) in White Patients with Mild to Moderate Essential Hypertension

Multi-Center, Placebo-Controlled Study Evaluating the Safety and Comparing the Antihypertensive Effect of XXX in Combination with XXX vs. XXX or XXX

An Eight-Week, Double-Blind, Placebo-Controlled, Comparative Fixed Dose Study of XXX vs. the Conventional XXX Tablet in Patients with Mild Essential Hypertension

Parallel Comparison of Three Doses of XXX and Placebo in Patients with Mild to Moderate Hypertension AND Extension

Open Label Study of the Long Term Safety of Oral XXX-SR as Treatment for Mild to Moderate Essential (G30) Hypertension

A Double-Blind, Parallel, Dose Ranging Study of the Efficacy and Safety of Oral XXX-SR vs. XXX in the Treatment of Mild to Moderate Essential Hypertension

Evaluation of Low Dose XXX in Combination with XXX in Mild to Moderate Essential Hypertension

CLINICAL TRIAL EXPERIENCE (*continued*):

A Study of the Effect of XXX, XXX, XXX, and Placebo on Vascular Resistance in Hypertensive Patients

A Phase II, Double-Blind Dose Ranging Comparison of Two Dosing Regimens with XXX in Patients with Mild to Moderate Hypertension AND Extensions

Multifactorial Study to Determine the Dose Response Characteristics When XXX SR is Combined with Hydrochlorothiazide

A Double-Blind, Multi-Center, Randomized Parallel Study to Evaluate the Safety and Efficacy of XXX Once a Day vs. XXX Once a Day vs. Placebo Once a Day in the Treatment of Hypertension

Pilot Study of the Determination of the Duration of Action of XXX SR Plus Hydrochlorothiazide in Patients with Mild to Moderate Essential Hypertension

XXX Dose-Range Study in Hypertensive Patients for Reversal of Hydrochlorothiazide-Induced Hypokalemia

The Dose Response of XXX on Blood Pressure and Heart Rate in Patients with Mild to Moderate Hypertension

Long Term, Double-Blind Evaluation of the Efficacy and Safety of Oral XXX, Compared to Oral XXX in Patients with Essential Hypertension

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

A Worldwide, Open Label, Clinical Trial to Examine the Long Term Safety and Tolerability of XXX in Pediatric Migraineurs for the Treatment of Migraine With or Without Aura

A Worldwide, Randomized, Double Blind, Placebo-Controlled, Parallel Group Clinical Trial to Evaluate the Safety and Efficacy of XXX for the Acute Treatment of Migraine in Children and Adolescents

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Crossover Trial to Evaluate the Efficacy and Tolerability of XXX 10mg for the Treatment of Acute Migraine in XXX Non-Responders

A Randomized, Multicenter, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of a Combination Product Containing XXX and XXX for the Acute Treatment of Migraine in Adolescents

A Randomized, Double-blind, Double-dummy, Placebo-controlled, Crossover Study to Evaluate the Efficacy of XXX versus XXX for the Acute Treatment of Migraine when administered during the Moderate-Severe Pain Phase of the Migraine

A Long-Term Safety Study of a Combination Product Containing XXX and XXX for the Treatment of Migraine in Adolescents

A randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and tolerability of XXX for a single moderate or severe headache in adults diagnosed with probable migraine without aura

A randomized, double-blind, single migraine attack, placebo-controlled, parallel-group, multi-center study to evaluate the efficacy and tolerability of the XXX tablets vs. placebo when administered during the mild pain phase of menstrual migraine in women with dysmenorrheal

A randomized, double-blind, multi-center, placebo-controlled, cross-over study to determine the consistency of response for the XXX administered during the mild pain phase for the acute treatment of multiple migraine attacks

Obesity

A Double Blind, Multi-Center, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of 400 mg of XXX and 120 mg of XXX Administered Individually or Combined Orally Three Times Per Day with a Reduced Calorie Diet (RCD) in Obese Subjects

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multicenter, Randomized, Parallel-Group, Placebo-Controlled, Efficacy and Safety Trial to Evaluate the Effect of XXX on Weight in Obese and Overweight Subjects

A Multicenter, Randomized, Double Blind, Placebo Controlled Study Comparing the Safety and Efficacy of XXX Sustained Release (SR)/ XXX Sustained Release (SR) and Placebo in Obese Subjects

