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AFFILIATIONS:

Berlin Medical Associates
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EDUCATION:

1990 - 1994 Doctor of Osteopathic Medicine
Philadelphia College of Osteopathic Medicine, Philadelphia, PA

1986 - 1990 Bachelor of Arts
University of Maryland - College Park, College Park, MD

INTERNSHIP:

1994 - 1997 Family Medicine Internship and Residency
University of Medicine and Dentistry- School of Osteopathic Medicine, Stratford, NJ

CERTIFICATION:

American College of Osteopathic Family Physicians, Diplomat

LICENSURE:

State of New Jersey - Physician - 25MB06370200

MEMBERSHIP:

American College of Osteopathic Family Physicians
American Osteopathic Association
Committee of Interns and Residents
Lambda Omicron Gamma
New Jersey Association of Osteopathic Physicians and Surgeons
National Medical Society

PROFESSIONAL EXPERIENCE:

Principal Investigator, 2015 - present
Hassman Research Institute, LLC., Berlin, NJ

Medical Director, 2001 - present
Comprehensive Clinical Research, Berlin, NJ

Investigator, 1998 - present
Comprehensive Clinical Research, Berlin, NJ

Family Practice, 1998 - present
Berlin Medical Associates, Berlin, NJ

Founder / President/ Sub-Investigator 1998 - 2001
Clinical Managed Care Research, San Diego, CA

Physician/ Sub-Investigator, 1997 - 1998
Family Practice Associates Medical Group, Santee, CA

INVESTIGATOR EXPERIENCE:

Acne • Addiction • ADHD • Allergies • Alzheimer's Disease • Ankle Sprain • Anxiety • Asthma
Atrial Fibrillation • Axillary Hyperhidrosis • Birth Control • Cancer Pain Cancer Screening
Carpal Tunnel Syndrome • Chronic Pain • COPD • COVID-19 • Crohn's Disease • Dermatitis
Depression • Device • Diabetes (Type 1 & 2) • Diabetic Kidney Disease
Elevated C-Reactive Protein • Endometriosis Erectile Dysfunction • Fibromyalgia
Gastroparesis • GERD • Glucose Monitoring • Healthy • Heartburn • Hepatic Function
Hepatitis B & C • Hormone Replacement Therapy • Hypercholesterolemia • Hyperlipidemia/
Dyslipidemia Hypertension • Hypertriglyceridemia • Influenza • Insomnia
Irritable Bowel Syndrome (IBS) • Lactose Intolerance • Migraine • Metabolic Syndrome
Molluscum Contagiosum • Multiple Sclerosis • Muscle Spasm • Narcolepsy
Neurogenic Orthostatic Hypotension • Neuropathic Pain • Nonalcoholic Fatty Liver Disease
(NAFLD) • Nonalcoholic Steatohepatitis (NASH) • Niacin-Induced Flushing • Nocturia
Obesity • Opioid Dependence • Opioid-Induced Constipation • Osteoarthritis • Osteoporosis
Otitis Externa • Overactive Bladder • Pneumonia • Prostate Cancer • Pruritus • Psoriasis

INVESTIGATOR EXPERIENCE (*continued*):

Renal Function • Respiratory Illness • Rheumatoid Arthritis • Rosacea • Sinusitis Sleep Apnea
Tendonitis • Ulcerative Colitis • Urinary Incontinence • Uterine Leiomyomata
Urinary Tract Infection (UTI) • Vaccine • Women's Health

INVESTIGATOR INTEREST:

Actinic Keratosis • Alopecia Areata • Bipolar Disorder • Cognitive Impairment • Conjunctivitis
Epilepsy • Esophagitis • Graves' Disease • Hyperkalemia • Parkinson's Disease
Post-Traumatic Stress Disorder (PTSD) • Primary Biliary Cirrhosis • Schizophrenia
Systemic Lupus Erythematosus • Thyroiditis • Uveitis • Vitiligo

CLINICAL TRIAL EXPERIENCE:

Phase I

A Phase Ib Double-Blind, Randomized, Placebo-Controlled Study of Single and Repeat Dose Administration of XXX in Moderate to Severe, Painful Osteoarthritis of the Knee

A Phase I, Open-Label, Single Ascending Dose Study to Assess the Safety and Pharmacokinetics of XXX in Patients with Osteoarthritis of the Knee

A Phase I Randomized, Double Blind, Placebo Controlled, Multiple Ascending Dose Study to evaluate the Safety, Tolerability, and Pharmacokinetic Properties of XXX Administered Subcutaneously in Subjects with Nonalcoholic Steatohepatitis (NASH) or with nonalcoholic fatty liver disease (NAFLD) and at increased risk of NASH

A Phase Ib Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of XXX in Subjects with Nonalcoholic Steatohepatitis (NASH)

A Phase I, Randomized, Double-blind, Placebo-controlled, Ascending Multiple-dose Study to Determine the Safety and Tolerability, Pharmacokinetics, and Pharmacodynamics of Orally Administered XXX in Subjects with Type 2 Diabetes Mellitus

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

A Phase I Double-blind, Placebo-Controlled, Multiple Ascending Dose Study to Determine the Safety, Tolerability and Pharmacokinetics of XXX Oral Solution in Healthy Adults

A Phase Ib, Multi-center, Randomized, Double-blind, Vehicle-controlled Study Assessing the Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of XXX in Subjects with Atopic Dermatitis

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase I, Randomized, Double-blind, Third-party Open, Placebo-controlled, Dose Escalating Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single and/or Multiple Intravenous and/or Subcutaneous Doses of XXX in Healthy Subjects who may be Mildly Atopic Subjects with Chronic Rhinosinusitis with Nasal Polyps, and Subjects with Moderate Severe Atopic Dermatitis

A Phase Ib Randomized, Active Controlled, Double-Blind, Cross-Over Pharmacokinetic/ Pharmacodynamic and Safety Study in Healthy Adults after Single-Dose XXX Injection

A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase Ib Study to Assess the Pharmacokinetics and Safety Associated with Maximal Use of XXX, 0.5% Ointment Administered Twice Daily in Subjects with Pruritus Associated with Psoriasis Vulgaris Lesions

A Phase I, Randomized, Double-blind, Placebo-controlled, Ascending Multiple-dose Study to Determine the Safety and Tolerability, Pharmacokinetics, and Pharmacodynamics of Orally Administered XXX in Subjects with Type 2 Diabetes Mellitus

A Phase Ib, Randomized, Blinded, Placebo-controlled, Multiple Ascending-dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Subcutaneous XXX in patients with Type 2 diabetes mellitus and Nonalcoholic fatty liver disease

A Phase I, Open label, Multicenter, Single Dose Study to Evaluate the Pharmacokinetics of XXX in Healthy Subjects with Normal Renal Function and Subjects with Impaired Renal Function and A Phase I, Open label, Multicenter, Single Dose Study to Evaluate the Pharmacokinetics of XXX in Healthy Subjects with Normal Hepatic Function and Subjects with Impaired Hepatic Function

A Phase I, Open label, Multicenter, Single Dose Study to Evaluate the Pharmacokinetics of XXX in Healthy Subjects with Normal Renal Function and Subjects with Impaired Renal Function and A Phase I, Open Label, Multicenter, Single Dose Study to Evaluate the Pharmacokinetics of XXX in Healthy Subjects with Normal Hepatic Function and Subjects with Impaired Hepatic Function

A Phase I, Study Comparing the Pharmacokinetics of Intranasal XXX in Subjects with Severe Renal Impairment and Subjects with Normal Renal Function

A Phase I, Systemic Pharmacokinetics of Intranasal XXX in Hepatic-impaired Individuals

A Phase Ib, Randomized, Double-Blind, Multiple-Dose Ranging Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Antiviral Activity of XXX in Subjects With Chronic Hepatitis C Virus Infection

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase I, Multi-dose, Randomized, Blinded, Vehicle-and Active Comparator-controlled, Sequential Dose Cohorts, Multi-center Trial to Assess the Safety, Pharmacokinetics, ad Proof of Concept Efficacy of Topical XXX Ointment, Applied Twice Daily for 28 Days, in Adult Subjects with Atopic Dermatitis

A Phase I, Double-Blind, Randomized, Placebo-Controlled, Single and Multiple Dose Ranging Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Antiviral Activity of XXX in Treatment Naive Subjects with Chronic Hepatitis C Virus Infection

A Phase I, randomized Double-blind, Placebo-controlled, Ascending Multiple-dose Study to Evaluation the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX in Healthy Subjects and Subjects with Mild to Severe Crohn's Disease

A Randomized, Double-Blind, Placebo-Controlled Ascending-Dose Phase Ib Safety of Three Different Doses of an Alpha-7 Nicotinic Acetylsholine Receptor Agonist XXX or Placebo in Patients with Mild to Moderate Probable Alzheimer's Disease

A Phase Ib, Multicenter, Double-Blind, Randomized, Placebo-Controlled, Crossover Clinical Trial of XXX 100 mg and XXX 200 mg in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Diet and Exercise

Phase II-IV

Addiction

Hair, Urine, and Saliva Procurement Protocol for the Development of Drugs of Abuse Tests

A Phase II, Multi-Center Trial of XXX in the treatment of Cocaine Use Disorder

A Phase III, Open-Label, Long-Term Safety and Tolerability Study of Depot XXX in Treatment-Seeking Subjects With Opioid Use Disorder

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Assess Efficacy of Multiple Subcutaneous Injections of Depot XXX Over 24 Weeks in Treatment-Seeking Participants With Opioid Use Disorder

A Prospective Evaluation of Treatment Satisfaction with XXX in Opioid Dependent Subject

A Phase III, Study to Evaluate the Safety, Tolerability, and Efficacy of XXX for use in Conjunction with XXX in Adults with Opioid Use Disorder Prior First Dose of XXX

A Phase III, Randomized, Non-inferiority, Multicenter Study to Assess Early Treatment Efficacy of XXX Versus XXX and to Explore Switching Between Treatments

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IV, Multi-center, Open-Label, 24-Week, Follow-Up Study to Assess Safety, Efficacy, and Treatment Adherence For Maintenance Treatment of Opioid Dependence With XXX

Allergy/ Asthma/ COPD

A Multicenter, Randomized, Double Blind, Placebo-Controlled, Phase III Study to Determine if XXX Prevents Clinically Symptomatic Respiratory Illness in the Elderly

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-controlled, Parallel-Group Study to Evaluate the Efficacy, Durability, Safety, and Tolerability of XXX in Subjects with Lactose Intolerance

A Randomized, Single-dose, Double-blind, Double-dummy, Four-period, Four-sequence, Four-treatment, Placebo and Active-controlled, Comparative, Multiple-center, Crossover-design, Bronchoprovocation Study to Evaluate the Pharmacodynamic Equivalence of XXX to XXX in Patients with Stable, Mild Asthma

A Phase IV, 26-Week Randomized, Double-Blinded, Active Controlled Study Comparing the Safety of Mometasone Furoate/Formoterol Fumarate MDI Fixed Dose Combination Versus Mometasone Furoate MDI Monotherapy in Adolescents and Adults With Persistent Asthma

A Phase II, Randomized, Placebo-controlled, Parallel Group Study to Assess the Efficacy, Safety, and Pharmacokinetics of XXX in Steroid-free Patients With Mild to Moderate Persistent Asthma

A Phase III, Large Simple Safety Study of XXX Inhalation Solution in Subjects with COPD

A Phase II, Multi-center, Randomized, Double-blind, Placebo-controlled, Parallel Group, Repeated-dose Study to Evaluate the Efficacy, Safety, Tolerability, and Pharmacokinetics of Three Different Dosing Regimens of Inhaled XXX in Patients With Persistent Asthma

A Phase III, Efficacy and Safety of XXX at Two Dose Levels (200 µg Twice Daily, 400 µg Twice Daily) vs. Placebo When Administered to Patients With Moderate to Severe Chronic Obstructive Pulmonary Disease (COPD)

A Phase III, Long-Term, Randomized, Double-Blind Study of the Safety, Tolerability and Efficacy of XXX At Two Dosage Levels When Administered to Patients With Moderate to Severe, Stable Chronic Obstructive Pulmonary Disease

A Phase III, Long-term, Randomized, Double-blind Extension Study of the Safety, Tolerability, and Efficacy of XXX at Two Dose Levels When Administered to Patients With Moderate to Severe Chronic Obstructive Pulmonary Disease

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IV, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Evaluation the Efficacy and Impact on Health Related Quality of Life of XXX 5 mg Once Daily Given for 2 Weeks in Subjects 18 Years of age and Older with Seasonal Allergic Rhinitis

