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CONTACT INFORMATION:

Site Selection and Information:
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EDUCATION:

1963 Doctor of Medicine
University of Texas Medical Branch, Galveston, TX

1960 Masters Business Administration
Northwestern University, Chicago, IL

1958 Bachelor of Arts, Major: Chemistry
Texas Tech University, Lubbock, TX

INTERNSHIPS AND RESIDENCIES:

1964-1967 Neurology Residency
University of Iowa, Iowa City, Iowa

1963-1964 Medical Internship
Methodist Hospital, Dallas, Texas

1959-1960 Administrative Residency
Brackenridge Hospital, Austin, Texas

CERTIFICATIONS:

Texas Medical Board License Number D0915
American Board of Sleep Medicine (Diplomat), 1999
American Academy of Sleep Medicine (Fellow)
American Society of Neuro Rehabilitation (Diplomat), 1997
American Board of Neurology (Fellow), 1979

PROFESSIONAL EXPERIENCE:

Medical Director and Advisor, 2012 – Present
www.sleepdisorders.com online resource for subjects with sleep disorders

Principal Investigator, 2001 – Present
FutureSearch Trials, Austin, TX

Founder and President, 2000 - Present
Sleep Medicine Consultants, Austin, TX

Hospital Staff, 1999 – Present
Brackenridge, St. David's, Seton, Texas NeuroRehab Center, Heart Hospital of Austin

Private Practice, Neurology, 1967 – Present
Austin, TX

Austin Neuro Diagnostics, 1975
Austin, TX

Founder, 1970
Austin EEG and Neuroscience Laboratory, Austin, TX

Founder, 1970
Austin Neurological Clinic, Austin, TX

Medical Director
Texas State University Sleep Lab, San Marcos, TX
REM Sleep Center, Austin, TX

CLINICAL RESEARCH EXPERIENCE:

Phase I • Age-Associated Memory Impairment (AAMI) • Alzheimer's Disease • Asthma
Carpal Tunnel Syndrome • Chronic Idiopathic Constipation • Chronic Pain
Chronic Obstructive Pulmonary Disease • Delayed Sleep Phase Syndrome • Dementia • Diabetes (Type II) • Diabetic Neuropathy • Epilepsy • Excessive Daytime Sleepiness • Fibromyalgia
Idiopathic Hypersomnia • Insomnia • Irritable Bowel Syndrome with Constipation or Diarrhea
Low Back Pain • Migraine • Multiple Sclerosis • Narcolepsy • Neuropathic Pain • Nonrestorative Sleep • Opioid-Induced Bowel Dysfunction • Obstructive Sleep Apnea/Hypopnea Syndrome
Osteoarthritis • Parkinson's Disease • Polysomnography (PSG) • Post Herpetic Neuralgia
Restless Legs Syndrome (RLS) • Shift Work Sleep Disorder • Spasticity • Stuttering • Tinnitus
Tourette's Disorder • Traumatic Brain Injury

ADDITIONAL TREATMENT EXPERIENCE:

Hypertension • Hyperlipidemia • Obesity • Stroke and Stroke Prevention

CLINICAL TRIAL EXPERIENCE:

Phase I Insomnia

A Phase I Clinical Trial to Characterize Symptoms of Excessive Daytime Sleepiness Following Treatment Withdrawal in Participants with Narcolepsy Type 1

A Phase I study designed to obtain consumer preference feedback on an integrated continuous positive airway pressure (CPAP)/mask system and the marketing materials created for this product

A Phase I,Multicenter, Open-label Study to Determine the Effects of XXX on Sleep in Healthy Subjects

Alzheimer's Disease

An Open-Label, Extension Study of the Effects of XXX in Subjects with Alzheimer's Disease or Behavioral Variant Frontotemporal Dementia

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 12-Month Trial of XXX in Subjects with Mild to Moderate Alzheimer's Disease (2 studies: Study A: Multinational, Randomized, Double blind, Placebo controlled, Parallel Group, 18 month, Study of XXX in patients with Mild Alzheimer's Disease AND Study B: Randomized Double blind, Placebo-controlled, Parallel group, 52 week study of 2 dose levels of XXX in pts w/treated or untreated Mild to Moderate Alzheimer's Disease)

Cognition

A Phase II, Randomized, Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group Study Comparing XXX with Placebo in Subjects with Age-Associated Memory Impairment (AAMI)

Epilepsy

Pilot Study to Evaluate a Baseline Prototype Device Designed to Collect ECG (Electrocardiogram) and Accelerometer Data

A Prospective Randomized 12-week Controlled Study of Visual Field Change in Subjects with Partial Seizures Receiving XXX or Placebo

A Phase III, 12-month, Open-label Study Evaluating the Safety and Tolerability of Flexible Doses of XXX as Adjunctive Therapy in Pediatric Patients Ages 1 month to 16 years with Partial Onset Seizures and Pediatric and Adult Patients Ages 5 to 65 years with Primary Generalized Tonic-Clonic Seizures

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Trial of XXX Controlled Release Formulation as Adjunctive Therapy in Adult Subjects with Partial onset Seizures

A Multi-center, Open-Label Study to Assess the Efficacy of as First Add-on Treatment in Adult Patients (17-65) with Partial-Onset Seizures. This Phase III b/IV Study will Assess Two Groups of Epilepsy Patients: Patients who are Not Responding to Monotherapy Anti-Epileptic Drug (AED) Treatment (Diagnosis ≤ 12 Months); OR Patients who Have Not Responded to More Than Two Treatments (Diagnosis ≥ 5 Years)

A Randomized, Double-Blind, Parallel-Group, Multi-center Study to Evaluate the Retention Rate, Efficacy, Safety, and Tolerability of XXX, XXX, and XXX as Adjunctive Therapy in Subjects with Partial Onset Seizures

A 9-11 Week Multi-center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Determine the Effects of Adjunctive XXX on the Sleep Architecture of Adult Subject (18 – 45 Years of Age) with Partial Onset Epilepsy Receiving a First Generation Anti-Epileptic Drug

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,Open-label Extension Study of XXX for 52 weeks in Pain Associated with Fibromyalgia

A Phase III,randomized, double-blind, double-dummy, placebo- and active-controlled, multi-center study of XXX in subjects with pain associated with fibromyalgia

A Phase IIIb Multicenter, Double-blind, Randomized, Placebo-controlled, 2-way Crossover Study of XXX in the Treatment of Fibromyalgia with Concurrent Antidepressant Therapy for Comorbid Depression

A Comprehensive Evaluation of Impacts and Possible Outcome Assessments

A Phase III Double-Blind, Randomized, Placebo-Controlled, Safety and Efficacy Study of Once Daily Controlled Release XXX in the Treatment of Patients with Fibromyalgia

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

A Safety and Tolerability Study Comparing XXX Given as an Oral Solution to a Single-Blinded Combination of Oral Tablets Plus Oral Solution in Subjects with Fibromyalgia

A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Multi-center Study of XXX o Evaluate Responsiveness of, and Estimate the Clinically Important Difference in, a Novel Fatigue Tool in Subjects with Fibromyalgia

The Safety and Tolerability Study Comparing XXX Given as an Oral Solution to a Single-Blinded Combination of Oral Tablets Plus Oral Solution in Subjects with Fibromyalgia

A Randomized Evaluation of a Low Frequency Investigational Device Employing Neuromodulation Therapy in Patients with Fibromyalgia: A Double-Blind, Placebo-Controlled Trial