A Phase III, Randomized, Double-Blind, Parallel-Design Study Comparing Multiple Doses of XXX to Placebo and Their Single-Agent Phentermine and Topiramate Constituents for the Treatment of Obesity in Adults

A 2-year, randomized, double-blind, placebo controlled phase III study to evaluate the long-term efficacy and safety of XXX in the treatment of obese subjects

A Phase Ilb/III Randomized, Placebo-controlled Clinical Trial to Study the Safety and Efficacy of XXX in Obese Patients and in Overweight Patients with Obesity-Related Co-mobidities Study

A 104-Week, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Assess the Safety and Efficacy of XXX in Obese Patients

An Open-Label Extension of Initial 16-Week Proof-of-Concept Study to Continue Administration of the XXX Orally Once-A-Day for 6 Additional Months (i.e., 28-weeks) in Obese Males and Females

A Double-Blind, Multi-Center, Randomized, Parallel-Group, 16-Week Study of the XXX Administered Orally Once-A Day with or without a Low Calorie Diet Lead-in in Obese Males and Females

A Two Year Study to Assess the Safety, Efficacy and Tolerability of the XXX in Obese Patients

Pain

A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study of the Safety and Efficacy of XXX in Patients with Postherpetic Neuralgia

Multinational, multicenter, randomized double-blind, placebo-controlled, parallel-group study of efficacy and safety of XXX administration for 4 weeks in patients with chronic peripheral neuropathic pain

An Open-label, Multicenter Study to Assess the Long-Term Safety of XXX Tablets 20 to 120 mg Once-daily in Subjects with Moderate to Severe Chronic Nonmalignant and Non-neuropathic Pain

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multicenter, Double-blind, Randomized, Placebo-controlled, Repeat Treatment (two cycle) Study of the Safety and Efficacy of XXX in Patients with Postherpetic Neuralgia

A Phase IIa, Randomized, Double-Blind, Placebo-Controlled, Two-Period Crossover Study to Evaluate the Safety, Tolerability, Preliminary Efficacy, and Systemic Exposure of Topical XXX in Subjects with Post-herpetic Neuralgia

A Long-Term Open-Label Safety Study of XXX Controlled-Release Capsules with Flexible Dosing to Treat Subjects with Moderate to Severe Chronic Pain

A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Dose-Loading Study to Evaluate the Efficacy, Safety, and Tolerability of XXX as Adjunctive Therapy in Subjects With Inadequately Controlled, Moderate to Severe, Chronic Low Back Pain

A Phase IIa, Double-Blind, Randomized, Parallel-Group, Multi-Centre, Study to Evaluate the Analgesic Efficacy of 28 Days Oral Administration of XXX with One-Dose Escalation Compared to Placebo in Peripheral Neuropathic Pain Patients with Mechanical Hypersensitivity

A Multicenter, Randomized, Double-Blind, Parallel, Placebo-Controlled, Pilot Analgesic Efficacy and Safety Study of XXX in Subjects with Postherpetic Neuralgia

A Randomized, Double-Blind, Placebo- and Active- Controlled Study of the Safety and Efficacy of XXX in Patients with Diabetic Peripheral Neuropathic Pain

An efficacy and safety study of XXX compared with a concurrent placebo control in subjects with neuropathic pain associated with post-herpetic neuralgia (PHN)

A dose-response study of XXX compared with concurrent placebo control and Lyrica (pregabalin), in subjects with neuropathic pain associated with diabetic peripheral neuropathy (DPN)

Open-Label Extension, Single-Arm, Flexible-Dosing, Phase III Trial with XXX Extended-Release (ER) in Subjects with Moderate to Severe Chronic Pain

A Multi-center, Randomized, Double-blind, Placebo-controlled Study with an Open-label Run-in to Assess the Efficacy, Tolerability, and Safety of XXX or XXX Compared to Placebo in Opioid-naive Subjects with Moderate to Severe, Chronic Low Back Pain

A Randomized, Double-Blind, Active-Controlled Crossover Study to Evaluate the Efficacy and Safety of XXX Tablets Compared With Immediate-Release Oxycodone for the Management of Breakthrough Pain in -Tolerant Patients With Chronic Pain

A Randomized-Withdrawal Phase III Study Evaluating the Safety and Efficacy of XXX Extended-Release (ER) in Subjects with Painful Diabetic Peripheral Neuropathy (DPN)

CLINICAL TRIAL EXPERIENCE (*continued*):