A Phase III, Multicenter, Double-Blind, Placebo-Controlled, Randomized, Parallel-Group Study to Evaluate the Clinical Effect of Oral XXX Versus Placebo During the Allergy Season in Patients With Seasonal Aeroallergen Sensitivity and Chronic Asthma Which is Also Active During Allergy Season

A Phase II, single dose, randomized, double-blind, crossover comparison of XXX and XXX in patients with moderate to severe asthma and persistent symptoms despite treatment with inhaled corticosteroids

A Clinical Study to Evaluate the Safety and Efficacy of the combination of 5mg XXX and 220 mg of XXX Sodium BID vs. 5mg XXX Orally Dissolving Tablet BID vs. XXX Sodium 22o mg Tablet BID in the Treatment of Allergic Rhinitis and Headache/Head Pain

A Phase III,12-Month Double-blind, Double-dummy, Randomized, Parallel group, Multicenter Efficacy and Safety Study of XXX pMDI 2 x 160/4.5µg bid and 2 x 80/4.5 µg bid Compared to XXX TBH 2 x 4.5 µg bid and Placebo in Patients with COPD

A Four Week Double Blind, Placebo Controlled Exploratory Evaluation of XXX Changes and Safety of XXX in Patients with Chronic Obstructive Pulmonary Disease (COPD)

A Phase III, Randomized, Blinded, Multicenter, Parallel Study Comparing the Efficacy and Safety of XXX at 0.5mg QD, 1.0mg QD, 1.0mg Bid, 2.0mg Bid and XXX at 4.00mcg Bid on Adolescents (12 Yrs of Age and Older) With Adults With Moderate to Severe Asthma

A Phase III, Prospective, Randomized, Double-blinded, Active-controlled Study for the Evaluation of the Efficacy, Safety and Pharmacoeconomics of oral XXX 800 mg once a day for 5 days vs. XXX 400 mg once a day for 10 days in the treatment of Acute Maxillary Sinusitis (AMS) in adults

A Double-Blind, Placebo and Active Controlled, Parallel Group Study of XXX Administered to Subjects (Adult/Adolescent) with Seasonal Allergic Rhinitis

A Phase III, Stratified, Randomized, Double-blind, Placebo-controlled, Parallel-group, 12 Week Trial Evaluating the Safety and Efficacy of XXX/ XXX Combination Product 100/50mcg Once Daily Versus XXX 100mcg Once Daily and Placebo in Symptomatic Pediatric Subjects (4-11 Years) With Asthma

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 12-Week Trial Evaluating the Efficacy and Safety of the XXX/XXX Combination Product 250 / 50 mcg Once Daily Versus XXX/XXX Combination Product 100 / 50 mcg Twice Daily Versus XXX 250 mcg Once Daily Versus Placebo in Symptomatic Adolescent and Adult Subjects With Asthma That is Not Controlled On Short-Acting Beta-Agonists Alone

A Phase II, Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Dose-Finding Study to Evaluate the Effectiveness of 28 Days of Treatment with XXX in Adult Asthmatics

Comparison of Sedation and Performance Impairment Measures in Untreated Healthy and Atopic Symptomatic Subjects Receiving Claritin®, Benadryl®, or Placebo

A Randomized, Double-Blind, Double-Dummy, Parallel-Group, Comparative Clinical Trial Evaluating XXX/XXX (250/50mcg BID via DISKUS) to XXX/XXX (36mcg/206mcgQID) Inhalation Aerosol in patients with Chronic Obstructive Pulmonary Disease (COPD)

Alzheimer's Disease

A Phase II /III 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-Confirmation of Pre-Study Site Visit

A Phase III, Randomized Double Blind Placebo Controlled Study of the Safety and Effectiveness of XXX for the Treatment of Mild to Moderate Alzheimer's Disease

A Phase IIIb, Prospective, Observation, Multicenter, Post Discontinuation Follow Up Study of Subjects with Alzheimer's Disease who Discontinued Treatment in XXX Phase III Clinical Studies XXX, XXX, XXX or failed to Enroll in XXX Phase III Clinical Study

A Phase III, Multicenter, Randomized, Double Blind, Placebo Controlled, Parallel-Group Efficacy and Safety Trial of XXX in Subjects with Mild to Moderate Alzheimer Disease Who Are Apolipoprotein E4 Non Carriers

A Phase IIa Multi-Center, Randomized, Double-Blind, Placebo Controlled Study to Investigate Efficacy and Safety of XXX in Patients with Mild to Moderate Alzheimer's Disease

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Efficacy and Safety Trial of XXX in Patients with Mild to Moderate Alzheimer's Disease who are Apolipoprptien E 4 Non-Carriers

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Safety and Efficacy Study of Oral XXX in Alzheimer's Disease

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Safety and Efficacy of XXX in Patients With Mild to Moderate Alzheimer's Disease

Anxiety

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

A Multicenter, Randomized, Open-label, Parallel Design Trial to Compare Time to Response in the Symptoms of Anxiety to Concomitant Treatment with XXX and an SSRI or SNRI to Treatment with an SSRI or SNRI alone in subjects with Generalized Anxiety Disorder or Panic Disorder

A Phase III, Double-blind, Placebo-Controlled Fixed-Dose Study of XXX in Patients With Generalized Anxiety Disorder

A Phase II, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study To Evaluate The Efficacy And Safety Of Low-Dose XXX For Adjunctive Therapy In Adult Patients With Obsessive-Compulsive Disorder Who Have Not Adequately Responded To Treatment With A Serotonin Reuptake Inhibitor

Arthritis

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Single-Dose Study of XXX in Moderate to Severe, Painful Osteoarthritis of the Knee

A Phase III Open-label, 8-Week Study to Compare the Comfort and Ease of Use of Five Different Treatment Regimens for XXX Intra-articular Injection in Subjects With Chronic, Moderate-to-Severe Osteoarthritis Knee Pain

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX in Patients With Moderate-to-Severe Chronic Low Back Pain and Osteoarthritis of the Hip or Knee

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Single Dose, 52-week study to evaluate the safety and efficacy of intra-articular injections of study medication in subjects with chronic, moderate to severe osteoarthritis knee pain

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Enriched-enrollment, Randomized-withdrawal, Double-blind, Placebo-controlled, Multi-center Study to Assess the Efficacy, Tolerability, and Safety of XXX in Opioid-naïve Subjects with Moderate to Severe Chronic Pain due to Osteoarthritis of the Knee

A Phase III, Randomized, Double Blind Placebo and Oxycodone Controlled Multicenter Study of the Efficacy and Safety of XXX in Patients with Osteoarthritis of the Knee and Hip

A Phase III, Multicenter, Randomized, Long Term Study of the Safety of XXX in Patients with Osteoarthritis of the Knee and Hip

A Phase III, Multicenter, Randomized, Long Term Study of the Safety of XXX in Patients with Osteoarthritis of the Knee and Hip

A Phase III, Randomized, Double Blind, Placebo-Controlled Multicenter Study of the Analgesic Efficacy and Safety of XXX in Patients with Osteoarthritis of the Hip

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

A Phase II, Randomized, Multicenter, Double-Blind, Single Dose Study of the Analgesic Properties of XXX and Placebo in Subjects With Pain Caused by Mild to Moderate Osteoarthritis of the Knee

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Efficacy Study of XXX Extended-Release) Capsules in Subjects with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee

A Phase III, Efficacy and Safety of XXX in the Treatment of Osteoarthritis of the Knee: Pivotal Study II

Gastrointestinal Randomized Event and Safety Open-Label NSAID Study (GI Reasons): A Phase IV, Randomized, Open-Label, Blinded-Endpoint, Parallel Group Trial of GI Safety of XXX Compared with Non-Selective Nonsteroidal Anti-inflammatory Drugs (NSAIDS) in Osteoarthritis Patients

A 13-Week, Phase III, Multicenter, Randomized, Parallel-Group, Double-Blind, Placebo bid and XXX 500 mg bid, Controlled Study on the Efficacy on Signs and Symptoms, and Safety of XXX 750 mg bid, in Patients with Osteoarthritis of the Hip

A Phase III, 53 Week Study on Analgesic Efficacy and Safety of XXX : 26-Week, Randomized, Parallel-Group, Double-Blind, Placebo (13 Weeks)- and XXX (26 Weeks)-Controlled, Multicenter Study of XXX (375 mg Bid and 750 mg Bid) With a 26-Week XXX -Controlled Safety Follow-up in Subjects With Osteoarthritis of the Knee, and a 1-week Post-treatment Safety Follow-up

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Efficacy and Safety of the XXX 5% Patch When Used as Adjunct Treatment in Patients with Osteoarthritis of the Knee Receiving Sub-Optimal Pain Relief from Their Current Sub-Optimal Pain Relief from Their Current Analgesic Regimen

A Randomized, Double-Blind, Placebo Controlled, Proof of Concept, Efficacy and Safety Study of XXX and XXX in Treating the Signs and Symptoms of Osteoarthritis of the Knee

A Phase III, Parallel, Randomized, Open-Label, Multicenter, 52-Week Follow-up Safety Study of XXX (375 mg Bid and 750 mg Bid) in Subjects With Osteoarthritis of the Knee

A Phase III, Long-Term, Open-Label, Safety Study Of 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

A Phase III, Study of the Analgesic Efficacy and Safety of XXX : A Parallel, Randomized, Double Blind, 13 Week Placebo and Naproxen Controlled, Multicenter Study of XXX (375 mg Bid and 750 mg Bid) in Patients With Osteoarthritis of the Knee, Followed by Its Extension XXX

A Phase II, Double-Blind, Long-Term Evaluation of the Safety of XXX in Comparison to Oral XXX for the Treatment of the Signs and Symptoms of Osteoarthritis of the Knee

A Randomized, Multi-center, Double-blind, Parallel-group Study Assessing the Analgesic Efficacy and Safety of Different Dosages of XXX Bid Compared to Active Comparator Bid and Placebo Bid in Subjects with Chronic Knee-Joint Osteoarthritis

A Double-Blind, randomized, placebo-controlled multi-dose phase III Parallel group study of XXX for the Management of Moderate to Moderately Severe Chronic Pain of Osteoarthritis of the Hip and Knee in Adults

A Phase II, Double-blind, placebo-controlled evaluation of safety and efficacy of three doses of topically applied XXX gel in comparison to oral XXX for the treatment of the signs and symptoms of osteoarthritis of the knee

A Phase III, 12-week double-blind randomized placebo and active comparator-controlled parallel group study to investigate the efficacy and safety of XXX , 5mg 10mg 25mg and 50mg administered orally once daily in Adults with Osteoarthritis of the knee

A Phase III, 8-week Multi-center, Randomized, Double-blind, Placebo-controlled, Parallel Group Trial of XXX Gel 1% in Patients with Primary Osteoarthritis of the Hand

A Phase III, 12-week double-blind randomized placebo and active comparator-controlled parallel group study to investigate the efficacy and safety of XXX , 5mg 10mg 25mg and 50mg administered orally once daily in Adults with Rheumatoid Arthritis

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Randomized Double-blind Pilot Study Comparing the Efficacy and Safety of XXX 5% patch with placebo in patients with pain from Osteoarthritis of the Knee

A Phase III, Randomized, Double-Blind, Multicenter, Active-Control Study Evaluating the Efficacy and Safety of XXX in Subjects with Moderate to Severe Osteoarthritis Pain

A Phase III, Randomized, Double-Blind, Active-Comparator-Controlled, Parallel-Group Study to Evaluate the Safety of XXX in Patients With Osteoarthritis or Rheumatoid Arthritis

A Phase II Dose Ranging Study of XXX in Patients with Chronic Pain Due to Osteoarthritis

A Multi-Center, Randomized, Double-Blind, Placebo Controlled, Parallel Comparison of the Efficacy and Safety of Fixed-Dose Extended-Release XXX/XXX in the Relief of Moderate to Moderately Severe Chronic Osteoarthritis Pain of the Hip or Knee

Crohn's Disease

A Phase IIa, Randomized, Open-label, Parallel, Study to Determine the Tolerability, Pharmacokinetics, and Efficacy of XXX in Subjects with Crohn’s disease experiencing Abdominal Pain

Safety and Pharmacokinetics of Single Dose Intravenous Anti-IL-23 Antibody XXX in subjects with Crohn's Disease

A Phase II, Open label trial of XXX, a recombinant human granulocyte-macrophage colony stimulating factor (GM-CSF) in active Crohn's disease