A Multi-center, Randomized, Double-Blind, XXX-Referenced, Placebo-Controlled, Parallel-Group, Adaptive Design Study of XXX in Adult Female Outpatients with Fibromyalgia Syndrome

A Multi-center, Multiple Dose, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of the Safety and Efficacy of XXX in Female Patients with Fibromyalgia Syndrome

A Six-Month Open Label Extension Study of the Long-Term Safety of the XXX in Outpatient with Fibromyalgia Syndrome

A Multi-center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Adaptive-Design, Efficacy, Safety and Tolerability Study of 4 Fixed Oral Doses of XXX in Adult Outpatients with Fibromyalgia Syndrome

Insomnia

A Phase IIIb, Open Label Study to Evaluate Long-Term Safety and Tolerability of a Once Nightly Formulation of XXX for Extended-Release Oral Suspension XXX and the ability to switch from twice-nightly immediate release XXX to once-nightly XXX for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Subjects with Narcolepsy

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III multi-center, double-blind, randomized, placebo-controlled, parallel-group, polysomnography study to assess the efficacy and safety of XXX in adult and elderly subjects with insomnia disorder

A Phase III, Multi-center, Double-blind, Randomized, Placebo-controlled, Parallel-group, Polysomnography Study to Assess the Efficacy and Safety of XXX in Adult and Elderly Subjects with Insomnia Disorder

A Phase II, Randomized, 2-way Crossover, Double-blind Study to Compare the Efficacy, Safety, and Tolerability of 2 Doses of XXX Versus XXX in Elderly Subjects with Insomnia Disorder Without Psychiatric Comorbidity

A Phase III, multicenter, 12-month, randomized, double-blind, controlled study to evaluate the safety and efficacy of XXX in subjects 18 years or older with insomnia disorder. Subjects must report complaints regarding both sleep onset AND sleep maintenance

A Phase II, Randomized, Placebo-Controlled, DoubleBlind, Fixed-Dose, Multiple Cohort, Multiple Crossover, Dose-Finding Study of Oral XXX in Adults with Idiopathic Hypersomnia or Narcolepsy Type 2

A Phase II Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Bayesian Adaptive Randomization Design, Dose Response Study of the Efficacy of XXX in Adults and Elderly Subjects with Chronic Insomnia

A 12-Month, Open-Label Study to Evaluate the Safety, Tolerability, and Efficacy of XXX as Treatment for Patients With Excessive Sleepiness Associated With Mild or Moderate Closed Tramatic Brain Injury

A Phase III, Multi-center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Polysomnography Study to Evaluate the Safety and Efficacy of XXX in [adults and] Elderly Patients with Primary Insomnia

A Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multi-center Outpatient Trial of XXX in Adults with Nonrestorative Sleep

A Phase III, Efficacy and Safety of XXX in Insomnia Characterized by Sleep Maintenance Difficulties: A Six-Week, Randomized, Double-Blind, Placebo-Controlled, Polysomnography (PSG) Study

A Randomized, Double-Blind, Placebo-Controlled Subjective Study to Assess the Efficacy of XXX in Patients with Primary Insomnia characterized by Difficulty in Maintaining Sleep

A Phase II Randomized, Double-Blind, Placebo-and Active-Comparator-Controlled Study of the Safety and Efficacy of XXX in Outpatients with Insomnia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Double-Blind, Randomized, Parallel Group, Placebo-Controlled Sleep Laboratory Efficacy and Safety Study with XXX in Elderly Subjects with Chronic Primary Insomnia

A Fifty-Two Week Open Label Extension Trial, to Evaluate the Efficacy and Safety of XXX Trial in Outpatients with Chronic Primary Insomnia who Completed Clinical Trial

A Multi-center Randomized, Double-Blind, Placebo-Controlled, Parallel Study to Investigate the Efficacy and Safety of XXX in the Treatment of Primary Insomnia

An Efficacy and Safety of XXX on Sleep Maintenance Insomnia with a Sub-Study of the Effect of XXX on Stable Type II Diabetes Mellitus: A One Year, Multi-center, Randomized, Double-Blind, Placebo-Controlled Study

A Six Week, Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Efficacy and Safety, Sleep Lab Trial with XXX Trial in Patients with Chronic Primary Insomnia

A Randomized, Double Blind, Placebo-Controlled Study to Determine the Long-Term Efficacy and Safety of XXX in Adults with Chronic Insomnia

The Safety and Efficacy of XXX Taken in Combination with XXX

A 28-Day, Polysomnographic and Subjective Assessment of XXX for the Treatment of Primary Insomnia: A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Trial

A Multi-center, Randomized, Double Blind, Placebo-Controlled, Parallel Study to Investigate the Efficacy and Safety of XXX and Matching Placebo in Healthy Male and Female Subjects with Induced Transient Insomnia

A Phase II, Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Multi-center Proof-of-Concept Study to Evaluate the Safety and Efficacy of XXX Taken in Combination with XXX for the Treatment of Subjects with Chronic Insomnia

A Randomized, Double-Blind, Placebo-Controlled Study to Determine the Long-Term Efficacy and Safety of XXX in Adults with Chronic Insomnia

A Randomized, Double-Blind, Palcebo-Controlled, Cross-Over Study to Eveluate the Effects of XXX on Polysomnographic Sleep Recordings, Subjective Sleep Assessment, and Daytime Cognitive Function in Elderly and Nonelderly Subjects with Primary Insomnia

An Efficacy and Safety of XXX on Sleep Maintenance Insommia: A 12-Week Multi-center, Randomized, Double-Blind, Placebo-Controlled Study Followed by an Open Treatment Phase Extension with XXX for 40 Weeks Period

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Placebo-Controlled, Three-Way Cross-Over Study of XXX in Patients with Insomnia

A Randomized Double-Blind Comparison of XXX, XXX, and Placebo in the Treatment of Patients with Primary Insomnia

An Evaluation of the Long-Term Efficacy and Safety of XXX Compared to Placebo, When Both Are Administered Over a Long-Term Period "As Needed," in Patients with Chronic Primary Insomnia. (A Randomized, Double-blind, Placebo-Controlled, Parallel Group, Multi-center, Phase IIIb Clinical Study)

A Four-Week, Multi-center, Phase IIB Double-Blind, Placebo-Controlled, Randomized, Multiple Dose, Parallel-Group Study of the Efficacy and Safety of XXX Tablets in the Treatment of Sleep Maintenance Insomnia

A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Multi-center, Study of XXX in Healthy Adult Volunteers Participating in a Four-Hour Phase Advance Model of Transient Insomnia

A Randomized, Four-Way Cross-Over, Double-Blind, Placebo-Controlled, Multi-center Dose-Finding Trial with Three Dosages of XXX in Patients with Primary Insomnia

A Six-Month, Chronic Efficacy and Safety Study of XXX in Adult Subjects with Primary Insomnia: A Randomized Double-Blind, Placebo-Controlled Study

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Efficacy and Safety of a Modified Release Formulation of XXX in Elderly Primary Insomnia Patients with Sleep Maintenance Difficulties

A Randomized Double-Blind, Placebo-Controlled Paralled, Two-Week Objective Efficacy and Safety Study of XXX in Elderly Subjects with Primary Insomnia