A Long-Term, Open-Label, Safety Study of XXX Capsules in Subjects with Chronic Moderate to Severe Nonmalignant Pain

A Multicenter, Open-Label Study of the Safety and Efficacy of Long Term Use of XXX Extended Release (G-ER) Tablets in the Treatment of Patients with Postherpetic Neuralgia

A 12-Week, Open-Label Study With 3 Within-Patient Double-Blind Placebo-Controlled Periods to Evaluate the Efficacy and Safety of the XXX Treatment for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Noncancer-Related Chronic Pain

A Multicenter, Randomized, Double-Blind, Controlled Study of the XXX for the Treatment of Postherpetic Neuralgia

A Multi-Center, Standard of Care-Controlled Study to Evaluate the Long-Term Safety of the XXX for the Treatment of Chronic Low Back Pain

A Multi-Center, Double-Blind, Placebo Controlled Randomized Study of the XXX in the Treatment of Chronic Low Back Pain

A Randomized, Double-Blind, Controlled Study of the XXX for the Treatment of Postherpetic Neuralgia

A Phase III, Multi-center, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of the XXX tablets in the Treatment of Patients with Postherpetic Neuralgia

A Double-Blind, Placebo-Controlled, Multi-center Study to Assess the Safety and Efficacy of the XXX at Two Dose Levels in the Treatment of the Pain of Diabetic Neuropathy

Double-Blind, Placebo-Controlled, Parallel-Group Comparison of the Efficacy and Safety of Extended Release XXX 300 mg and 200 mg to Placebo in the Treatment of Chronic Low Back Pain

Open Label Assessment of the Safety and Effectiveness of Extended Release XXX in the Treatment of Chronic Non-Malignant Pain

Evaluation of the Safety and Effectiveness of XXX in Subjects with Chronic Pain of Benign Origin

A Multi-Center, Open-Label Study Evaluating the Safety and Tolerability of XXX Controlled-Release Tablets in Patients with Chronic Pain

A Multi-Center, Randomized, Double-Blind, Parallel Study Comparing the Efficacy and Safety of XXX Controlled-Release Tablets versus XXX versus Placebo in Patients with Chronic Back Pain

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multicenter, Randomized, Double-Blind, Single and Multiple-Dose, Parallel-Group Comparison Study of XXX 1200mg to 1800mg/Day and Placebo in Patients with Acute Low Back Pain

Evaluation of the Relative Potency and Safety of XXX with XXX Compared to XXX with XXX in Chronic Pain of Benign Origin

XXX vs. XXX vs. Placebo in the Treatment of Acute Back Pain

A Multicenter, Double-Blind, Placebo-Controlled, Parallel Group Study of the Effects of Oral (1000 mg daily) XXX in Patients with Painful Peripheral Symmetrical Diabetic Polyneuropathy

Schizophrenia

A Phase IV Post-XXX Study Interviews to obtain feedback on the digital therapeutic used in the XXX trial as well as new ideas for a future version

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

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 Randomized, Double-blind, Placebo-controlled, Parallel, 12 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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

Sleep

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

Dose-Ranging Trial; A Randomized, Double Blind, Parallel Group, Placebo Controlled, Multicenter Outpatient Trial of XXX in Adults with Primary Insomnia

Fifty-two weeks, open-label extension trial to evaluate safety and efficacy of XXX in outpatients with chronic primary insomnia who completed Clinical Trial Protocols

A Randomized, Double Blind, Placebo-Controlled, Parallel Group Study to Demonstrate the Subjective Treatment Effects of XXX on Sleep using a Post Sleep Questionnaire -Interactive Voice Response System (PSQ-IVRS) in an "At-Home Setting" in an Adult Population with Chronic Insomnia

A two-week, double-blind, placebo-controlled, randomized, parallel group, efficacy and safety, out-patient trial with XXX in patients with chronic primary insomnia

A Randomized, Double Blind, Active- and Placebo-Controlled, Parallel Group Safety Study Assessing Simulated Driving Performance in XXX Treated Patients with Restless Legs Syndrome

A Phase IV randomised, double-blind, active and placebo-controlled, 6-week trial to investigate the efficacy and safety of a starting (and fixed) dose of 0.25 mg XXX in patients with idiopathic Restless Legs Syndrome

A Double-Blind, Randomized, Multicenter, Placebo-Controlled, Parallel Groups Safety and Efficacy Extension Study of the XXX in the Treatment of Adult Outpatients with Primary Insomnia