A Phase III multicenter, double-blind, randomized, placebo-controlled 8-week retreatment study of XXX, 6ug/kg/day) in patients with active Crohn's disease and prior treatment response to XXX

A Phase II, Pilot, Double-Blind, Placebo-Controlled, Parallel Group, Two Stratum Study of the Safety, Tolerability, Immunologic and Clinical Activity, and Population Pharmacokinetics of XXX Administered for Four Weeks in Patients with Moderate to Severe Crohn's Disease

A Phase III, Multi-national, Multi-centre, Open label, 52-week Safety Study to Assess the Safety of Chronic Therapy with the Humanized anti-TNF PEG Conjugate XXX 400 mg sc, (dosed 4-weekly to Week 50), in the Treatment of Patients with Active Crohn's Disease who have previously completed studies XXX or XXX

A Phase III, multi-national, multi-centre, double-blind placebo controlled parallel group 26 week study to assess the maintenance of clinical response to humanised anti-TNF PEG conjugate XXX 400 mg sc, (dosed 4-weekly from Weeks 8 to 24), in the treatment of patients with active Crohn's disease who have responded to open induction therapy (dosed at Weeks 0, 2 and 4) with XXX

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III multi-national, multi-centre, open label, 52 week safety study to assess the safety of re-exposure after a variable interval and subsequent chronic therapy with the humanised anti-TNF PEG conjugate XXX 400 mg sc, (dosed at weeks 0, 2 and 4 then 4-weekly to Week 48), in the treatment of patients with active Crohn's disease who have previously been withdrawn from studies XXX or XXX due to exacerbation of Crohn's disease

Depression

A Phase IIa, Multicenter, Randomized, Double-Blind, Placebo-Controlled, 3-Arm Trial to Assess the Safety and Tolerability of a 7-Day Dosing with XXX 25 mg QD and 50 mg QD as Adjunctive Therapy in the Treatment of Patients Diagnosed with Major Depressive Disorder

A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter Study of XXX as Monotherapy in Patients with Major Depressive Disorder

A Phase II, Two-Part (Open-Label Followed by Double-Blind) Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of XXX in the Treatment of Adult Subjects With Moderate to Severe Major Depressive Disorder

A Randomized, Double-Blind, Placebo-Controlled, Phase IV, Relapse Prevention Study Evaluating the Efficacy and Safety of XXX (5, 10 and 20 mg) in Adults With Major Depressive Disorder

A Phase II, Multicenter, Randomized, Double-blind, Placebo controlled, Study to Evaluate the Efficacy and Safety of Adjunctive XXX in Major Depressive Disorder

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

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

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

A Phase III, Randomized, Double-blind, Active-controlled Trial to Assess the Efficacy and Safety of XXX Administered Orally to Subjects with Treatment Resistant Major Depressive Disorder

A Phase III efficacy and safety study of XXX for the adjunctive treatment of MDD

A Phase III multicenter study of the long-term safety and tolerability of XXX for the adjunctive treatment of MDD in adults who have inadequate response to antidepressants

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Long-Term, Open-Label Study of Safety and Tolerability of XXX as Adjunctive Therapy in Major Depressive Disorder

A Phase II, Randomized, Double Blind, Placebo Controlled Study to Evaluate XXX in Subjects with Major Depressive Disorder and Inadequate Response to Antidepressant Therapy

A Randomized, Placebo-Controlled, Double-Blind Study of XXX Fixed-Dose 12 mg and 18 mg Once Daily as Adjunctive Treatment for Patients With Major Depressive Disorder Who Are Partial Responders to Selective Serotonin Reuptake Inhibitor Treatment

Dermatology

A Phase III Randomized, Double-blind, Placebo-controlled, Efficacy Study of the Neurokinin-1 Receptor Antagonist XXX in Patients with Atopic Dermatitis

A Phase II, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Oral XXX for Moderate to Severe Puritis in Adult Subjects with Atopic Dermatitis

A Phase III, Multi-Center, Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Study Comparing the Efficacy and Safety of XXX and Vehicle Gel Once Daily in the Treatment of Molluscum Contagiosum

A Phase IIb, Randomized, Double-Blind, Vehicle-controlled, Parallel-group, Dose Ranging Study to Assess Efficacy, Safety, Tolerability, and Pharmacokinetics of XXX Topical Cream Applied Once or Twice Daily for 12 weeks in Participants with Mild to Moderate Chronic Plaque Psoriasis

A Phase III, Double-Blind, Randomized, 8-Week, Vehicle-Controlled Efficacy and Safety Study of XXX Cream Followed by a Long-Term Safety Extension Period in Adolescents and Adults With Atopic Dermatitis

A Randomized, Double-blind, Placebo-controlled, Efficacy Study of the Neurokinin-1 Receptor Antagonist XXX in Patients with Atopic Dermatitis

An Exploratory, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Phase II Study to Evaluate the Safety, Tolerability, and Efficacy of XXX Ointment for the Symptomatic Treatment of Persistent Pruritus and Psoriasis in Subjects Being Treated with Calcipotriene Ointment

A Multicenter, Randomized, Double-blind, Parallel Group, Vehicle-controlled Study to Evaluate the Safety and Efficacy of 1% and 3% Topical XXX Gel (Hy01) in Patients with Papulopustular Rosacea

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Vehicle-Controlled Study to Evaluate the Efficacy and Safety of Topical Administration of XXX for 12 Weeks in the Treatment of Moderate-to-Severe Acne Vulgaris

An Open Label, Randomized, Actual Use Study of XXX Auto-Injector Device in Patients with Atomic Dermatitis

A Phase IIa, Double-Blind, Randomized, Placebo-controlled, Exploratory Study to Evaluate the Safety, Biological Activity and Pharmacokinetics of XXX in Adult Patients With Moderate-to-Severe Atopic Dermatitis

A Phase II study of XXX in Adult and Adolescent Subjects with Atopic Dermatitis

A Phase II Randomized, Double-Blind, Vehicle-Controlled Ascending Multiple Dose and Clinical Proof-of-Concept Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX in Adult Patients with Mild to Moderate Atopic Dermatitis

A Phase II, Randomized, Double-Blind, Vehicle-Controlled Trial to Evaluate the Safety and Efficacy of XXX Cream in Patients with Moderate to Severe Atopic Dermatitis

A Phase IIb, Randomized, Double-blinded, Placebo-controlled, Dose-ranging Study to Evaluate the Efficacy and Safety of XXX in Adult Subjects With Moderate-to-Severe Atopic Dermatitis

A Randomized, Single-Blind, Phase II Study to Determine the Safety, Tolerability, and Systemic Exposure of 3 Dose Regimens of Topically Applied XXX Gel in Subjects With Acne Vulgaris

A Phase II, Randomized, Double Blind, Parallel Group, Placebo-Controlled Dose Finding and Efficacy Study of XXX in the Treatment of Subjects With Chronic Pruritus

A Phase III, Safety and Efficacy Study to Compare XXX Dermal Gel and Vehicle Control in Patients with Acne Vulgaris

A Phase II, randomised, double-blind, placebo-controlled, efficacy, safety, tolerability, and pharmacokinetics of multiple doses of XXX administrated by intravenous infusion to patients with moderate to severe chronic plaque psoriasis

A Phase II, Multicenter Randomized Placebo-Controlled, Double-Blind, Parallel-group study to evaluate the Efficacy and Safety, and Pharmacokinetics of XXX in Adult subjects with Atopic Dermatitis

A Phase II, Randomized, Multicenter, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of 3 Different Doses of XXX Compared to Placebo in the Treatment of Facial Acne Vulgaris

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Phase II, Double-Blind, Placebo-Controlled Trial to Evaluate the Safety and Efficacy of XXX Gel in Adult Patients With Mild to Moderate Atopic Dermatitis

A Phase III, Multi-Site, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of 2 Oral Doses of XXX in Subjects with Moderate to Severe Chronic Plaque Psoriasis

A Phase III, Multi-Center, Double Blind, Randomized, Vehicle Controlled, Parallel Group Study to Compare XXX Topical Gel 0.1%/2.5% to XXX Topical Gel and Both Active Treatment to a Vehicle control in the Treatment of Acne Vulgaris

A Phase III, multi center, open label study of the long-term safety and tolerability of 2 oral doses of XXX in subjects with moderate to severe chronic plaque psoriasis

A Phase III multi-site, randomized, mixed blind, parallel group treatment withdrawal and retreatment study of the efficacy and safety of 2 oral doses of XXX in subjects with moderate to serve chronic plaque psoriasis

A Phase III, Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel-Group Study to Compare XXX 1%/ XXX 5% Topical Gel to a Comparator XXX/XXX Topical Gel, and Both Active Treatments to a Vehicle Control in the Treatment of Acne Vulgaris

A Phase III, Double-Blind, Randomized, Phase III, Parallel Group Study Evaluating the Efficacy and Safety of XXX in Patients With Severe Recalcitrant Nodular Acne

A Phase III, Double-Blind, Randomized, Parallel Group Study Evaluating the Efficacy and Safety of XXX in Patients With Severe Recalcitrant Nodular Acne

A Phase II, Multicenter, Randomized, Double-Blind, Vehicle-Controlled Study of the Efficacy, Safety and Tolerability of XXX in Adult Patients With a Diagnosis of Atopic Dermatitis (AD) With Moderate to Very Severe Pruritus

A Multi-Center Double-Blinded, Randomized, Vehicle-Controlled, Parallel-Group Study Comparing XXX Ointment 0.1% to XXX Ointment 0.1% and Both Active Treatments To A Vehicle Control In The Treatment Of Atopic Dermatitis

A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Efficacy and Safety Study of 2 Doses of XXX (400 mg BID and 800 mg BID) in Patients With Atopic Dermatitis

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Comparing the Efficacy and Safety of XXX to XXX and Placebo in Subjects With Moderate to Severe Chronic Plaque Psoriasis

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multi-center, Open-label Continuation Study in Moderate to Severe Plaque Psoriasis in Subjects Who Completed a Preceding Psoriasis Study With XXX

A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel- Group Study Comparing XXX Cream, 5% to XXX Cream, 5% and Bothe Active Treatments to a Vehicle Control in the Treatment of Actinic Keratosis of the Face or Scalp

A Phase II, Multicenter, Randomized, Double-Blind, Vehicle-Controlled Study of the Efficacy, Safety and Tolerability of XXX in Adult Patients With a Diagnosis of Atopic Dermatitis (AD) With Moderate to Very Severe Pruritus

A Multi-Center, Double Blind, Randomized, Vehicle-Controlled, Parallel-Group Study Comparing XXX Ointment 0.03% and Both Active Treatments to a Vehicle Control in the Treatment of Atopic Dermatitis

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Comparing the Safety and Efficacy of Two Dosing Regimens of XXX to Placebo in Subjects With Moderate to Severe Chronic Plaque Psoriasis

A Phase II, Multicenter Randomized Double-Blind Dose Ranging Study to Evaluate XXX Versus Placebo in the Treatment of Severe Acne Vulgaris with nodules

A Randomized, Double-Blind, Multiple-Site, Placebo-Controlled Study Comparing XXX/ XXX Topical Gel to XXX Topical Gel XXX/XXX in the Treatment of Moderate to Severe Acne Vulgaris

A Randomized, double-blind Active-controlled study to evaluate the Efficacy of XXX ointment compared to XXX ointment in the treatment of Psoriasis Vulgaris

A Multicenter, Randomized, Double blind, Placebo controlled Phase III Study of Subcutaneously Administered XXX in the Treatment and Retreatment of Subjects with Moderate to Severe Plaque Psoriasis

A Randomized, Evaluator-Blind, 3-Arm, Multi-Center Study to Evaluate the Safety and Efficacy of Topically Applied XXX Gel 0.05% vs. XXX Gel Vehicle and XXX Lotion for the Treatment of Pediatric Subjects with Mild to Moderate Atopic Dermatitis

A Randomized, Double Blind, Placebo Controlled, Parallel Group Study to assess the Safety and Efficacy of the Three Dose Levels of XXX in the Treatment of Chronic Plaque Psoriasis

A Phase III, Randomized, Double-Blind, Multi-Center Study to Evaluate the Safety and Efficacy of XXX vs. XXX in the Treatment of Uncomplicated Skin and Soft Tissue Infections with Suspected or Confirmed Gram-Positive Bacterial Pathogens

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Multiple-Site, Placebo-Controlled Study Comparing 1% XXX / 5% XXX Topical Gel to XXX Topical Gel 1% XXX / 5% XXX in the Treatment of Moderate to Severe Acne Vulgaris