A Phase III, Randomized, Double-Blind, Placebo-Controlled, PSG Plus Outpatient Study to Determine the Safety and Efficacy of XXX in Adults with Chronic Insomnia

A Phase III, Open-Label, Fixed-Dose Study to Determine the Safety of Long Term Administration of XXX in Subjects with Chronic Insomnia

A North American, Four-Week, Multi-center, Phase IIB Double-Blind, Placebo-Controlled, Randomized, Multiple Dose, Parallel-Group Study of the Efficacy and Safety of XXX Tablets in the Treatment of Sleep Maintenance Insomnia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Efficacy and Safety of A Modified Release Formulation of XXX in Adult Primary Insomnia Patients with Sleep Maintenance Difficulties

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Long-Term Safety and Efficacy of Two Dose Levels of XXX in Adult Patients with Primary Insomnia

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Efficacy and Safety of a Modified Release Formulation of XXX in Adult Primary Insomnia Patients with Sleep Maintenance Difficulties

A Phase III, Open-Label, Outpatient, Extension Study to Assess the Long-Term Safety of a Modified Release Formulation of XXX in Adult Primary Insomnia Patients with Sleep Maintenance Difficulties

A Phase III, Randomized, Double-Blind Placebo-Controlled, PSG Plus Outpatient Study to Determine the Safety and Efficacy of XXX in Adults with Chronic Insomnia

A Phase III, Open-Label, Fixed-Dose Study to Determine the Safety of Long Term Administration of XXX in Subjects with Chronic Insomnia

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Long-Term Safety and Efficacy of Two Dose Levels of XXX in Adult Patients with Primary Insomnia

The Comparison of Efficacy and Safety of XXX and Placebo in Patients with Primary Insomnia. A Double Blind, Randomized, Placebo-Controlled, Parallel Group Study

Migraine

A Phase III, Multicenter, Open-Label 52-Week Extension Study To Evaluate The Long-Term Safety And Tolerability Of Oral XXX For The Prevention Of Migraine In Participants With Chronic Or Episodic Migraine

A Phase III, Double-Blind, Randomized, Placebo Controlled, Safety and Efficacy Trial of XXX intranasal (IN) for the Acute Treatment of Migraine

A Phase III, Multicenter, Open-Label Study Evaluating the Long-Term Safety, and Tolerability of Monthly Subcutaneous Administration of XXX for the Preventive Treatment of Episodic and Chronic Migraine in Pediatric Patients 6 to 17 Years of Age

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Comparing the Efficacy, Safety, and Tolerability of Subcutaneous Administration of XXX Versus Placebo for the Preventive Treatment of Episodic Migraine in Pediatric Patients 6 to 17 Years of Age

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Comparing the Efficacy, Safety, and Tolerability of Subcutaneous Administration of XXX Versus Placebo for the Preventive Treatment of Chronic Migraine in Pediatric Patients 6 to 17 Years of Age

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled, Crossover Study to Evaluate the Efficacy, Safety, and Tolerability of Oral XXX in the Treatment of Migraine When Administered During the Prodrome

A Phase III, 12-Month Study to Evaluate the Safety and Tolerability of XXX (Nasal Powder) in the Acute Treatment of Migraine

A Phase IV, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel Group Study to Evaluate the Efficacy and Safety of XXX as a Therapy for the Prevention of Migraine in Subjects Ages 6-11 Years

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy, Safety, and Tolerability of Oral XXX for the Prophylaxis of Migraine in Participants with Episodic Migraine Who Have Previously Failed 2 to 4 Classes of Oral Prophylactic Treatments

A Phase II/III Open-label, Long-Term, Safety Trial of XXX Intranasal (IN) for the Acute Treatment of Migraine

Comprehensive Assessment of XXX Efficacy in Subjects With High Frequency Episodic Migraine With at Least 1 Previously Failed Preventive Treatment: a Global, Double-blind, Placebo-controlled Phase IV Study

A Phase IV, Effect of XXX on Disability and Work Productivity in Employed Subjects With Episodic Migraine Who Have Previously Failed 1 or More Migraine Preventive Treatments

The Effect of XXX on Disability and Work Productivity in Employed Subjects With Episodic Migraine Who Have Previously Failed 1 or More Migraine Preventive Treatments

A Phase III, Randomized, Double-blind, Single-dose, Placebo-controlled Study to Assess the Efficacy and Safety of XXX for the Acute Treatment of Migraine in Adults

An Open-Label Study to Assess the Long-term Safety of XXX for the Acute Treatment of Migraine in Adults.

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II: Double-Blind, Randomized, Placebo Controlled, Dose-Ranging Trial of XXX for the Acute Treatment of 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, Randomized, Double-Blind, Comparator-Controlled, Placebo-Controlled Study to Assess the Efficacy and Safety of Oral XXX in the Treatment of Acute Migraine Pain, With or Without Aura, and the Prevention of Migraine-Associated Nausea and Vomiting (MANV)

A Randomized, Double-blind, Single-dose, Placebo-controlled Study to Assess the Efficacy and Safety of XXX for the treatment of acute Migraine in adults with prior inadequate response.

A Phase III, Multicenter, Randomized, Open-label Study to Evaluate the Longterm Safety and Tolerability of Oral XXX for the Prevention of Migraine in Patients with Episodic Migraine

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

A Prospective, Randomized, Vehicle-Controlled, Double-Blind, Phase II Study to Assess the Safety, Tolerability, and Efficacy of XXX Delivered as an Intranasal Spray for Preventive Treatment in Subjects with Episodic Migraine

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Comparing the Efficacy, Safety and Tolerability of monthly Subcutaneous Administration of XXX Versus Placebo for the Preventive Treatment of Migraine in patients with inadequate response to 2 to 4 other preventive treatments

A Long-Term, Open-Label Study to Evaluate the Safety of XXX in the Acute Treatment of Migraine

A Multicenter, Open Label, Long-Term Safety Study of XXX in Patients with Acute Migraines

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

A Phase III, Double-Blind, Randomized, Placebo Controlled, Safety, Efficacy, Trial of XXX for the Acute Treatment of Migraine

A Phase III, Multicenter, Randomized, Double-Blind, Placebo Controlled, Efficacy, Tolerability, and Safety Study of XXX in Episodic Migraine With or Without Aura

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multicenter, Randomized, Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of Oral XXX in the Acute Treatment of Migraine With or Without Aura

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Single Attack Study to Evaluate the Efficacy, Safety and Tolerability of Oral XXX in 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 Phase III, Study of Three Doses of XXX (50 mg, 100 mg and 200 mg) Compared to Placebo in the Acute Treatment of Migraine: A Randomized, Double-blind, Placebo-controlled Parallel Group Study

An Observational Research Study: Prospective Cohort Study to Describe Patient-Reported Outcomes in Subjects with Migraine Eligible for Prophylaxis

A Phase III, Multicenter, Randomized, Double-Blind, Parallel-Group Study Evaluating the Long-Term Safety, Tolerability, and Efficacy of Subcutaneous Administration of XXX for the Preventive Treatment of Migraine

A Phase III, Multicenter, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Parallel-Group Study Comparing the Efficacy and Safety of 2 dose regimens of subcutaneous administration of XXX versus Placebo for the Preventive Treatment of Episodic Migraine

A Phase III, Multicenter, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Parallel-Group Study Comparing the Efficacy and Safety of 2 dose regimens of subcutaneous administration of XXX versus Placebo for the Preventive Treatment of Chronic Migraine