CLINICAL TRIAL EXPERIENCE (*continued*):

An Open-Label Extension Trial to Investigate the Safety and Tolerability of Long-Term Treatment with the XXX in Subjects with Idiopathic Restless Legs Syndrome

A 12 month, randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-center, Long-Term Safety Study of the XXX in the Treatment of Elderly Outpatients with Primary Insomnia

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Five-Arm Parallel-Group Trial to Investigate the Efficacy and Safety of Four Different Transdermal Doses of the XXX in Subjects with Idiopathic Restless Legs Syndrome

An Open-Label, 52-Week Extension Study Assessing the XXX Safety and Efficacy in Patients with Restless Legs Syndrome

Women's Health

A Randomized, Placebo-Controlled, Double-Blind Phase III Clinical Study to Investigate the Long-Term Safety of XXX in Women Suffering From Vasomotor Symptoms (Hot Flashes) Associated with Menopause

A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Dose-Ranging Study of the XXX in Postmenopausal, Women with Overactive Bladder

A Phase II, 8-Week, Multi-Center, Randomized Double-Blind, Placebo Controlled, Parallel Group Study Evaluating The Efficacy, Tolerability and Safety of the XXX for Stress Urinary Incontinence in Women

A Multicenter, Double-Blind, Double-Dummy, Randomized, Placebo-Controlled Study Comparing a 2.2 mg /0.69 mg XXX Combination Transdermal Patch, and a 1 mg XXX Transdermal Patch with a Placebo Patch in Postmenopausal Women to Determine the Lowest Effective Dose of XXX for the Relief of Moderate to Severe Hot Flushes

A Multicenter, Randomized, Double-Blind Exploratory Study Investigating the Pharmacodynamic Profile of Two Different Hormone Replacement Therapy Regimens: Conjugated Estrogens Plus , versus Micronized Estradiol Plus Cyclophasic Addition of XXX versus Placebo in Postmenopausal Women

An Open-Label Study to Evaluate the Contraceptive Efficacy and Safety of the Transdermal Contraceptive System of XXX and XXX with the Oral Contraceptive XXX

A Multicenter, Randomized, Double-Blind, Parallel Group, Dose-Ranging Study to Evaluate the Safety of a XXX Hormone Replacement Therapy Regimen of XXX and XXX and Its Effect on Endometrial Histology and Vaginal Bleeding in Postmenopausal Women

CLINICAL TRIAL EXPERIENCE (*continued*):

Multi-Center Study Comparing the Efficacy and Safety of a Once-A-Week XXX Transdermal Drug Delivery Patch with XXX

A Double-Blind, Comparative Study of XXX (With and Without a Loading Dose) vs. XXX vs. Placebo in the Treatment of Primary Dysmenorrhea

Evaluation of Safety and Efficacy of Fixed Doses of XXX and XXX Acetate

Research Project on Estrogen Therapy during Menopause

Urinary Tract Infections

A Multi-Center, Comparative Trial of XXX (500MG Q.D.) vs. XXX (250 MG T.I.D.) in the Treatment of Acute and Uncomplicated Urinary Tract Infections

A Multi-Clinic, Randomized Comparison of the Efficacy and Safety of 3-Day Therapy with XXX versus 10-Day Therapy with XXX in the Treatment of Acute, Uncomplicated Urinary Tract Infections

Vaccines

Safety and Immunogenicity in Adults of Revaccination with XXX Vaccine 10 Years after a Previous Dose

Efficacy Study of XXX High-Dose Vaccine Compared With XXX Vaccine in Elderly Adults

Antibody Persistence and Response to Revaccination with either XXX Vaccine Approximately Three Years Following Initial Vaccination in Adults Who Participated in previous Sanofi Pasteur Trial

Safetyand Immunogenicity of Revaccination with Influenza Vaccine in Healthy Adult Subjects aged 18 to 64 Years who were Previously Vaccinated with XXX

Lot Consistency, Immunogenicity, and Safety Study of Three Lots of XXX Vaccine Administered by Intradermal Route in Comparison with Standard XXX Administered Intramuscularly in Adult Subjects 18 to 64 Years