An Open-Label, Multicenter Study to Evaluate the Safety and Tolerability of Intramuscular Administration of XXX in Subjects with Chronic Plaque Psoriasis who have Completed Studies XXX or XXX

A Double-Blind, Dose Comparison, Retreatment Study to Evaluate the Efficacy and Safety of Intramuscular Administration of XXX in Subjects with Chronic Plaque Psoriasis Who Have Previously Completed Study XXX

Diabetes

A Phase IIa Randomized, Double-blind, Placebo-controlled, Study to Evaluate the Efficacy and Safety of XXX in Subjects with Diabetic Kidney Disease

A Phase II, Multicenter, Randomized, Double blind, Placebo- controlled, Parallel Dose Cohort Study to Evaluate the Efficacy and Safety of Twelve Once-Weekly Subcutaneous Doses of XXX in Subjects with Type 2 Diabetes (T2DM) Not Well Controlled by Metformin

A Phase III, Randomized, Multicenter, Open-Label, Parallel-Group Clinical Study Comparing the Safety and Efficacy of XXX in Type 1 Diabetes Mellitus Patients

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate XXX in Subjects With Type 2 Diabetes Mellitus Who Are Not Adequately Controlled by Metformin Alone

A Phase III, Randomized, Multi-center, Double-Blind, Parallel-Group Clinical Study Comparing the Efficacy and Safety of XXX Produced by Two Manufacturing Processes in Type 1 Diabetes Mellitus Patients

A Phase III, Randomized, Double-Blind, Active-Controlled Study to Evaluate the Effects of XXX versus XXX in Subjects with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control by Metformin

A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Add-on Study of XXX in Adults with Uncontrolled Type 2 Diabetes on Metformin Therapy

A Phase II, 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 Phase IV, Pragmatic Clinical Trial to Compare the Real-World Use of XXX Versus Standard delivery of Insulin in Type 2 Diabetic Patients XXX

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, 12-week randomized, double-blind, Parallel-group, placebo-controlled study to determine the efficacy and safety of XXX when administered to subjects with Type 2 Diabetes Mellitus

A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Phase IIa Study With an Open-Label Active Group to Assess the Efficacy and Safety of Once-Daily XXX in Type 2 Diabetic Patients Inadequately Controlled With Metformin

A Phase III, Efficacy and Safety of XXX Once Weekly Versus Insulin XXX Once Daily as Add on to Metformin With or Without XXX in Insulin-naïve Subjects With Type 2 Diabetes

A Phase IV, Efficacy and Safety of Switching From XXX to XXX in Subjects With Type 2 Diabetes Not Achieving Adequate Glycaemic Control on XXX and XXX

A Phase II, 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Assess the Efficacy, Safety, and Tolerability of Delayed-Release XXX in Subjects With Type 2 Diabetes Mellitus

A Phase II, Randomized, Double-blind, Double-dummy, Placebo and Active-controlled, Multicenter, Parallel Group Study to Evaluate the Efficacy and Safety of XXX in Patients with Type 2 Diabetes mellitus

The Phase III, Efficacy of Insulin XXX/XXX in Controlling Glycaemia in Adults With Type 2 Diabetes Inadequately Controlled on GLP-1 Receptor Agonist and OAD Therapy (XXX Switch)

A Phase IIb, Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled, Parallel-Group Study to Assess the Pharmacodynamic Response and Safety of Three Dose Levels of XXX Injection Following 20 Weeks of Once-Weekly Subcutaneous Dosing in Adult Subjects With Inadequately Treated Type 2 Diabetes Mellitus

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 (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) and an Additional Antihypertensive Medication

Awareness, Detection and Drug Therapy in Type 2 Diabetes and Chronic Kidney Disease

A Phase II, Randomized, Placebo-Controlled, Factorial, Double-Blind, Double-Dummy, Parallel-Group, Multicenter Study to Determine the Efficacy and Safety of 25 mg and 50 mg of XXX in Combination With XXX 100 mg in Subjects With Type 2 Diabetes Mellitus

A Phase II, Efficacy and Safety of XXX Compared With Placebo in Patients With Type 2 Diabetes Mellitus Inadequately Controlled by Diet and Exercise and up to One Oral Anti-diabetes Agent

CLINICAL TRIAL EXPERIENCE (*continued*):

Evaluation of the Acceptability of the XXX 4mm x 32G Pen Needle for Injections of Long Acting or Basal Insulin Doses Above 40 Units

A Phase III, Multicenter, Randomized, Open-label Clinical Trial Comparing the Efficacy and Safety of a XXX -Based Treatment Paradigm to a XXX -Based Treatment Paradigm in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Metformin Monotherapy

A Phase IV, 26-week Randomised, Controlled, Open Label, Multicentre, Multinational, Treat to Target Trial Investigating the Impact of Dietary Intervention on Weight Change and the Relationship Between Weight Change and Baseline Body Mass Index (BMI) in Subjects With Type 2 Diabetes Inadequately Controlled on Oral Antidiabetic Drugs (OADs) Initiating Insulin Therapy With Insulin XXX in Combination With XXX

A Phase IIb, Randomized, Placebo-Controlled, Dose-Range Finding Clinical Trial to Study the Safety and Efficacy of XXX in Patients With Type 2 Diabetes Mellitus and Inadequate Glycemic Control

A 24-week, Multicenter, Randomized, Double-blind, Age-Stratified, Placebo controlled, Phase III Study with a 28-week Extension Period to Evaluate the Efficacy and Safety of XXX 10 mg once daily in Patients with Type 2 Diabetes, Cardiovascular Disease and Hypertension who Exhibit Inadequate Glycemic Control on Usual Care

A Phase IIa, Multicenter, Double-Blind, Randomized, Active-Controlled, Parallel-Arm Clinical Trial to Study the Efficacy and Safety of XXX Compared to XXX in Patients With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin Therapy

A Phase II, Randomized, Double-Blind, Double-Dummy Placebo-and Active-Controlled, Multicenter Study to Determine the Efficacy and Safety of XXX in Subjects With Type 2 Diabetes Mellitus

A Phase III, multicenter, randomized, double blind (double dummy), active-comparator controlled study to compare the efficacy, safety and tolerability of XXX vs. XXX in type 2 diabetes patients inadequately controlled with sulfonylurea (SU) monotherapy or metformin plus sulfonylurea combination therapy

A Phase III, Randomized, Double-Blind, Active-Controlled Study of Patients With Cardiovascular Disease and Diabetes Mellitus Not Adequately Controlled With XXX or XXX : Comparison of Switching to Combination Tablet XXX/XXX Versus Switching to XXX or Doubling the Statin Dose

A Randomized, Double Blind, Placebo Controlled Phase II Study to Evaluate the Effect of Different Dose Levels of XXX on Proteinuria as Assessed by Changes in the Urinary Albuminuria/Creatinine Ratio (ACR) in Patients with DN on ACEi/ARB

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IIa, Multicenter, Randomized, Placebo- and Active-Comparator Controlled, Cross-Over Clinical Trial to Study the Safety and Efficacy of XXX in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control

A Phase III, Randomized, Double-Blind, Placebo Controlled, Parallel Group Study of the Efficacy and Safety of XXX as Add-on to XXX Therapy for Type 2 Diabetes Mellitus (T2DM)

A Phase III, Randomized, Double Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of XXX as Monotherapy for Type 2 Diabetes Mellitus

A Phase III, Randomized, Double-Blind, Placebo and Active-Controlled, Parallel-Group, Multicenter Study to Determine the Efficacy and Safety of XXX When Used in Combination With Metformin Compared With Metformin Plus XXX, Metformin Plus XXX, and Metformin Plus Placebo in Subjects With Type 2 Diabetes Mellitus

A Phase III, Randomized, Open-label, Parallel-group, Multicenter Study to Determine the Efficacy and Long-term Safety of XXX Compared With Insulin in Subjects With Type 2 Diabetes Mellitus

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Determine the Efficacy and Safety of XXX When Used in Combination With XXX With or Without Metformin in Subjects With Type 2 Diabetes Mellitus

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Determine the Efficacy and Safety of Two Dose Levels of XXX Compared With Placebo in Subjects With Type 2 Diabetes Mellitus

A Phase III, Randomized, Double-blind, Placebo and Active-Controlled, Parallel-group, Multicenter Study to Determine the Efficacy and Safety of XXX Administered in Combination With Metformin and XXX Compared With Metformin Plus XXX and Placebo and With Metformin Plus XXX and XXX in Subjects With Type 2 Diabetes Mellitus

A Phase IIb, Multicenter, Randomized, Double-Blind, Placebo-Controlled Dose-Range Finding Clinical Trial of XXX in Patients With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Insulin

A Phase III, Multi-centre, Randomised, Open-label, Cross-over Study to Explore Effectiveness, Safety, and Preference of a New Disposable Pen XXX vs. XXX in Subjects With Type 1 or Type 2 Diabetes

A Phase II, Randomized, Double-Blind, Placebo-Controlled, 24-Week Study to Evaluate the Efficacy and Safety of XXX Compared to XXX in Subjects With Type 2 Diabetes

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Randomized, Double-Blind, Placebo-and Active-Controlled, Multi-center Study to Determine the Efficacy and Safety of XXX in Subjects With Type 2 Diabetes

A Phase III, Effect of XXX Compared to XXX , Both in Combination With Metformin in Subjects With Type 2 Diabetes AND A 26-week, Randomised, Open-label, Active Comparator, Three-armed, Parallel-group, Multi-centre, Multinational Trial With a 52-week Extension

A Phase IV, Effect of Two Different Fasting Blood Glucose Titration Targets in Glucose Control in Patients With Type 2 Diabetes Using Insulin XXX Once Daily in Combination With 1-3 Oral Agents

A Phase III, Open-Label, Multi-Center, Follow on Study Examining the Long-Term Safety and Efficacy of Insulin in Subjects with Type II Diabetes Mellitus

A Phase III, Open-Label, Multi-Center, Follow on Study Examining the Long-Term Safety and Efficacy of Insulin XXX in Subjects with Type II Diabetes Mellitus

A Phase III, Multicenter, Randomized, Double-Blind Study to Determine the Efficacy and Safety of the Addition of XXX 25 mg versus Dose Titration from 30 mg to 45 mg of XXX HCI in Subjects with Types 2 Diabetes Mellitus Who Have Inadequate Control on A Combination of Metformin and 30 mg of XXX HCI Therapy

A Phase II, Open Label, Multi-Center, Long-Term Follow-up Study to Evaluate the Safety of XXX in Subjects With Type 2 Diabetes Mellitus

A Phase IIb, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate Safety and Efficacy of XXX in Subjects With Type 2 Diabetes Mellitus

A Phase III, Open Label, Multi-Center, Randomized, Parallel Group Study Comparing the Efficacy and Safety of Insulin XXX and Regular Human Insulin in Patients With Type 2 Diabetes Mellitus

A Phase III, Open Label, Multi-Center, Randomized, Parallel Group Study Comparing the Efficacy and Safety of Insulin XXX and Regular Human Insulin in Patients With Type 1 Diabetes Mellitus

A Phase III, Multicenter, Double-Blind Study to Determine the Efficacy and Safety of XXX plus XXX HCI, XXX Alone or XXX HCI Alone in Subjects with Type 2 Diabetes

A Phase III, Effect of Inhaled XXX Insulin Plus Metformin & XXX vs XXX Plus XXX & XXX on HbA1c in Subjects With Type 2 Diabetes

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Twenty-Six Week, Open-Label, Multicenter, Randomized, Parallel Group Trial to Investigate Efficacy and Safety of XXX and XXX Combination Tablet XXX in a TID Regimen Compared to a BID Regimen and BID XXX in Subjects With Type 2 Diabetes

A 54 Week Open Randomized, Parallel Arm, Controlled Study Designed to Assess the Clinical Benefit of the One Touch Ultra 2 System

A Phase II, Randomized, Double-Blind, Parallel, Placebo-Controlled, Study to Evaluate the safety and Tolerability of Oral XXX Capsules (15 mg) in Combination with Insulin in Subjects with Type 2 Diabetes

A Phase III, Effect on Glycemic Control of XXX in Combination With XXX Plus XXX vs. XXX Plus XXX in Subjects With Type 2 Diabetes

A Phase III, XXX Effect and Action in Diabetes (LEAD-3): Effect on Glycemic Control of XXX vs. XXX in Type 2 Diabetes

A Phase IV, Comparison of XXX Therapy to XXX Therapy With XXX on the Overall Glycemic Control of Patients With Type II Diabetes Previously Treated with Oral Agents Combined With XXX