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of XXX in Patients with Chronic Migraine – the XXX Study

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of XXX in Patients with Episodic Migraine – the XXX Study

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

An Phase II Open-label Extension (OLE) Study to Assess the Long-term Safety and Efficacy of XXX in Chronic Migraine Prevention

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III Randomized, Multicenter, Double-Blind, Placebo Controlled, Two-Arm Study Evaluating Efficacy of a Single Dose XXX (10 mg vs. Placebo) in Patients with Acute Migraine Headache With or Without Aura

A Phase IIb, Randomized, Doub-Blind, Placebo-Controlled Study of XXX in Patients with Episodic Migraine

A Phase II, Multicenter, Double-Blind, Placebo-Controlled, Parallel Group, Multi-dose Study to Compare the Efficacy and Safety of Subcutaneous XXX with Placebo for the Preventive Treatment of Chronic Migraine

A Phase II,Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Study Comparing the Efficacy and Safety of Two Doses of Subcutaneous XXX with Placebo for the Preventive Treatment of High Frequency Episodic Migraine (HFEM)

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of XXX in Patients with Migraine

A Phase II, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of XXX in Episodic Migraine Prevention, Dosed monthly by subcutaneous (SC) injection.

A Phase IIb Double blind Randomized Placebo controlled, Dose-ranging Trial of XXX for the Acute Treatment of Migraine

A Safety, Tolerability, and Efficacy Study of XXX in the Treatment of Acute Migraine Headache

Pain

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of XXX in Patients With Diabetic Neuropathic Pain

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel-Group Study to Evaluate the Efficacy and Safety of XXX in Subjects with Diabetic Peripheral Neuropathic Pain

A Phase II, Randomized, Double-blind, Placebo and Active Comparator-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of XXX in the Treatment of Diabetic Peripheral Neuropathic Pain

A Phase II, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multiple-Dose Study to Assess the Efficacy and Safety of XXX in Subjects with Neuropathic Pain Associated with Diabetic Peripheral Neuropathy

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IIa, Multicenter, Randomized, Double-blind, Placebo-controlled and Active-controlled, Parallel-group Study Evaluating the Analgesic Efficacy and Safety of XXX in Subjects with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Titration-to-Effect Study of Orally Administered XXX in Patients with Osteoarthritis of the Hip or Knee

A Phase III, Open-Label, Long-Term Safety and Tolerability Study of XXX in Patients with Irritable Bowel Syndrome with Constipation (IBS-C)

An Open-label Phase III Trial to Evaluate the Safety and Tolerability of XXX Tablet, in Patients with Moderate-to-Severe Chronic Noncancer Pain

A Second Phase III, Randomized, 12-Week, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of XXX in Patients with Irritable Bowel Syndrome with Constipation (IBS-C)

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

A Phase III, Randomized, Double Blind, Placebo and Active-Controlled, Multicenter, Parallel-Group Study of the Analgesic Efficacy and Safety of XXX in Adult Patients with Chronic Low Back Pain

A Phase II, Double-blind, Placebo-controlled, Randomised Dose Ranging Trial to determine the safety and efficacy of two dose levels of XXX (angiotensin II type 2 receptor antagonist) administered orally in patients with postherpetic neuralgia

A Phase III Multicenter, Open-Label, 52-week study to Evaluate the Long Term Safety and Tolerability of XXX in Subjects with Moderate to Severe Chronic Noncancer Pain

A Phase III Double-Blind, Placebo-Controlled Study to Assess the Efficacy, Safety, and Tolerability of XXX in Opioid-Naïve Subjects with Moderate to Severe Chronic Low Back Pain

A Safety and Efficacy Evaluation of XXX Laxative in Constipated Adults

A Phase IIa, Randomized, Double-Blind, Multicenter, Placebo and Active-Controlled Study to Assess Analgesic Efficacy and Safety of XXX in Subjects with Painful Diabetic Peripheral Neuropathy

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Topically Applied XXX Ointment in Patients with Postherpetic Neuralgia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized Double-blind, Placebo-controlled, Parallel-group, Multicenter, Phase III Study to Evaluate the Long-term Safety of XXX for the Treatment of Opioid-induced Constipation in Subjects with Non-malignant Chronic Pain Receiving Opioid Therapy

A Double-blind, Randomized, Vehicle-controlled, Parallel-group Evaluation of XXX and Vehicle Nasal Sprays in the Treatment of Postherpetic Neuralgia of the Trigeminal Nerve

A National, 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 Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Assess the Safety and Efficacy of XXX in Subjects with Type 2 Diabetes and Diabetic Peripheral Neuropathy

A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel-group Study of XXX in the Treatment of Opioid-induced Constipation in Subjects with Non-malignant Pain Receiving Opioid Therapy

A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of XXX in Subjects with Postherpetic Neuralgia

A Phase II Multicenter, Randomized, Double-Blinded, Placebo-Controlled Study Using a Bayesian Adaptive Design to Assess the Efficacy, Safety, Tolerability, and Serum Exposure of Multiple Doses of XXX in Subjects with Painful Lumbar Radiculopathy

A Phase III open-label extension study of up to 52 weeks to assess the safety, tolerability, and analgesic efficacy of XXX in the management of moderate to severe chronic pain requiring ATC opioid analgesia for an extended period of time

A Phase III, 6-Month, Open-Label, Extension Study to Evaluate the Safety of XXX at 15 to 90 mg Every 12 Hours for Relief of Moderate to Severe Pain in Patients with Chronic Low Back Pain Who Require Opioid Treatment for an Extended Period of Time

A Phase III, 12-Week, Randomized, Double-Blind, Placebo-Controlled, Randomized-Withdrawal Study to Evaluate the Efficacy and Safety of XXX at 30 to 90 mg Every 12 Hours for Relief of Moderate to Severe Pain in Opioid-Experienced Patients with Chronic Low Back Pain Who Require Opioid Treatment for an Extended Period of Time

A Randomized, Double-Blind, Placebo- and Active-Controlled Study to Evaluate the Safety and Efficacy of XXX in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Randomized, Double-blind, Placebo- and Active-controlled, Parallel-group, Multicenter Study Evaluating the Analgesic Efficacy and Safety of XXX in Subjects With Moderate to Severe Chronic Pain Due to Postherpetic Neuralgia (PHN) pursuant to Protocol XXX

A Phase III, Double-blind, Placebo-controlled, Multicenter, Randomized Withdrawal Study to Evaluate the Analgesic Efficacy, Safety, and Tolerability of XXX in Opioid-Experienced Subjects with Moderate to Severe Chronic Low Back Pain Requiring Around-the-clock Opioid Analgesia for an extended period of time

A Phase III, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Safety, Tolerability, and Efficacy Study of XXX Versus Placebo in Opioid-Experienced Subjects with Moderate to Severe Chronic Low Back Pain

A Phase III Open Label Safety Study of XXX in Subjects with Osteoarthritis or Chronic Low Back Pain

A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase III Study to Evaluate the Efficacy and Safety of XXX for the Treatment of Opioid-Induced Constipation in Adults taking Opioid Therapy for Chronic Non-Cancer Pain AND A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase III Study to Evaluate the Long-Term Safety and Tolerability of XXX for the Treatment of Opioid-Induced Constipation in Adults taking Opioid Therapy for Chronic Non-Cancer Pain