A Phase IIIb, Prospective, Observer-blind, Randomized, Controlled Multicenter Study to Evaluate Immunogenicity and Safety of XXX Biologicals' Tetanus Toxoid, Reduced Diphtheria Toxoid and acellular Pertussis Vaccine, Adsorbed XXX Compared to XXX Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed, when Administered as a Booster Vaccination in Adults Aged 19 to 64 Years of Age

CLINICAL TRIAL EXPERIENCE (*continued*):

Safety and Immunogenicity of Tetanus and Diphtheria Toxoids Adsorbed Combined with Component Pertussis (TdcP) Vaccine Compared to Tetanus and Diphtheria Toxoids Adsorbed (Td) in Adolescents and Adults 11 - 64 Years of Age

Other Indications

A Phase III Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Trial of 14 Day Treatment with XXX 20 mg Once Daily in Subjects with Frequent Heartburn

A Phase III, Randomized, Double-Blind Trial of XXX For the Detection of Myocardial Perfusion Defects Using Single-Photon Emission Computed Tomography (SPECT) Myocardial Perfusion Imaging (MPI)

An Open Label, 26-Week Study Assessing XXX Safety and Efficacy in Subjects with Spasticity Associated with Multiple Sclerosis

A Randomized, Double Blind, Placebo-Controlled Efficacy and Safety Study of XXX in Subjects with Spasticity due to Multiple Sclerosis

Immune Modulation through Nutritional Supplements to Defend Against Respiratory Virus Induced Inflammation

Clinical Trial for Evaluation of Vermillion's Blood Test to Predict the Probability of Peripheral Artery Disease

A Multicenter, Randomized, Active-Control, Phase IIIB Study to Evaluate the Cardiovascular Safety of XXX in Subjects With Gout and Cardiovascular Comorbidities

A 12-Week, Randomized, Double-Blind, Placebo-Controlled Study of XXX in Subjects with Diarrhea-Predominant Irritable Bowel Syndrome

A Double-Blind Randomized Study to Compare the Efficacy, Safety and Local Tolerability of a 0.5% XXX Cream Compared to a Topical Vehicle Control in Subjects with Pediculus Humanus Capitis Infestation

A Double-Blind Randomized Study To Compare the Safety, Local Tolerability and Efficacy of a 0.5% XXX Cream Compared to a Topical Vehicle Control in Subjects with Pediculus Humanus Capitis Infestation

A Randomized, Double-Blind, Active Controlled Study to Evaluate the Immunogenicity of Quadrivalent LAW in Children

Noninvasive Blood Ethanol Measurement with Near Infrared Spectroscopy

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Randomized, Double-Blind, Parallel Group, Placebo Controlled, Multicenter Study to Assess the Efficacy and Safety of the Beta-3 Agonist XXX (25 mg qd and 50 mg qd) in Subjects with Symptoms of Overactive Bladder

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Efficacy Study Comparing 4 Weeks of Treatment with XXX 20 mg qd to Placebo qd in Patients with Heartburn and Sleep Disturbances Associated with Gastroesophageal Reflux Disease (GERD)

A Randomized, Double-Blind, Phase III Study of the Efficacy and Safety of XXX in Subjects Requiring NSAID Treatment

A Multi-Site, Cross-Sectional, Non-Treatment, Prospective Trial to Collect Bio-Fluids and Neuropsychiatric Data from Cognitively Normal Elderly Subjects

A randomized, double-blind, parallel-group, multicentre, phase III study to assess the effect of XXX 20 and 40 mg od versus placebo on the occurrence of peptic ulcers during 26 weeks in subjects on continuous low-dose acetylsalicylic acid (ASA)

A Randomized, Multi-center, Double-blind, Placebo-controlled, Parallel-group Comparative Study to Assess Vigilance and Cognitive Function Upon Awakening in Patients with Seasonal Allergic Rhinitis after a Nighttime Dose of XXX or XXX

A 6-Month, Phase III, Randomized, Double-blind, Parallel-group, Controlled, Multi-center Study to Evaluate the Incidence of Gastric Ulcers Following Administration of Either XXX or XXX in Subjects Who Are at Risk for Developing NSAID-associated Ulcers

Lung Cancer Early Detection Defining Lung Cancer Risk in Current & Former Women Smokers

A randomized, double-blind, parallel group study to investigate the efficacy and safety of treatment with the XXX administered once daily for 4 years, alone and in combination, on the improvement of symptoms and clinical outcome in men with moderate to severe symptomatic benign prostatic hyperplasia