A Multicenter, Randomized, Double-blind, Placebo-controlled Comparison study to Determine the Efficacy and Safety of XXX When Used in Combination with a Sulfonylurea in Subjects with Type 2 Diabetes

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of XXX When Used in Combination With Insulin in Subjects With Type 2 Diabetes

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of XXX Compared With Placebo in Subjects With Type 2 Diabetes

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of XXX When Used in Combination With XXX in Subjects With Type 2 Diabetes Mellitus

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of XXX When Used in Combination With Metformin in Subjects With Type 2 Diabetes

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of XXX When Used in Combination With a Sulfonylurea in Subjects With Type 2 Diabetes

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IV, Durability of Twice-Daily Insulin XXX Low Mixture Compared to Once-Daily Insulin XXX When Added to Existing Oral Therapy in Patients With Type 2 Diabetes and Inadequate Glycemic Control

A Phase III, Efficacy and Safety Comparison of Insulin XXX and Insulin Glargine Plus Insulin XXX in Patients With Type 2 Diabetes

A Phase III, Multicenter, Randomized, Double-Blind Factorial Study of the Co-Administration of XXX and Metformin in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control

A Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Study of the Safety and Efficacy of XXX Compared to Placebo in the Treatment of Patients with Type 2 Diabetes Mellitus

A Phase III, Efficacy and Safety Comparison of Insulin XXX Plus Insulin XXX Versus Insulin Glargine Plus Insulin XXX in Type 2 Diabetes

A Phase III, Efficacy and Safety Comparison of Insulin XXX Plus Insulin XXX Versus Insulin Glargine Plus Insulin XXX in Type 1 Diabetes

A Phase III, Multicenter, Open-Label, Randomization Trial to Compare the Efficacy and Safety of XXX 70/30 BID in Combination with Metformin and XXX to Metformin and XXX Alone in Insulin Naive Subjects with Type 2 Diabetes

A Phase II, Double-Blind, Randomized, Placebo-Controlled, Proof-of-Concept Study of the Efficacy, Safety and Tolerability of XXX in combination with XXX In Subjects with Type 2 Diabetes

A Phase III, Multicenter, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of the Addition of XXX to Patients with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on XXX Therapy

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX Monotherapy in Patients with Type 2 Diabetes Mellitus and Metabolic Syndrome

A Multicenter, Double-Blind, Randomized, Placebo and Active Controlled Dose-Range Finding Study of XXX in Patients with Type 2 Diabetes Mellitus with Inadequate Glycemic Control

A randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Determine the Efficacy and Safety of XXX When Used in Combination With XXX With or Without Metformin Plus Sitagliptin in Subjects With Type 2 Diabetes Mellitus

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Substituting XXX for a XXX vs. a 3rd Oral Agent as add-on Therapy in Patients Failing a XXX & XXX or Metformin Combination

A Phase III, Double-Blind, Randomized, Active-Controlled XXX and Metformin Comparator Study in Type 2 Diabetic Patients Inadequately Controlled on Diet and Exercise

A Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XXX Added to Insulin in Patients With Inadequately Controlled Type 2 Diabetes Mellitus

A Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of the Addition of XXX to Patients With Type 2 Diabetes With Inadequate Glycemic Control on Combined Metformin and Sulfonylurea Therapy

A Phase IV, Comparison of Glycemic Control Achieved With a 31 Gauge x 6 mm XXX Needle vs. a BD 29 Gauge x 12.7 mm XXX Needle in Subjects With Diabetes Mellitus and a BMI Exceeding 30 kg/m2: An Open Label, Randomized, Two-Period Crossover Study

A Prospective, Multicenter, Double-Blind with In-House Blinding, Randomized, Comparative Study to Evaluate the Efficacy, Safety and Tolerability of XXX vs. XXX in the Treatment of Diabetic Foot Infections in Adults

A Multi-Center, Randomized, Open-Label, Crossover Trial in Insulin-Requiring Type 1 Subjects With Diabetes: Preference and Frequency of Blood Glucose Monitoring Comparison with XXX and Vial/Syringe/Separate Meter

XXX in Type 2 Diabetic Subjects: A Fifty-Two Week Double-Blind, Parallel, Active-Controlled (XXX and XXX) Study (Followed by a Fifty-Two Week Open-Labeled Extension) to Investigate Safety and Efficacy

XXX vs. XXX Comparative Efficacy and Safety: An Open-Label, Randomized, Parallel Group, Multicenter Study in the Treatment of Subjects with Type 2 Diabetes Inadequately Treated With Diet and Exercise

XXX vs. XXX in Combination With Metformin, Comparative Efficacy and Safety: an Open-label, Randomized, Parallel Group, Multicenter Study in the Treatment of Subjects with Type 2 Diabetes Inadequately Controlled With Sulfonylurea or Metformin Monotherapy or Low-Dose Glucovance

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX L-000414380 Monotherapy in Patients with Type 2 Diabetes Mellitus and Metabolic Syndrome

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multicenter, Randomized, Double-Blind, Parallel Group Trial Comparing the Safety and Efficacy of XXX/XXX to XXX As First Line Therapy In Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control With Diet and Exercise

Proof of Concept Trial of XXX in Patients With Type II Diabetes Mellitus

A Phase III, Multicenter, Randomized, Open label Clinical Trial comparing the Efficacy the Safety of XXX the Fixed-Dose Combination of XXX and Metformin to that of XXX in Patients with Type 2 Diabetes Mellitus

Fibromyalgia

A Phase IIa, Randomized, Double-Blind Placebo-controlled, Parallel-group Study to Assess the Analgesic Efficacy and Safety of XXX in Patients with Fibromyalgia

A Phase III, Open-Label Extension Study Based on Protocol 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

Epidemiological Study of Fibromyalgia in the US extension study

A Comparative Study of Epidemiological Study of Fibromyalgia in the United States

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Study of XXX in Subjects With Fibromyalgia

A Phase III, Open-Label, Safety and Efficacy Study of XXX in Subjects with Fibromyalgia

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Study of XXX in Subjects with Fibromyalgia

An evaluation of the burden of illness among adults in the US with fibromyalgia

Hepatitis B & C

A Phase III, Multicenter, Randomized, Open-Label Study to Investigate the Efficacy and Safety of XXX/XXX Fixed-Dose Combination ± XXX for 8 Weeks and XXX/XXX Fixed-Dose Combination for 12 Weeks in Treatment-Naive Subjects With Chronic Genotype 1 HCV Infection

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multicenter, Randomized, Open-Label Study to Investigate the Efficacy and Safety of XXX/XXX Fixed-Dose Combination ± XXX for 12 and 24 Weeks in Treatment-Experienced Subjects With Chronic Genotype 1 HCV Infection

A Phase III, Multicenter, Randomized, Double-Blind, Study to Investigate the Efficacy and Safety of XXX + XXX for 12 or 16 Weeks in Treatment Experienced Subjects With Chronic Genotype 2 or 3 HCV Infection

A Phase III, Multicenter, Open-Label Study to Investigate the Efficacy and Safety of XXX with XXX and XXX for 12 Weeks in Treatment-Naive Subjects With Chronic Genotype 1, 4, 5, or 6 HCV Infection

A Long Term Follow Up Registry Study of Subjects Who Achieve a Sustained Virologic Response in XXX -sponsored trials in subjects with Chronic Hepatitis C Infection

A Phase IIb, Randomized, Double-Blind, Placebo-Controlled Trial Evaluation Response Guided Therapy using Combinations of Oral Antivirals XXX with XXX and XXX in Treatment Experienced Subjects with Chronic Genotype 1 Hepatitis C Virus Infection

A Phase IV, Randomized, Open Label, Active Controlled, Superiority Study to Evaluate the Efficacy and Safety of XXX in Combination with XXX Versus Standard of Care XXX Monotherapy or XXX Monotherapy for 48 weeks in Non-Cirrhotic Subjects with HBeAg-Positive or HBeAg-Negative Chronic Hepatitis B

A Phase IIb, Randomized, Double Blinded, Placebo Controlled Trial Evaluating 16 And 24 Weeks of a Four Drug Regimen and 24 Weeks of a three drug Regimen of XXX, XXX, and XXX with and without XXX Followed by Response Guided PEG and RBV in Treatment Naive Subjects with Chronic Genotype 1 Hepatitis C Virus Infection

Hypercholesterolemia/ Hyperlipidemia/ Dyslipidemia

A Phase II placebo controlled randomized double blind parallel Group study to evaluate the efficacy and safety of XXX in patients with hypercholesterolemia and Hypertension

A Phase III, 6-Week, Randomized, Double-Blind, Placebo XXX -Controlled Study to Assess the Efficacy and Safety of Add-On XXX to Statin Therapy in Subjects With Persistent Hypertriglyceridemia and High Risk for Cardiovascular Disease

A Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Administering Multiple Oral Doses of XXX Alone and With XXX

A Phase IV, Randomized, Double Blinded, Active Controlled, Parallel Group Study of XXX 4 mg vs. XXX 40 mg in Patients with Primary Hyperlipidemia or Mixed Dyslipidemia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, 30-Week, Multicenter, Randomized, Double-Blind, Parallel-Group Study of the Combination of XXX and XXX Compared to XXX Monotherapy in Dyslipidemic Subjects With Stage 3 Chronic Kidney Disease

A Phase III, Worldwide, Multicenter, Double-Blind, Randomized, Parallel, Placebo-Controlled Study to Evaluate the Long-term Efficacy, Safety and Tolerability of XXX/XXX in Patients With Dyslipidemia

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of XXX as Add-on Therapy in High Risk Hypercholesterolemic Patients

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

A Phase II, Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled Study to Assess the Efficacy, and Tolerability of XXX Co-Administered With XXX in Patients With Primary Hypercholesterolemia

A Phase III, Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and Efficacy of XXX in Combination With XXX and XXX to XXX in Combination With XXX in Subjects With Combined (Atherogenic) Dyslipidemia

A Phase III, Multicenter, Randomized, Double-Blind, Parallel Group, 12 Week Study to Evaluate the Efficacy and Safety of Extended-release (ER) XXX/XXX in Patients With Primary Hypercholesterolemia or Mixed Dyslipidemia

A Phase III, Multicenter, Randomized, Double-Blind, Parallel, 12-Week Study to Evaluate the Efficacy and Safety of XXX/XXX Combination Tablet Versus XXX in Elderly Patients With Hypercholesterolemia at High or Moderately High Risk for Coronary Heart Disease

A 12 Week Open-Label, Randomized, Parallel Group, Multicenter, Phase IIIb Study to Compare the Efficacy and Safety of XXX 10mg and 20mg in Combination with XXX 10mg And XXX 40 mg and 80 mg in Combination with XXX 10mg (fixed dose combo) in Patients with Hypercholesterolemia and Coronary Heart Disease or a CHD Risk Equivalent, Atherosclerosis or a 10 year CHD Risk of >20%

A Phase III, Multicenter, Randomized, Double-Blind, "Crossover" Design Study to Evaluate the Lipid-Altering Efficacy and Safety of XXX Combination Tablet Compared to XXX + XXX Coadministration in Patients With Primary Hypercholesterolemia and Mixed Dyslipidemia

A Multi-Center, Prospective, Longitudinal, Randomized, Double-Blind, Phase III Study to Evaluate the Efficacy and Safety of Daily Administration of XXX 40 mg or XXX 160 mg or XXX (the Combination of XXX and XXX 40/160 mg) for 12 Weeks Followed by a 52-Week Open-Label Safety Phase of the XXX Alone in the Treatment of Combined Hyperlipidemia

CLINICAL TRIAL EXPERIENCE (*continued*):

A 4-Week Dose-Ranging Study to Evaluate Antidyslipidemic Effects, Other Pharmacodynamic Effects, Safety and Tolerability of XXX with Concomitant Open-Label XXX Therapy in Patients with Elevated Triglycerides, Elevated Low Density Lipid Cholesterol and Abdominal Obesity: Randomized, Double-Blind, Placebo-Controlled, Multi-Centre, Parallel-Group Study with XXX as Reference Treatment

A Phase III, Worldwide, Multicenter, Double-Blind, Parallel Study to Evaluate the Tolerability of XXX Versus Niacin Extended-Release

A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Assess the Efficacy, Safety, and Tolerability of XXX in Patients With Primary Hypercholesterolemia or Mixed Hyperlipidemia

A Phase III, double-blind, randomized, placebo-controlled factorial study to evaluate the efficacy and safety of XXX and XXX alone and in combination in subjects with hypercholesterolemia