A Phase III, Double-blind, Placebo-controlled, Multicenter, Randomized withdrawal Study to Evaluate the Analgesic Efficacy, Safety, and Tolerability of XXX in Opioid-naïve Subjects with Moderate to Severe Chronic Low Back Pain Requiring Around-the-clock Opioid Analgesia for an Extended Period of Time

A Phase II Study, Assessing the Content Validity of XXX in Patients with Chronic Opioid-Induced Constipation

An Open-label Evaluation of XXX Extended Release (ER) in Subjects with Moderate to Severe Chronic Pain Following Conversion from XXX

A Multi-center, 12-week, Double-blind, Placebo-controlled, Randomized Withdrawal Study to Determine the Efficacy and Safety of XXX Extended-release Capsules in Subjects with Moderate to Severe Chronic Low Back Pain

A Phase IV, Randomized, Double-Blind, Parallel-Arm Clinical Trial to Compare the Clinical Effectiveness of XXX vs. XXX in Subjects with Moderate to Severe Low Back Pain

A Phase IIa, Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group Clinical Trial to Evaluate the Safety and Efficacy of XXX in Patients with Painful Diabetic Neuropathy

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Placebo and Active Comparator-Controlled Study of XXX for Treatment of Neuropathic Pain Associated with Diabetic Peripheral Neuropathy

A Phase II, Multinational, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study of Efficacy and Safety of XXX 20MG and 120MG Twice Daily for 4 Weeks in Patients with Chronic Peripheral Neuropathic Pain

A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of XXX controlled-release Tablets to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to XXX) in Opioid-experienced Subjects with Controlled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy

A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of XXX controlled-release Tablets to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to XXX) in Opioid-experienced Subjects with Uncontrolled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy

An Open Label, Safety and Tolerability Study of Multi-Layer, Extended-Release Tablets of XXX in the Treatment of Patients with Moderate to Severe Acute Pain of Up to 30 Days, of Non-Malignant Origin

A Phase IV, Open Label, Study of Safety and Effectiveness of XXX Tablets in the Treatment of Patients with Post herpetic Neuralgia in Clinical Practice

A Multicenter, Randomized, Double-blind, Placebo-controlled Study with an Open-label Run-in to Assess the Efficacy and Safety of XXX Tablets Once-daily in Subjects with Moderate to Severe Chronic Low Back Pain

A Randomized, Double-blind, Placebo-controlled, Parallel-group Study of XXX for the Treatment of Opioid-induced Constipation (OIC) in Subjects with Non-malignant Chronic Pain Receiving Opioid Therapy

Qualitative Study to Assess the Content Validity of the Modified Insomnia Severity Index (ISI) in Chronic Pain Patients

A 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*):

Open Label Long Term Safety Study: An Open-Label Study to Assess the Long-Term Safety of XXX in Patients with Opioid-Induced Constipation (OIC)

A Randomized, Double-blind, Placebo-controlled, Multicenter Trial with an Enriched Study Design to Assess the Efficacy and Safety of XXX Controlled-release Tablets Compared to Placebo in Opioid-experienced Subjects with Moderate to Severe Pain due to Chronic Low Back Pain who Require Around-the-clock Opioid Therapy

Validation of Short Treatment Satisfaction Questionnaire for Use in Neuropathic Pain Patients Treated with XXX

A Phase II, 52-week, Open-label, Long-term Treatment Evaluation of the Safety and Efficacy of XXX in subjects with moderate to severe Chronic Pain

A Multicenter, Double-blind, Placebo-controlled, Cross-over Study of the Safety and Efficacy of XXX in Patients with Post-herpetic Neuralgia (PHN)

A Phase III Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC)

A Phase IV Multi-center, Primary Care-Based, Open-Label Study to Assess the Success of Converting Opioid-Experienced Patients, with Chronic, Moderate to Severe Pain, to XXX Using a Standardized Conversion Guide, and to Identify Behaviors Related to Prescription Opioid Abuse, Misuse, and Diversion

A Phase III, Multicenter, 12-Month, Open-Label, Single-Arm, Safety Study of XXX and XXX Extended-Release Capsules in Subjects With Moderate to Severe Chronic Non-cancer Pain

A 12-week placebo-controlled, double-blind, randomized withdrawal study to evaluate the efficacy and safety of XXX in subjects with moderate to severe chronic low back pain

A Multi-center, 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-Treatment, Two-Period Cross-Over Study to Evaluate the Safety Tolerability, Preliminary Efficacy and Systemic Exposure of XXX in Patients with Post Herpetic Neuralgia

A Phase IIa, Randomized, Double-Blind, Placebo-Controlled, Two-Treatment, Two-Period Cross-Over Study to Evaluate the Safety Tolerability, Preliminary Efficacy and Systemic Exposure of Topical XXXin Patients with Post Herpetic Neuralgia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Placebo-Controlled, Multi-center Trial with an Enriched Study Design to Assess the Efficacy and Safety of XXXCompared to Placebo in Opioid-experienced Subjects with Moderate to Severe Chronic Low Back Pain

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Single-Dose Study of the Safety and Efficacy of Subcutaneously Administered XXX in Patients with Osteoarthritis of the Knee

A Multi-center, Double-Blind, Randomized, Placebo-Controlled, Repeat Treatment (two cycle) Study of the Safety and Efficacy of XXX in Patients with Post-herpetic Neuralgia

A Randomized, Double-Blind, Placebo-Controlled with Open-label Run-in Assessing Efficacy, Tolerability, Safety of XXX Compared to Placebo in Opioid-Naïve Subjects with Moderate to Severe, Chronic Pain Due to OA of the Knee

A Phase III Randomized, Double-Blind, Placebo-Controlled, Multi-center Study of the Analgesic Efficacy and Safety of the Subcutaneous Administration of XXX in Patients with Osteoarthritis of the Knee

A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of the Efficacy and Safety of XXX in Patients with Chronic Low Back Pain

A Phase IIb, Randomized, Double-Blind, Two-Arm, Multi-center, Placebo-Controlled, Study to Assess the Efficacy and Safety of XXX in Subjects with Moderate to Severe Chronic Low Back Pain (CLBP)

A Phase IIa, Randomized, Blinded, Placebo- and Active-controlled, 2-Period Crossover Study to Assess the Analgesic Efficacy, Safety, and Tolerability of XXX in Subjects with Post herpetic Neuralgia

A Randomized, center, Double-Blind, Parallel-Group Trial with Controlled Adjustment of Dose Assessing the Analgesic Efficacy and Safety of a New Analgesic Compared with Placebo in Subjects with Painful Diabetic Peripheral Neuropathy

An Open-Label 52-Week Safety Study of SR XXX in Adult Outpatients with Chronic Neuropathic Pain Associated with Diabetic Peripheral Neuropathy

A Double-Blind, Randomized, Parallel-Design, Placebo-Controlled, Multi-center, Study of Two Doses of XXX in Adult Outpatients with Pain Associated with Chronic Diabetic Neuropathy

A Multi-center, Randomized, Double-Blind, Placebo Controlled Study of the Effect of XXX at Two Doses for 24-Weeks Treatment on the Rate of Regeneration of Epidermal Nerve Fibers in Patients with Mild Diabetic Peripheral Neuropathy

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II Multi-center, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy, Safety and Tolerability of XXX in Subjects with Diabetic Painful Neuropathy and Small Fiber Neuropathy Associated with Impaired Glucose Tolerance Followed by a Double-Blind Safety Extension and an Open Label Safety Extension