A Multicenter, Double-Blind, Placebo-Controlled, Replicative, Pivotal Safety and Efficacy Study of Two Dosage Regimens of XXX (5 mg and 2.5 mg) in Outpatients with Acute Skeletal Muscle Spasm

A Double-Blind Placebo-Controlled, Dose-Confirmation Study of the Safety and Efficacy of Two Dosage Regimens of XXX in Outpatients with Acute Skeletal Muscle Spasm

A Double-Blind, Parallel Multi-Center Study to Determine the Efficacy and Safety of XXX Topical Gel Compared with Placebo in Acute Lateral Epicondylitis

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Open-Label, Evaluator-Blind, Bilateral, Paired Comparison Study of the Effects of XXX Versus No Therapy in the Treatment of Dry Skin of the Heels

Controlled Evaluation to Determine Clinical Anti-Inflammatory Activity of XXX/ XXX Gel and XXX Gel in the Treatment of Tinea Pedis

A Double-Blind, Placebo-Controlled Study to Determine the Safety and Efficacy of XXX in the Treatment of Benign Prostatic Hyperplasia

A Double-Blind, Dose-Ranging Study to Evaluate the Effects of Doses as Needed up to Twice Daily of XXX 5 mg, 10 mg, 20 mg, or Antacid, as Compared to Placebo in the Treatment of Intermittent Heartburn

A Multi-Center, Double-Blind Study to Evaluate the Safety and Efficacy of XXX 40 mg o.d. vs. XXX 20 mg o.d. on the Healing of Active Duodenal Ulcer in Outpatients as Compared with XXX 300 mg h.s. Followed by a Forty-Eight Week Double-Blind Assessment of the Safety of Repeated Treatment with XXX 20 mg o.d. or 40 mg o.d. vs. XXX 300 mg h.s. on Endocrine Cells in the Gastric Fundus

Double-Blind Comparison of Small Particle Aerosol XXX and Placebo in Patients with Influenza Pneumonia

A Double-Blind Study to Evaluate the Effects of XXX 20 mg. A.M. or 20 mg A.M. 3 of 7 days as Compared to Placebo During 6 Months Continued Treatment of Patients with Erosive Esophagitis Healed Following 4 to 8 Weeks of XXX 40 mg A.M.

XXX vs. XXX in Streptococcal Pharyngitis/Tonsillitis, Bronchitis and Lobar Pneumonia/Bronchopneumonia

Evaluation of Intravenous Antecubital Site Shield and Wrist Arterial Line Site Shield in the Hospitalized Patient

A Comparison of Oral XXX and XXX in the Treatment of Skin and Soft Tissue Infections

A Double-Blind, Dose Ranging Study to Evaluate the Effects of XXX 40 mg h.s. and 20 mg b.i.d. as Compared to Placebo in the Symptomatic Relief of Patients with Symptoms of Gastroesophageal Reflux with a Normal Esophagus or Mild Endoscopic Esophagitis Over a Period of Six Weeks

Reversal of the Central Effects of Versed by Intravenous XXX or Placebo After General Anesthesia in Outpatients Premedicated with a Narcotic

CLINICAL TRIAL EXPERIENCE (*continued*):

A Double-Blind, Placebo-Controlled Study on the Efficacy and Safety of XXX 12 mg Administered Once a Day or Twice a Day in Treatment of Patients with Acute Skeletal Muscle Spasm of the Neck or Low Back

Development of Workshop on Preventative Medicine and Health Screening of Well Adults

AWARDS, HONORS, and MEMBERSHIPS IN HONORARY SOCIETIES:

1974 Phi Kappa Phi
1974 Phi Beta Kappa
1970 National Merit Scholar

PUBLICATIONS:

Gordon S, Thompson K, Ruoff G, Imig J, Barden P, Schwenker C and the Transdermal Estradiol Patch Study Group. Efficacy and Safety of a 7-day Transdermal Estradiol Drug Delivery System: Comparison with Conjugated Estrogens and Placebo. American Fertility Society, Montreal Canada, October 19936 and XIV FIGO World Congress, Montreal Canada, September 1994 (Berlex Laboratories/3M Pharmaceuticals)

Weir M, Gray J, Paster R, Saunders E for the Trandolapril Multicenter Study Group. Differing Mechanisms of Action of Angiotensin-Converting Enzyme Inhibition in Black and White Hypertensive Patients. Hypertension. 1995; 26:124-130