A Phase III, Worldwide Multicenter double-blind, randomized, parallel, placebo-controlled study to evaluate the lipid-altering efficacy, safety and tolerability of XXX in patients with primary hypercholesterolemia or mixed Hyperlipidemia

A Phase III, double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of XXX (50mg or 100mg) when co-administered with XXX (10mg to 40mg) in subjects with primary hypercholesterolemia AND An Open Label extension study to evaluate the efficacy and safety of XXX in subjects with hypercholesterolemia

A Phase IV, multi-center, randomized, double-blind, double-dummy study evaluating the safety and efficacy of the addition of XXX to XXX or XXX in the treatment of diabetic hypertensive subjects

A Study to Evaluate the Efficacy and Safety of XXX and XXX Coadministration in Patients with Mixed Hyperlipidemia

A Phase III, Multicenter, Randomized, Double-Blind Study to Evaluate the Lipid-Altering Efficacy and Safety of the XXX/XXX Combination Tablet Versus XXX in Patients with Primary Hypercholesterolemia

A Phase III, multicenter, double-blind, randomized, parallel group, 6-week study to evaluate the efficacy and safety of XXX/XXX combination tablet vs. XXX in patients with hypercholesterolemia

A 26-week, Double Blind, Randomized, Multi-centre, Phase IIIb, Parallel Group Study to Compare the Efficacy and Safety of XXX (40mg) with XXX (80mg) in Subjects with Hypercholesterolemia and Coronary Heart Disease or CHD Equivalents

CLINICAL TRIAL EXPERIENCE (*continued*):

A 12-Week, Randomized, Open-label, 3-Arm Parallel-group, Multicenter, Phase IIIb Study Comparing the Efficacy and Safety of XXX with that of XXX and XXX in Achieving NCEP ATP III LDL-C Goals in High-risk Subjects with Hypercholesterolemia in the Managed Care Setting

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, "Factorial" Design Study to Evaluate the Lipid-Altering Efficacy and Safety of XXX/XXX Combination Tablet in Patients with Primary Hypercholesterolemia

A Phase III, Comparison of Treatment with XXX and XXX Coadministration Versus XXX in Attaining the National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III Coronary Heart Disease (CHD) or CHD Risk equivalent Strata Low-Density Lipoprotein Cholesterol (LDL-C) Target Level

A multicenter, eight-week treatment, single step titration, open-label study assessing the percentage of patients achieving low density lipoprotein cholesterol target with XXX starting doses of 10 mg, 20 mg, 40 mg, and 80 mg

A Phase III, 6 Week Open Label, Dose Comparison Study to Evaluate the Safety and Efficacy of XXX vs. XXX, XXX, and XXX in Subjects With Hypercholesterolemia

Randomized, Double-Blind, Placebo-Controlled Study of XXX As Monotherapy in Patients With Primary Hypercholesterolemia XXX

A Double-Blind Placebo-Controlled Dose Ranging Trial to Evaluate the Efficacy of XXX on Bone Mineral Density and Markers for Bone Turnover in Post-Menopausal Women With Dyslipidemia and At Risk for Osteoporosis

A Phase III, Open-label Multinational, Multicentre, Extension Trial to Assess the Long-Term Safety and Efficacy of XXX in Subjects in XXX Clinical Trial Program Trial Program

Hypertension

A Phase III, XXX for the Treatment of Hypertension (XXX): A Multicenter, Randomized, Double-Blind, Parallel-Group Study Evaluating the Efficacy and Safety of a Fixed-Dose Combination of XXX Plus XXX vs. XXX and XXX in Subjects With Essential Hypertension

The Efficacy and Safety of XXX 150/12.5 mg and XXX 300/25mg in Patients with Hypertension Uncontrolled on Monotherapy

A Phase II, Worldwide, Multicenter, Double-Blind, Randomized, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy & Tolerability of XXX When Added to Ongoing Therapy With XXX -Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) in Patients With T2DM and Hypertension

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Randomized, Double-Blind, Placebo and Active Comparator Controlled Study to Assess the Efficacy and Tolerability of XXX in Hypertensive Patients

A Phase III, Randomized, Double-Blind, Parallel Group Study Evaluating the Efficacy and Safety of Co-Administration of a Triple Combination Therapy of XXX, XXX in Subjects with Hypertension

A Phase IV, Prospective Open Label, Single Arm Study to Evaluate the Safety and Efficacy of an XXX Based Treatment Regimen in Elderly Patients with Hypertension

A Phase IV, Randomized, Double-Blind, Placebo-Controlled Trial Examining the Efficacy and Safety of XXX Versus Therapeutic Lifestyle Changes or Usual Care in Simultaneously Achieving Blood Pressure and Lipid Goals in a Newly Diagnosed and/or Treatment-Discontinuer Hypertensive and Hypercholesterolemic Subject Population

A Phase IV, randomized, double-blind, placebo-controlled, forced-titration, phase IV study comparing XXX 80mg & hydrochlorothiazide 25mg versus XXX 160 mg & hydrochlorothiazide 25 mg taken orally for 8 wks in patients with stage 1 or stage 2 hypertension

A Phase III, Randomized, double-blind, placebo-controlled factorial study evaluating the efficacy and safety of co-administration of XXX plus XXX compared to monotherapy in patients with mild to severe hypertension

A Phase IV, prospective, randomised, open-label, blinded end-point, forced-titration trial to compare XXX/XXX (XXX combined with hydrochlorothiazide 80 mg/12.5 mg) to XXX(XXX combined with hydrochlorothiazide 160 mg/12.5mg), for the control of mild-to-moderate hypertension in obese patients with type-2 diabetes mellitus using ambulatory blood pressure monitoring

A randomized, double-blind, multicenter, positive-controlled, parallel group study to evaluate the safety and efficacy of XXX and XXX administered in combination compared to XXX monotherapy in hypertensive patients not adequately controlled with XXXX alone

A Phase IV, Prospective, Randomized, Open-Label, Blinded-Endpoint, Parallel Group 6-week Treatment Study Comparing XXX combined with Hydrochlorothiazide (40 mg/12.5 mg or 80 mg/12.5 mg) Tablets with XXX combined with Hydrochlorothiazide (50 mg/12.5 mg) Tablets using Ambulatory Blood Pressure Monitoring in Patients with Mild-to-Moderate Hypertension

The Efficacy and Safety of XXX Added to Hydrochlorothiazide for the Treatment of Hypertension in Subjects Non-Responsive to Hydrochlorothiazide Alone

A Randomized, Double-Blind, Placebo-Controlled, Forced Titration Study of Ascending Doses of XXX, XXX, and XXX in Patients with Essential Hypertension

CLINICAL TRIAL EXPERIENCE (*continued*):

A Double-Blind, Placebo-Controlled, Randomized Study to Evaluate the Efficacy and Safety of Ranging Doses of XXX for the Treatment of Mild to Moderate Hypertension

Influenza

A Multi-center, Randomized, Double-blind, and Placebo-controlled Phase II Clinical Study to Investigate the Safety and Efficacy of Two Doses of XXX Compared to Placebo in Subjects With Acute Uncomplicated Influenza

A Phase III, Multicenter, Randomized, Double-blind Study of a Single Dose of XXX 40 mg Compared with Placebo or XXX 75 mg Twice Daily for 5 Days in Patients with Influenza at High Risk of Influenza Complications

A Phase IIb, Randomized, Double-Blind, Placebo Controlled, Parallel-Group, Multicenter Study of 2 Dose Levels of XXX Administered as Monotherapy and One Dose Level of XXX Administered in Combination With XXX for the Treatment of Acute Uncomplicated Seasonal Influenza A in Adult Subjects

A Phase I / II Randomized, Double Blind, Placebo-Controlled, Multicenter Study Evaluating the Safety and Pharmacokinetics of Different Dosing Regimens of XXX in Healthy Adult Subjects and Adult Subjects With Uncomplicated Influenza

A Phase II, Randomized, Double-Blind, Placebo-Controlled Multicenter Study Evaluating the Efficacy and Safety of Two Doses of XXX in Adult Patients With Uncomplicated Influenza

Evaluation of the Clinical Performance of XXX (Device) Influenza Ag A/B/A (H1N1) Pandemic Rapid Test

A Phase II, Randomized Double Blind, Placebo-Controlled, Parallel Arm Study to Investigate the Efficacy and Safety of Inhaled XXX Twin Caps Dry Powder Inhaler in Adults with Symptomatic Influenza A and B Infection

Migraine

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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

A Phase III, Double-Blind, Randomized, Placebo Controlled, Safety and Efficacy Trial of XXX Orally Disintegrating Tablet (ODT) for the Acute Treatment of 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 Phase II/III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy, Safety, and Tolerability of Multiple Dosing Regimens of Oral XXX in Episodic Migraine Prevention

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, Parallel Group, Double-Blind, Randomized, Placebo Controlled, Phase 3 Trial to Evaluate the Efficacy, and Safety, of XXX Administered Intravenously in Patients with Chronic 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, multicenter, randomized, double blind, parallel group, single dose, placebo-controlled study comparing the efficacy and safety of a combination of XXX and XXX vs. placebo in the acute treatment of migraine

CLINICAL TRIAL EXPERIENCE (*continued*):

A Six-Month Phase II/III, Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Evaluate the Safety, Tolerability, and Efficacy of XXX for Prevention of Menstrually Related Migraine in Female Patients With Episodic Migraine

A Randomized, Double Blind, Placebo Controlled, Parallel Group, Phase III Study of XXX in Adult Migraineurs for a Single Migraine Followed by Open Label Extension

Non-Alcoholic Steatohepatitis (NASH)

A Phase IIa, Randomized, Double-blind, Placebo-controlled Study Evaluating the Safety and Efficacy of XXX in Subjects with Non Alcoholic Steatohepatitis (NASH)

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX for the Treatment of Liver Fibrosis in Adult Subjects with Nonalcoholic Steatohepatitis (NASH)

A Randomized, Double-blind, Placebo Controlled, 3-part, Adaptive Design, Multicenter Study to Assess Safety, Tolerability and Efficacy of XXX in Patients with Non-Alcoholic Steatohepatitis (NASH)

Obesity

A Randomized, Double-blind, Dose-finding Study to Evaluate the Change in Weight After 24 Weeks Treatment With 8 Doses of XXX Compared to Placebo in Obese or Overweight Adults, Followed by 24 Weeks Treatment With 2 Doses of XXX and Placebo

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

A Phase 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-Morbidities, Followed by a 1-Year Extension

A Phase II, Double-Blind, Multi-Center, Randomized, Parallel-Group, Yearlong Study to Assess the Efficacy and Safety of 0, 800, or 1600 mg/Day of XXX Administered Orally Once Daily With a Reduced Calorie Diet in Obese Males and Females AND Extension Study

A Phase II / III, 18-month study to assess the efficacy, safety and tolerability of XXX in obese patients

A 2-Year Study to Assess the Efficacy, Safety, and Tolerability of XXX in Obese Patients

CLINICAL TRIAL EXPERIENCE (*continued*):

Opioid-Induced Constipation

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 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 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 II, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of XXX for the Treatment of Opioid Induced Constipation (OIC) in Subjects with Chronic Pain Receiving Opioid Therapy

A Phase III, Open Label 52-week Study to Evaluate the Safety and Efficacy of XXX Given Orally for the Treatment of Opioid-induced Constipation (OIC) in Patients With Chronic Non-cancer Pain

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 IV, Randomized, Double-blind, Placebo-controlled, Clinical trial of Structured Opioid Discontinuation versus Continued Opioid Therapy in Suboptimal and Optimal Responders to High-dose Long-term Opioid Analgesic Therapy for Chronic 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

A Phase III, Randomized, Double-Blind, Placebo and active-controlled, Multicenter, Parallel-Group study of the Analgesic efficacy and safety of XXX in adult subjects with Chronic Low Back Pain

A Phase III, Randomized Double Blind, Multiple Center Placebo Controlled Study Comparing the Safety and Efficacy of a Multiple Dose of Generic XXX Topical 1.3% to XXX Patch in Acute Pain Due to Minor Ankle Sprain

CLINICAL TRIAL EXPERIENCE (*continued*):

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, 12-Week, Randomized, Double-Blind, Placebo-Controlled, Randomized-Withdrawal Study to Evaluate the Efficacy and Safety of XXX Extended-Release Tablets XXX at 30 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, 6 Month Open Label Extension Study to Evaluate the Safety of XXX Extended Release Tablets XXX at 15-90 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, Multi-Center, Randomized, Double-blind, Placebo-Controlled, Safety, Tolerability, and Efficacy Study of XXX Versus Placebo in Opioid-Naive Subject with Moderate-to-Severe Chronic Low Back Pain