The Investigation of the Efficacy and Pharmacokinetics of XXX in Subjects with Neuropathic Pain Associated with Post-Herpetic Neuralgia (PHN) Who Have Had an Inadequate Response to XXX Treatment

A Phase III Multi-center, Randomized, Double-Blind, Placebo-Controlled, Flexible-Dose Study of the Safety and Efficacy of XXX Tablets in the Treatment of Patients with Post-herpetic Neuralgia" ("Study") in accordance with Sponsor's Protocol

A Double-Blind, Placebo-Controlled, Randomized, Parallel Group Study Evaluating the Efficacy and Tolerability of Oral Medication TID, Versus Placebo in the Treatment of Post Herpetic Neuralgia

A Phase III Multi-center, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Once-Daily XXX Extended Release Tablets in the Treatment of Patients with Post-herpetic Neuralgia

A Randomized, Double-Blind Study Comparing the Safety and Efficacy of the XXX Patch 5% with Placebo in Patients with Pain from Carpal Tunnel Syndrome

A Phase II Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Dose-Loading Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in Subjects with Moderate to Severe Chronic Low Back Pain

A Phase II Randomized, Double-Blind, Multi-Dose, Active- and Placebo-Controlled, Multi-center, Parallel Group Study of the Analgesic Effect of XXX in Adult Patients with Chronic Low Back Pain

A Phase III, 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 Patients with Moderate to Severe Chronic Low Back Pain

A Phase III 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-Naïve Subjects with Moderate to Severe, Chronic Pain Due to Osteoarthritis of the Knee

A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy, Safety and Tolerability of XXX in Subjects with Moderate to Severe, Chronic Knee or Hip Pain From Osteoarthritis

CLINICAL TRIAL EXPERIENCE (*continued*):

Parkinson's Disease

A Phase III, Double-Blind, Placebo-Controlled, Randomized Study Comparing the Efficacy, Safety, and Tolerability of XXX Agonist Versus Placebo in Patients with Early Parkinson's Disease

An Open-Label, Long Term, Flexible Dose Study of Safety, Tolerability, and Therapeutic Response in Patients with Parkinson's Disease

The Safety and Efficacy of XXX in the Treatment of Patients with Psychosis Associated with Parkinson's Disease

A Phase IIIb, Randomized, Double-Blind, Double-Dummy XXX-Controlled, Parallel Group Study of Two Years Treatment with XXX or XXX as Adjunctive Therapy in Patients with Parkinson's Disease Not Optimally Controlled on XXX

Respiratory

A Phase III, 24 week treatment, multicenter, randomized, double blinded, double dummy, parallel-group, clinical trial evaluating the efficacy and safety of XXX fixed-dose combination BID compared with each monotherapy

A Phase III, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of XXX in patients with Uncontrolled Asthma who are on Inhaled Corticosteroids and a Second Controller Medication

A Phase IV Safety and Efficacy Study of Inhaled XXX Combination versus Inhaled XXX in the Treatment of Adolescent and Adult Subjects with Asthma

Restless Legs Syndrome

A Remote, Double-Blind, Randomized, Placebo-Controlled Study of XXX in Adolescent Subjects with Idiopathic Restless Legs Syndrome

A Randomized, Double-Blind, Placebo-Controlled, Fixed-Dose, Parallel-Group Study to Compare the Efficacy, Tolerability, and Safety of 3 Doses of XXX With Placebo in the Treatment of Subjects With Moderate-to-Severe Primary Restless Legs Syndrome

A Phase IIIb, Double-blind, Randomized, Placebo-controlled Study of XXX and it's Effect on All-day Fuctioning and Quality of Life in Subjects with Moderate to Severe Idiopathic Restless Legs Syndrome

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IIIb multi-center, randomized, double-blind, placebo-controlled, parallel-group, polysomnography (PSG) study to investigate safety and efficacy of the XXX in subjects with restless legs syndrome and end-stage renal disease requiring hemodialysis

A Randomized, Double-blind, Placebo-controlled, Safety and Efficacy Study of XXX in the Treatment of Moderate to Severe Restless Legs Syndrome (RLS)

A Multicenter, Open-label, 2-group, Dose Escalation Study of Monotherapy Administration of XXX in Pediatric Subjects with Idiopathic Restless Legs Syndrome

A Phase II, Open-label, Long-term, Follow-up Study to determine the Safety, Tolerability and Efficacy of XXX as Monotherapy in Adolescents with Restless Legs Syndrome

A Fixed Dose Randomized, Double-Blind, 12-week Study of XXX Subjects with Moderate to Severe Idiopathic Restless Legs Syndrome

A Randomized, Double-Blind, Placebo-Controlled, 3-Way Crossover, Multi-center Polysomnography Study of XXX and XXX in Adults with Restless Legs Syndrome

A Fixed-dose, Randomized, 12-Week Placebo-Controlled, 52-week Comparator-Controlled, Double-Blind Study to Assess the Rates of Augmentation, Efficacy and Safety of XXX and XXX in Subjects with Moderate to Severe Idiopathic RLS

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

A Phase II, Double Blind, Placebo-Controlled, Randomized, Parallel-Group, Multi-center, Study to Evaluate the Efficacy and Safety of XXX in Subjects with Restless Legs Syndrome (RLS)

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

A Four-Week, Randomized, Double-Blind, Cohort Study to Evaluate the Safety and Tolerability of Converting From XXX Immediate Release (IR) to XXX Extended Release (XR) Formulation in Patients with Restless Legs Syndrome (RLS)

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 XXX in Subjects with Idiopathic Restless Legs Syndrome

A Randomized, Double Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX in Patients with Restless Legs Syndrome

CLINICAL TRIAL EXPERIENCE (*continued*):

A 12-Week, Double-Blind, Placebo-Controlled, Parallel Group Study to Assess the Efficacy of XXX in Patients Suffering From Restless Legs Syndrome (RLS)

A 12-Week Double-Blind, Placebo Controlled Study to Assess the Tolerability, Efficacy and Safety of XXX Dosed PRN in Subjects with Restless Legs Syndrome (RLS) who Respond to Open-Label Treatment with XXX

A 12-Week, Double-Blind, Placebo Controlled, Twice Daily Dosing Study to Assess the Efficacy and Safety of XXX in Patients Suffering From Restless Legs Syndrome (RLS) Requiring Extended Treatment Coverage

Sleep Disorders

A Phase II, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of 2 mg and 4 mg XXX Compared to Placebo in Patients with Narcolepsy with and without Cataplexy

A Multi-center, Randomized, Double-blind, Placebo-controlled, 3-Week Crossover Study to Assess the Efficacy and Safety of XXX in Subjects with Cataplexy and Excessive Daytime Sleepiness in Narcolepsy

A Double-Blind, Placebo-Controlled, Randomized-Withdrawal, Multicenter Study of the Efficacy and Safety of Low Sodium XXX with an Open-Label Safety Extension in Treatment of Idiopathic Hypersomnia

A Phase II, Randomized, Placebo-Controlled, Double-Blind, Crossover Study of Oral XXX in Adults with Idiopathic Hypersomnia

A Phase III, Double-Blind, Placebo-Controlled, Randomized-Withdrawal, Multicenter Study of the Efficacy and Safety of XXX in Subjects with Narcolepsy with Cataplexy