A Phase III, Multicenter, Non-comparative, Open-label Extension Study to Assess the Long-Term Safety of XXX Spray as Adjunctive Therapy in Patients With Uncontrolled Persistent Chronic Cancer-related Pain

A Phase III, Double Blind, Randomized, Placebo-controlled, Parallel Group Study of XXX Spray as Adjunctive Therapy in Relieving Uncontrolled Persistent Chronic Pain in Patients With Advanced Cancer, Who Experience Inadequate Analgesia During Optimized Chronic Opioid Therapy

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study With an Open-label Run-in to Assess the Efficacy and Safety of XXX Tablets 20 to 120 mg Once-daily in Subjects With Moderate to Severe Chronic Low Back Pain

A Phase III, 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 Nonneuropathic Pain

A multicenter, 12-month, open label, single arm, safety study of XXX and XXX Extended Release Capsules in Subjects with Moderate to Serve Chronic Noncancer Pain

A Phase III, randomized, double-blind, multi-center, placebo-controlled, parallel group study to evaluate the efficacy and safety of XXX topical gel 1% applied four times daily in subjects with acute ankle sprain

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IV, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Assess the Efficacy and Safety of XXX Patches in Adolescent Subjects with Ankle Spain

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 III, Double-Blind, Randomized, Placebo-Controlled Parallel Group Study of XXX Spray as adjunctive Therapy in Relieving Uncontrolled Persistent Chronic Pain in Patients With Advanced Cancer Who Experience Inadequate Analgesia during optimized Chronic Opioid Therapy

A Phase II /III, Multicenter, Randomized, Log Term Study of the Safety of XXX in Patients with Chronic Low Back Pain

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

A Phase III, Randomized, Double-Blind, Double-Dummy Trial of Two Sustained Release Formulations of XXX Compared to Placebo in Subjects With Acute, Painful, Musculoskeletal Spasm of the Lower Back

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

A Open-Label, Two-Stage, Phase II Study to Explore the Titration Schedule for Transitioning Opioid-Experienced Patients with Non-Malignant Moderate to Severe Chronic Pain from Current Opioid Therapy to the XXX Transdermal Therapeutic System XXX

Randomized, Double-Blind Trial of the Combination of XXX 250 -mg Tablets and XXX 50-mg Tablets Compared to Placebo and Either Product Alone in Patients with Acute, Painful Musculoskeletal Spasm of the Lower Back

A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Phase III Study of the Efficacy, Tolerability and Safety of XXX Topical Patch, 20% (KTP) in the Treatment of Pain Associated with Tendonitis or Bursitis of the Shoulder, Elbow, or Knee

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Phase III Study of the Efficacy, Tolerability and Safety of XXX Topical Patch in the Treatment of Pain Associated with Grade 1 or Grade 2 Ankle Sprain or Strain

A Phase III, Double-blind, Randomized, Placebo-controlled, Multicenter Study to Evaluate the Efficacy and Safety of XXX for the Treatment of Breakthrough Pain in Opioid Tolerant Cancer Patients

A Phase III, Multiple-Dose, Non-Randomized, Open-Label, Multicenter Study to Evaluate the Long-Term Safety and Effectiveness of XXX in the Treatment of Breakthrough Pain in Cancer Patients

A Randomized, double-blind Trial of XXX 350-mg and 250-mg tablets compared to placebo in patients with acute, painful musculoskeletal spasm of the lower back

A Randomized, double-blind Trial of XXX 350-mg and 250-mg tablets compared to placebo in patients with acute, painful musculoskeletal spasm of the lower back

A Phase III, Study of the Efficacy and Safety of 8 Mg XXX Extended-Release Compared to Placebo in Subjects With Persistent Pain

A Phase III, Open-Label Titration Followed by a Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy, Tolerability, and Safety of XXX Extended Release Tablets in Opioid-Experienced Patients With Chronic Low Back Pain

A Phase IV, Randomized, Open-Label Study Comparing the Efficacy and Safety of XXX Patch 5% With XXX 200 mg in Patients With Chronic Axial Low Back Pain

A Randomized, Double-Blind, Parallel-Group, Active-Controlled, Placebo-Controlled, Multicenter Trial to Study the Efficacy and Safety of XXX HCL Modified-Release (CMR) 15 mg and 30 mg in Subjects with Pain due to Muscle Spasms of Local Origin

Clinical Protocol for a Multicenter, Double-Blind, Placebo Controlled, Randomized Study of the Analgesic Efficacy, Safety and Tolerability of XXX 40mg over Seven Days in Patients Undergoing Anterior Cruciate Ligament Surgery

An Open-Label, Randomized, Parallel-Group, Active-Controlled Trial to Evaluate the Safety and Efficacy of Extended-Release XXX in Patients Requiring Opiates for Control of Moderate to Severe Chronic Pain

A Multicenter, Open-Label, Multidose, 52-Week Study Designed to Assess the Safety of XXX in the Treatment of Moderate to Severe Non-Malignant Chronic Pain

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Trial to Assess the Efficacy and Safety of 200, 400 and 600 mg/day XXX in Subjects with Painful Diabetic Neuropathy

A Multi-Center, Open-Label, Follow-On Trial to Assess the Long-Term Safety and Efficacy of XXX in Subjects with Painful Diabetic Neuropathy

Sleep Disorders

A One-Month, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Active Comparator, Parallel-Group Study of the Efficacy and Safety of XXX in Subjects 55 Years and Older with Insomnia Disorder

A Phase III, Double-Blind, Randomized, Placebo-Controlled, Multicenter, 30-Night Polysomnographic Study of XXX in Elderly Patients With Primary Insomnia

A Phase III, Double-Blind, Randomized, Placebo-Controlled, Multicenter, 30-Night Polysomnographic Study of XXX in Adult Patients With Primary Insomnia

A 1-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 OSAH Syndrome

A Phase III, Randomized, Double-Blind, Single-Dose, Placebo-Controlled, Multicenter Study of XXX 250 mg and 500 mg in Transient Insomnia Induced by Sleep Phase Advance

A Phase III, 1 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 (100, 200, and 400 mg/Day) in Children and Adolescents With Excessive Sleepiness Associated With Obstructive Sleep Apnea/Hypopnea Syndrome

Vaccine Studies

A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of XXX, a Non-replicating XXX Vaccine, for the Prevention of COVID-19

Comparative Randomized Study of Safety and Immunogenicity Of A Non-Adjuvanted Respiratory Syncytial Virus (RSV) Vaccine Versus An RSV Vaccine Adjuvanted With Aluminum Phosphate When Administered Concomitantly With A Licensed Influenza Vaccine In High-Risk Adults > 65 Years Of Age

CLINICAL TRIAL EXPERIENCE (*continued*):

Open, randomized, phase II, clinical trial to compare the immunogenicity and safety of a booster dose of XXX vaccine co-administered with a booster dose of Merck and Company's MMR II, to that of separate injections of XXX vaccine, Aventis Pasteur's IPV (IPOL R) and MMR II administered as booster doses to healthy children 4 to 6 years of age

A Phase IV, Multicenter, Double-blind, Randomized, Placebo Controlled Study to Estimate the Effect of XXX on Vaccine Antibody Response in Subjects with Rheumatoid Arthritis

Women's Health

A Randomized, Double-blind, Multicenter Integrated Phase I/III Study in Postmenopausal Women With Osteoporosis to Compare the Pharmacokinetics, Pharmacodynamics, Efficacy, Safety and Immunogenicity of XXX and XXX

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 Phase III, Randomized, Placebo-controlled, 12-week Double-blind Study, followed by a Single-arm Open-label Treatment Period, to Assess the Efficacy and Safety of XXX in Women Suffering From Moderate to Severe Vasomotor Symptoms (Hot Flashes) Associated with Menopause

A Phase III, Intravaginal XXX Against Sexual Dysfunction which Study is described in the Protocol XXX

A Phase I, Randomized, Open-Label, Multicenter Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX (Test vs. Reference) Following Intramuscular Administration to the Gluteal Muscle in Healthy Female Subjects

A Phase III, Multicenter, Randomized, Placebo-Controlled, Parallel-Group Trial With An Open Label Extension Phase To Evaluate The Safety And Efficacy Of Subcutaneously Administered XXX In Premenopausal Hypoactive Sexual Desire Disorder (HSDD) (With Or Without Decreased Arousal)

A Phase II, Randomized, Double-blind, Placebo-controlled, Multiple Dose Study to Assess the Safety and Efficacy of Multiple Dosing Regimens of XXX in Post-Menopausal Women With Low Bone Mineral Density

A Phase II, Randomized, Double-blind, Placebo-controlled Clinical Trial Evaluating the Safety and Efficacy of Oral XXX in the Prevention of Postmenopausal Osteoporosis in Women at Increased Risk of Fracture

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multicenter, Open-Label Study to Evaluate The Efficacy and Safety of A Combination Oral Contraceptive Regimen XXX For The Prevention of Pregnancy of Pregnancy in Women

A Phase III, Open Label Study of the Contraceptive Efficacy of XXX and XXX

A Phase III, Open-Label Study of the Safety and Efficacy of a Low Dose Oral Contraceptive Containing XXX and XXX

A Phase II, double-blind randomized, placebo-controlled dose-ranging study of the effects of XXX in the reduction of symptoms associated with Endometriosis in Reproductive aged women

A Phase III, Study to Evaluate XXX in the Treatment of Postmenopausal Osteoporosis

A Phase III, 12-Month, Extension Study to Evaluate the Safety of XXX in Subjects With Uterine Leiomyomata

A Phase III, 12-Month, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Two Doses of XXX Versus Placebo in Subjects With Uterine Leiomyomata

A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety of the Hormone Replacement Therapy Combination Drug Product XXX/XXX in Postmenopausal Women With Concomitant Disease and Medical Known to Potentiate the Risk of Hyperkalemia

A Phase III, open-label, multicenter, multinational, contraception study of XXX (20 mg) and XXX (5 mg) injectable suspension administered subcutaneously

A Proof-of-Concept Study of Oral XXX in Premenopausal Women with Endometriosis

A Prospective, Randomized, Double-Blind, Multi-Center, Comparative Trial to Evaluate the Efficacy of XXX Once Daily Extended Release 500 mg Tablets QD For 3 Days Versus Conventional XXX 250 mg Tablets BID for 3 Days in The Treatment of Patients with Uncomplicated Urinary Tract Infection

Other Indications

The XXX study is a prospective, observational multi-site study without randomization. The primary objective of the study is to evaluate the performance characteristics of a blood-based XXX test to detect colorectal cancer in a screen-relevant, average risk population.