A Phase III, Long-Term, Open-Label Safety and Maintenance of Efficacy Study of XXX in the Treatment of Excessive Sleepiness in Subjects with Narcolepsy or Obstructive Sleep Apnea

A Phase III, Twelve-Week, Double-Blind, Placebo-Controlled, Randomized, Parallel-Group, Multicenter Study of the Safety and Efficacy of XXX in the Treatment of Excessive Sleepiness in Subjects with Obstructive Sleep Apnea (OSA)

A Phase III, Twelve-week, Double-blind, Placebo-controlled, Randomized, Parallel-group, Multicenter Study of the Safety and Efficacy of XXX in the Treatment of Excessive Sleepiness in Subjects with Narcolepsy

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II/III Double-Blind, Placebo-Controlled, Randomized-Withdrawal, Multicenter Study of the Efficacy and Safety of XXX with an Open-Label Pharmacokinetic Evaluation and Safety Extension in Pediatric Subjects with Narcolepsy with Cataplexy

A twelve-week, double-blind, placebo-controlled, randomized, parallel-group, multi-center study of the safety and efficacy of XXX in the treatment of excessive daytime sleepiness in subjects with narcolepsy

A Four-week, Double-blind, Placebo-controlled, Randomized, Cross-over Study of the Safety and Efficacy of XXX in the Treatment of Excessive Daytime Sleepiness

A Phase III, Randomized, Double Blind, Placebo-Controlled, Parallel-Group Study to Assess the Efficacy and Safety of XXX Treatment in Children and Adolescents with Excessive Sleepiness Associated with Narcolepsy

A Short-Term (Eight-Week) Open-Label Study, followed by a Long-Term Evaluation, to Assess Patient-Reported Outcomes with XXX Treatment for Excessive Sleepiness in Adults with Narcolepsy or Obstructive Sleep Apnea/Hypopnea Syndrome

A Randomized Phase II, Double-Blind, Placebo-Controlled, Multi-center Crossover Study of XXX as a Daily Treatment for Excessive Daytime Sleepiness (EDS) Associated with Narcolepsy

A One-Year Open Label, Flexible Dosage Extension Study to Assess the Safety and Continued Effectiveness of XXX Treatment in Children and Adolescents with Excessive Sleepiness Associated with Narcolepsy or Obstructive Sleep Apnea/ Hypopnea Syndrome

A Phase III, Randomized, Double Blind, Placebo-Controlled, Parallel-Group Study to Assess the Efficacy and Safety of XXX Treatment in Children and Adolescents with Excessive Sleepiness Associated with Obstructive Sleep Apnea/Hypopnea Syndrome

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of XXX at a Target Dosage of XXX as Treatment for Adults with Excessive Sleepiness Associated with Obstructive Sleep Apnea/Hypopnea Syndrome with Comorbid Major Depressive Disorder or Dysthymic Disorder

A Short-Term (Eight-Weeek) Open-Label Study, Ollowed by a Long-Term Evaluation, to Assess Patient-Reported Outcomes with XXX Treatment for Excessive Sleepiness in Adults with Narcolepsy or Obstructive Sleep Apnea/Hypopnea Syndrome

A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of XXX as Treatment for Adults with Residual Excessive Sleepiness Associated with Obstructive Sleep Apnea/Hypopnea Syndrome

CLINICAL TRIAL EXPERIENCE (*continued*):

A 12-Month, Open-Label, Flexible-Dosage Extension Study of the Safety and Efficacy of XXX in the Treatment of Patients with Excessive Sleepiness Associated with Narcolepsy, Obstructive Sleep Apnea/Hypopnea Syndrome, or Chronic Shift Work Sleep Disorder

A Consumer Preference Study of the XXX All-in-One Positive Airway Pressure System on adult patients with Obstructive Sleep Apnea (OSA)

A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Tolerability of XXX Treatment (150 mg) in Improving Clinical Condition Late in the Shift and in Improving Functional and Patient-Reported Outcomes in Adult Patients with Excessive Sleepiness Associated with Shift Work Disorder

A 12 week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dosage, Study to Evaluate the Efficacy and Safety of XXX as Treatment for Patients with Excessive Sleepiness Associated with Mild or Moderate Closed Traumatic Brain Injury

A Randomized, Double-Blind, Placebo-Controlled, Parallel, Proof of Concept Study to Evaluate the Effectiveness of XXX to Advance the Timing of Sleep in Individuals with Delayed Sleep Phase Syndrome (DSPS)

A Phase III Multi-center, Randomized, Double-Blind, Placebo Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of 12 Weeks of Study Drug XXX as Treatment for Adults with Excessive Sleepiness Associated with Chronic Shift Work Sleep Disorder (SWSD)

Other Indications

A Pivotal Trial – IDE Medical Device. Targeted Hypoglossal Neurostimulation Study

A Double-blind, Randomized, Placebo-controlled, Parallel-group, Phase IV Study to Evaluate the Effect of XXX on Long-term Cardiovascular Safety and COPD Exacerbations in Patients with Moderate to Very Severe COPD

A Phase III, 28-Week, Multi-Center, Randomized, Double-Blind, Parallel-Group, Active-Controlled Safety Extension Study to Evaluate the Safety and Efficacy of XXX, XXX and XXX in Subjects With Moderate to Very Severe COPD, With XXX as an Active Control

A Phase III, Randomized, Double-Blind (Test Products and Placebo), Chronic Dosing (24 Weeks), Placebo-Controlled, Parallel Group, Multi-Center Study to Assess the Efficacy and Safety of XXX, XXX , and XXX in Subjects With Moderate to Very Severe COPD, Compared With Placebo and XXX as an Active Control

A Phase III, Clinical Evaluation Of The Safety Of XXX When Administered Once Daily To Subjects With Spasticity Due To Multiple Sclerosis (MS): An Open Label, Long Term, Safety Trial

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Safety and Efficacy of Fixed-dose Once-daily XXX in Children and Adolescents with Tourette's Disorder

An Phase III Open-Label, Multicenter Study Evaluating the Safety and Tolerability of Once-daily XXX in Children and Adolescents with Tourette's Disorder

A Phase III Study to Assess Repeat Treatment Efficacy and Safety of XXX in Subjects with Irritable Bowel Syndrome with Diarrhea (IBS-D)

A Placebo-Controlled Randomized Withdrawal Evaluation Of The Efficacy And Safety of XXX In Subjects With Spasticity Due To Multiple Sclerosis

A Phase III, Six-month Randomized, Active Comparator, Open label, Multi-center Study to Evaluate Patient Outcomes, Safety and Tolerability of XXX in patients with Relapsing Remitting MS who are candidates for MS Therapy Change from previous Disease Modifying Therapy

A Multicenter, Randomized, Placebo-controlled, Double-blinded Study of the Efficacy and Safety of XXX in Subjects with Opioid-Induced Bowel Dysfunction

A Randomized, Double-blind, 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 Randomized, Double-Blind, Placebo-Controlled, Clinical Evaluation of the Efficacy, Safety and Tolerability of XXX in Patients with Subjective Tinnitus AND an Open-Label, Long-Term Treatment Study to Assess the Long-Term Safety and Tolerability and Efficacy of XXX in Patients with Subjective Tinnitus

A Three-Arm, Double-Blind, Placebo-Controlled Clinical Trial to Assess the Efficacy, Safety and Tolerability of XXX for the Treatment of Adults with Stuttering

An Eight -Week, Double Blind, Randomized, Multi-center, Flexible-Dose, Placebo Controlled Pilot Study of XXX in Patients with PDS Followed by a 52-Week Open-Label Extension Pharmacogenomics Blood Sampling Protocol for XXX

PRESENT ACTIVITIES:

Sleep Medicine Consultants, Founder, 2001- present
FutureSearch Trials of Neurology & Sleep Disorders, Principal Investigator, 2001 - present
The Sleep Center of Austin, Medical Director, Austin, TX

PAST ACTIVITIES:

American Heart Association, Capital Area, President, 2001-2002, Special Task Force, 1977-1978
American Stroke Association, Operation Stroke, Chairman, 2001-2002
Austin EEG and Neuroscience Laboratory, Founder
Austin Neuro Diagnostics, Inc., President and Founder (CT Scanner, Neurochemistry Lab, Vascular Lab)
Austin Neurological Clinic, Founder, 1970
Austin Neurological Society, Charter Member 1972, Program Chairman
Central Texas Imaging Center, Medical Advisory Board, 1985-1992
Critical Connections, Board Member, 2006-2010
Depomed, Inc., Consultant 2012
Examiner, American Board of Neurology and Psychiatry, 1981
Hospital Staff: St. David's, Seton, & Heart Hosp. of Austin, Central Texas Medical Center
Medical Science Center, Owners' Association, President, 1979-1980
Multiple Sclerosis Society, Central Texas Chapter, Board
Neurological Consultant, University of Texas Women's Athletics, 1985-1992
REM Sleep Center, Medical Director, Texas State University/San Marcos, TX
Seton Hospital League House, Chairman of Board, 1999-2008
Seton Shoal Creek Hospital, Board of Trustees, 1990-2000, Chief of Staff, 1980-1982
Shoal Creek Hospital, Sleep Lab, Assoc. Director and Founder, 1979-1989
Sleepdisorders.com, Medical Director and Advisor, 2012
Texas Medical Association, Socio-Economic Committee, 1981-1986 & House of Delegates 2003-2008
Texas Medicine, Editorial Consultant
Texas Neurological Society, President, 2000-2001, Exec. Com., 1998-2010, Program Chairman, 1998
Texas NeuroRehab Center, Medical Director of Comprehensive Rehab, 1980-2010
Texas State University, San Marcos, TX, Polysomnography Program, Co-Medical Director
United Fund Coordinator, Travis County Medical Society, 1974
Volunteer Physician, Caritas of Austin, Brackenridge Neurology Service, 1967-1987
Volunteer Physician, Project Access of Austin

SPECIAL HONORS:

Brown Schools Rehab Center Physician of the Year (1994)
Roger McCary Award for Physician Excellence 1997
Texas Medicine, Editorial Consultant
Seton Hospital League House, Chairman of the Board, 2001-2008
Texas Neurological Society, Past President 2000-2001
Capital Area American Heart Association, President, 2001-02, Austin, TX
Health Initiative Leader, American Heart Association, Texas, 2003
Distinguished Service Award, American Heart Association, Texas 2002
AMA Physician Recognition Award (2004-2009)

MEMBERSHIPS:

Texas Medical Association
Travis County Medical Society
Texas Neurological Society (Fellow)
Austin Neurological Society
American Academy of Neurology (Fellow)
World Federation of Neurology
Am. Clinical Neurophysiology Society (Fellow)
American Heart / Stroke Council
American Academy of Sleep Medicine (Fellow)
American Board of Sleep Medicine
World Association of Sleep Medicine
American Sleep Apnea Association
Southern Sleep Society
Pickwick Society of National Sleep Foundation
Roger McCary Society
National Stroke Association

SPEAKER'S BUREAU AND PRESENTATIONS:

Jazz Pharmaceutical National Advisory Board 2004-2014
UCB Neupro Advisory Board 2009-2014
Depomed Consultant, 2011-2012
Boehringer-Ingelheim, 2004-2010
GSK, (RLS) 2003-2009
Member, Cephalon Advisory Panel, 2009-2010
Sanofi National Speaker's Bureau, 2002-2009
Forest Laboratories, Inc., 2009
Takeda, 2005-2008
Sepracor, 2003-2008
Sleep Disorders, Stroke and Heart Attack (El Paso Heart Conference 2009)
Texas Advanced Nurse Practitioner Conference, 9/2008
Atlanta School of Sleep Medicine (San Antonio), Lecturer 2006 - 2009
Sleep Disorders in Rehabilitation Setting (Brown Schools Annual Conf)
Grand Rounds, Seton Medical Center, Insomnia, 2006
Grand Rounds, Heart Hospital, Sleep Disordered Breathing, Cardiovascular & Cerebrovascular Disease, 2006
USA Today National Hotline - Sleep Disorders, Ntl. Sleep Foundation (Washington, DC 2000, 2001)
Sleep Disorders Interview, KTBC 2006, KXAN 2003
Stroke interviews, KKMJ and KVUE 1999-2001, 2006
Stroke Rehab (Puerto Rico Heart Assoc. / San Juan), 1998
Stroke Prevention (Marble Falls, Llano, Austin, Bastrop)/Brackenridge Hospital 9/2001-11/2002
Grand Rounds Brackenridge Hospital, Austin Internal Medicine Society
Parkinson's and Music Therapy (Cleveland, Ohio), 2000
Parkinson's Disease (McAllen, HealthSouth, Parkinson's Capital Area Society)

POSTERS AND PUBLICATIONS:

1. Benes, H., Thein, S.G., Andry, Sr., J.M., Hudson, J.D., Villa, K.F., Chen, D., Carter, L.P., Wang, H., Lu, Y., Black, J., Maynard, J., A Phase 3, Randomized, Placebo-Controlled, Double-Blind, Multicenter, 12-Week Study of the Safety and Efficacy of JZP-110 in the Treatment of Excessive Sleepiness in Patients with Obstructive Sleep Apnea: SF-36 and EQ-5D-5L Measures *Presented at SLEEP 2017, the 31st Annual Meeting of the Associated Professional Sleep Societies*, Boston, MA, June 3–7, 2017

2. Elshoff, Jan-Peer, Hudson, J.D., Picchietti, D.L., Ridel, K., Walters, A.S., Doggett, K., Moran, K., Oortgiesen, M., Ramirez, F., Schollmayer, E., Pharmacokinetics of Rotigotine transdermal system in adolescents with idiopathic restless legs syndrome (Willis–Ekbom disease) *Sleep Medicine Journal*, Abstract June 2016

3. Jan-Peer Elshoff, Kimberly Doggett, Erwin Schollmayer, Kimberly Moran, Marga Oortgiesen, John Hudson, Keith Ridel, Arthur S. Walters, Daniel L. Picchietti
   Poster: Pharmacokinetics of Rotigotine in Pediatric Patients with Idiopathic Restless Legs Syndrome/Willis-Ekbom Disease Following Multiple Patch Applications presented at the *Child Neurology Society (CNS) Meeting*, 7-10 October 2015, Gaylord National Harbor Resort & Convention Center, National Harbor, MD

4. Hudson, J.D., UCB, A Multicenter, Open-Label, 2-Group, Dose Escalation Study of Monotherapy Administration of Rotigotine in Pediatric Subjects with Idiopathic Restless Legs Syndrome, *Clinical Study Report (CSR)*, August 2014

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