A Multicenter, Randomized, Double-Blinded, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of Topically Applied XXX Gel, 15% in Subjects with Axillary Hyperhidrosis

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Multi Center, Randomized, Double Blind, Placebo Controlled Parallel Group Study to Evaluate the Safety, Tolerability, and Efficacy of XXX in Subjects with Irritable Bowel Syndrome Experiencing Abdominal Pain

A Phase II Randomized, Double-blind, Placebo-controlled, Parallel Group Trial to Assess the Efficacy and Safety of XXX versus Placebo after 12 weeks of Treatment in Patients with Nonalcoholic Fatty Liver Disease (NAFLD) with or without Type 2 Diabetes Mellitus

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Tolerability of XXX Infusions in Subjects With Parkinson's Disease and Cognitive Impairment

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

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

A Phase III, Multi-center, Randomized, Double-masked Study to Evaluate the Clinical Efficacy and Safety of XXX Ophthalmic Suspension Compared to Placebo in the Treatment of Bacterial Conjunctivitis

A Phase III, Multi-center, Randomized, Double-masked Study to Evaluate the Clinical Efficacy and Safety of XXX Ophthalmic Suspension Compared to XXX and Placebo in the Treatment of Adenoviral Conjunctivitis

An International Phase III, Randomized, Double-Blind, Placebo- and Active XXX-Controlled Multicenter Extension Study to Evaluate the Long-Term Safety and Efficacy of XXX in Patients with Symptoms of Overactive Bladder

An International Phase III, Randomized, Double-Blind, Placebo- and Active XXX-Controlled Multicenter Study to Evaluate the Safety and Efficacy of XXX in Patients with Symptoms of Overactive Bladder

A Phase IIIb, Multicenter, Randomized, Double-blind Study to Evaluate the Efficacy and Safety of XXX or XXX for the treatment of schizophrenia in subjects hospitalized for acute exacerbation

A Multicenter, Open-label Trial to Evaluate the Safety and Tolerability of XXX in the Treatment of Subjects with Bipolar I Disorder

A Multicenter, Randomized, Double-blind Trial of XXX versus Placebo for the Acute Treatment of Subjects Manic Episodes, With or Without Mixed Features, Associated With Bipolar I Disorder

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of XXX During a 28-week Treatment Period as Adjunctive Therapy to Antipsychotic Treatment for the Prevention of Relapse in Patients with Schizophrenia

A Phase III, Randomized, Double-blind, Multicenter, Parallel-group, Placebo-controlled, Dose-optimization Safety and Efficacy Study of XXX Compared with Placebo in Preschool Children Aged 4-5 Years with Attention-deficit/Hyperactivity Disorder

XXX device study to evaluate new oral fluid collection device to be used in drug screen tests

A Randomized, Double-blind, Placebo-controlled Phase II Study of XXX in Adults with Post-Traumatic Stress Disorder (PTSD)

A Phase II, Two-Part Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Efficacy of XXX Oral Solution in Patients with Parkinson's Disease (PD) of Moderate Severity Responding to immediate release oral Levodopa/Carbidopa and Withdrawn from Levodopa/ Carbidopa

A Phase II Study to Assess the Effect and Safety of XXX in Subjects with Neurogenic Orthostatic Hypotension

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

A Phase II, Multicenter, Randomized, Double-blind, Placebo- and Active-controlled Trial of XXX (1 - 3 mg/day) as Monotherapy or as Combination Therapy in the Treatment of Adults with Post-traumatic Stress Disorder (PTSD)

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 Military-Related Post-traumatic Stress Disorder (PTSD)

An Multi-center, Prospective, Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of XXX as an Add-on Treatment for Schizophrenia in Adults

A Phase III, Multicenter, Randomized, Double-blind, Double dummy, Placebo-controlled Study of the Efficacy and Safety of XXX in Subjects with Bipolar I Disorder Experiencing an Acute Manic Episode

A Phase II, Double-blind, Randomized, placebo-controlled parallel group, multicenter 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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Randomized, Double-blind, Placebo-controlled, Parallel Group Fixed Dose Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in the Treatment of Subjects with Overactive Bladder

A Phase III, 52-week, multicenter, open label study to evaluate the effectiveness of an Intramuscular Depot Formulation of XXX as a Maintenance Treatment in Patients with Bipolar I Disorder

A Phase II, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Multiple-Dose Study to Determine the Safety and Efficacy of Orally Administered XXX in Subjects With Diarrhea-Predominant Irritable Bowel Syndrome (IBS-D)

Design Validation of the XXX Shielded IV Catheter

A Phase II, Open-label, Dose Exposure Confirmation Study to Evaluate the Pharmacokinetics and Safety and Tolerability of XXX in Adult Patients With Nonvalvular Atrial Fibrillation or Atrial Flutter

A Phase III, double blind, Placebo-Controlled Study to Evaluate New or Worsening Lens Opacifications in Subjects with Non-metastatic Prostate Cancer Receiving XXX for Bone Loss due to Androgen-Deprivation

A Phase III, Active XXX Controlled, Randomized, Double-Blind, Parallel-Arm Study to Evaluate Efficacy and Safety of XXX In Preventing Stroke and Systemic Embolism in Patients with Nonvalvular Atrial Fibrillation

A Phase IV, Multicenter, Randomized, Double-Blind, Double-Dummy, Parallel-Group Efficacy Study Comparing 8 Weeks of Treatment with XXX (40 mg qd) to XXX (30 mg qd) for the Healing of Erosive Esophagitis in Patients with Moderate or Severe Erosive Esophagitis

A Phase III, Open Label, Single Arm, Extension Study to Evaluate the Long Term Safety and Sustained Efficacy of XXX in the Treatment of Postmenopausal Osteoporosis

A Phase III, Multi-center, Randomized, Double-blind, Placebo-controlled, Parallel Group Trial of Fourteen Day Treatment With XXX 15 mg or 30 mg Once a Day in Frequent Nighttime Heartburn

A Phase II, Randomized, Double-Blinded, Parallel Group, Multicenter Study of XXX vs. XXX for the Treatment of Community Acquired Pneumonia

A Phase III, multicenter, randomized, double-blind, parallel-arm, 53 week dose comparison study of the efficacy and safety of 25mg QD and 50mg qd of XXX Oral Tablets and 800mg BID of XXX in the maintenance of remission in subjects with Ulcerative Colitis

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, randomized double-blind, placebo-controlled multicenter study to assess the efficacy, safety, and tolerability of XXX alone and in combination with XXX given orally in patients suffering from symptomatic (ono-erosive) gastroesophageal reflux disease (sGERD)

A Dose-Ranging Study to Evaluate the Tolerability of XXX and its Effects on Niacin-Induced Flushing in Lipid Clinical Patients and Extension Study

A Randomized, Double-Blind, Placebo-Controlled Endpoint Selection and Questionnaire Validation Study to Assess the Niacin Induced Flushing Caused by XXX

A Phase IV, Multi-Center, Randomized, Blinded, Parallel-Group Study of XXX Compared with XXX in Combination with Oral XXX , Intravenous XXX or Both in Subjects with Relapsing-Remitting Multiple Sclerosis Who Have Breakthrough Disease on XXX Monotherapy

A Phase III, Randomized, Double-Blind, Placebo-controlled study to evaluate XXX in the treatment of bone loss in subjects undergoing Androgen-Deprivation therapy for non-metastatic prostate cancer

One Touch Ultra Test Strip Palm Equivalency Clinical Study

A Randomized, Evaluator-Blinded Comparison of the Efficacy and Safety of XXX Solution 0.2% with XXX and XXX and XXX Solution in the Treatment of Acute Diffuse Otitis Externa in Children, Adolescents, and Adults

A Phase IV, Randomized, Open-Label, Active Controlled Study to Compare the Effects of XXX and XXX on Glucose Tolerance in Subjects With Metabolic Syndrome

An Open-Label, Long-Term, Phase III Trial of the Safety and Efficacy of XXX in Male Subjects with Erectile Dysfunction

A Randomized, Placebo-Controlled, Double-Blind, Parallel Design Phase III Bridging Trial of the Efficacy and Safety of XXX 300 mcg in Male Subjects with Erectile Dysfunction

An Open-Label, Parallel Design, Twelve Month Phase III Trial of the Safety and Efficacy of XXX in Male Patients with Erectile Dysfunction

A Phase III, 12-Week, Randomized, Double-Blind, Placebo- Controlled Study of XXX and Fixed Dosing Regimens of XXX in Female Subjects With Severe Diarrhea-Predominant Irritable Bowel Syndrome Who Have Failed Conventional Therapy

Open-Label, Multi-Center Study to Assess Safety, Tolerability and Effectiveness Associated with the use of ADDERALL XR in Adults with Attention Deficit Hyperactivity Disorder and Evaluate an ADHD-specific Novel Quality of Life Measure

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Double-Blind, Randomized, Multicenter, Parallel Group Study to Establish Dose-Response, Safety and Efficacy of XXX as Monotherapy in Patients with Newly Diagnosed Epilepsy

A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Phase III Study of XXX 20 mg in the Primary Prevention of Cardiovascular Events Among Subjects with Low Levels of LDL-Cholesterol and Elevated Levels of C-Reactive Protein

A Double-Blind, Placebo-Controlled, Randomized US Study to Evaluate the Effect of XXX Prolonged Release on Nocturia in Patients with Symptoms of Overactive Bladder (OAB)

An Open Label Extension and Long Term Safety Study of XXX PR Capsules in Children 5 to 11 Years of Age with Symptoms of Urge Urinary Incontinence Suggestive of Detrusor Instability

A Phase III, Randomized, Double Blind, Multicenter and Multinational Study to Determine the Efficacy and Safety of XXX Prolonged Release Capsules in Children 5 to 10 years of age with Symptoms of Urge Urinary Incontinence, Suggestive of Detrusor Instability

An open-label, multicenter multinational study to determine the safety and efficacy of XXX oral solution in children with symptoms of urge urinary incontinence Suffestive of Detrusor instability

A multi-site Open Clinical Study to Collect Biological Specimens and Phenotypic Data from a Large Cohort of Subjects for Inclusion in a Repository and use in Genomic, Serologic and Metabolic and Proteomic research studies

Comparative Dose Study of the Efficacy of Two Oral Doses of XXX in the Treatment of Community Acquired Pneumonia

Comparative Study of the Safety and Efficacy of XXX 150mg QD vs 150mg BID for the Treatment of Acute Bacterial Sinusitis

Protection During Saphenous Vein Graft Intervention to Prevent Distal Embolization

A Randomized, Placebo-Controlled, Double-Blind, Parallel Design Phase III Trial of the Efficacy and Safety of XXX In Male Patients with Erectile Dysfunction

A Double-Blind Placebo-Controlled Dose-Finding Trial to Evaluate the Efficacy and Safety of XXX in Subjects with Symptoms of Gastroesophageal Reflux Disease (GERD)

A Double-Blind Placebo-Controlled Dose-Finding Trial to Evaluate the Efficacy and Safety of XXX in Diabetic Subjects with Symptoms of Gastroparesis

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Parallel Group, Stratified, Randomized, Double blind, Placebo controlled Trial to Investigate the Efficacy and Safety of Three Different Dosages of Sustained Release XXX in Subjects with Overactive Bladder Showing Either Involuntary Detrusor Contractions of Normal Findings During the Baseline Urodynamic Assessment

Multi-Center Clinical Study to Determine the Effectiveness and Safety of XXX in the Screening of Women for Breast Cancer

TRAINING CREDITS:

5/2000 to Present, Preceptorship – Medical Students
Pennsylvania College of Technology
2004 to Present, Preceptorship – Medical Students
Arcadia University
2004 to Present, Preceptorship – Medical Students
Philadelphia College of Osteopathic Medicine

SPEAKING ENGAGEMENTS:

Novartis
Lecture: Hypertension

Daiichi-Sankyo
Lecture: Hypertension

Roche- multiple
Effectiveness of Oseltamivir in Preventing Influenza in Household Contacts

Sanofi-Aventis
Allergic Rhinitis, Seasonal Allergies

CONTINUING EDUCATION:

4/12 Janssen AI Good Clinical Practice (GCP) and Best Practices when Managing Clinical Trials
12/11 Pfizer GCP for Investigational Site Staff
3/11 NIDA Clinical Trials Network Good Clinical Practices
1/10 National Institutes of Health (NIH) Office of Extramural Research
NIH Web-based training course "Protecting Human Research Participants"
9/02 Investigator Support Initiative Training Course, Sponsor Pharmacia
2/01 Sponsor and FDA GCP Inspection Course Clinical Research Consulting Services
2/98 ClinTrials Research, Inc., Training on Conducting Successful Research Projects

PUBLICATIONS & ABSTRACTS:

2020 Manuscript in PLOS One *Development of a point of care clinical test for Ebola virus infection in humans*

2011 Manuscript in Current Medical Research & Opinion (CMRO) *Evaluation of a New Safety Peripheral IV Catheter Designed to Reduce Mucocutaneous Blood Exposure*

2010 Poster Presentations for EAPC (May 2011), Pain Week *Successful Dose-Finding with Sublingual Fentanyl (Abstral): Combined Results From 2 Open-Label Titration Studies*

2009 20th Annual Clinical Meeting of the American Academy of Pain Management, *"Long-term Safety and Tolerability of Sublingual Fentanyl" Abstract 36*

2009 5th World Congress of the World Institute of Pain, *Efficacy and Tolerability of Sublingual Fentanyl in Opioid-tolerant Cancer Patients with Breakthrough Pain: Interim Findings from Two Long-term, Phase Ill Multi-centre Studies.*

2003 Clinical Abstract, *Treatment of Type 2 Diabetes with a Combination Regimen of Repaglinide plus Pioglitazone*

2003 Clinical Abstract, *Randomized, Multicenter Comparison of Repaglinide Monotherapy vs. Nateglinide Monotherapy*

2001 JAMA *Effectiveness of Oseltamivir in Preventing Influenza in Household Contacts*

1999 Clinical Abstract, Hoechst Marion Roussel - *A Double-Blind, Multicenter, Randomized, Active-Controlled, Two-Arm Parallel-Group Comparative Study of the Efficacy and Safety of Oral HMR3647 vs. Oral Clarithromycin in the Treatment of Community Acquired Pneumonia in Adults*