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EDUCATION:

09/88 - 06/92 Doctor of Medicine
Oregon Health Sciences University, Portland, OR

09/84 - 06/88 BA, Chemistry
Robert D. Clark Honors College, University of Oregon, Eugene, OR

RESIDENCY:

06/92 - 07/95 Residency, Department of Internal Medicine
Emanuel and Good Samaritan Hospitals, Portland, OR

LICENSURE:

Oregon State Medical License, #MD18331, 1993 - Present
Board Eligible, Internal Medicine

PROFESSIONAL EXPERIENCE:

Investigator, 04/2016 - Present
Oregon Center for Clinical Investigations, Inc., Salem, OR

Hospice and Palliative Care Practice, 03/2007 - Present
Willamette Valley Hospice, Salem, OR

Associate Staff Physician, 09/2001 - Present
Salem Hospital, Salem, OR

Life Insurance Examiner, 11/2006 - 02/2007
Northwest Paramedical, Inc., Beaverton, OR

Sub-Investigator and Study Coordinator, 04/2002 - 10/2006
Congestive Heart Failure Patients and Cardiac Clinical Trials, Salem Hospital Ambulatory
Parenteral Enteral Services (SHAPES), Salem Heart Improvement Program, Salem, OR

Sub-Investigator and Study Coordinator, 04/2002 - 10/2006
Congestive Heart Failure Patients and Cardiac Clinical Trials, Salem Hospital Ambulatory
Parenteral Enteral Services (SHAPES), Salem Heart Improvement Program, Keizer, OR

Investigator, 10/2000 - 09/2006
Oregon Center for Clinical Investigations, Inc., Salem, OR

Medical Director, 02/1999 - 07/2000
HealthSouth Rehabilitation Center, Portland, OR

Investigator/ Internal Medicine Practice, 02/1999 - 07/2000
Westover Heights Clinic, Portland, OR

Internal Medicine Practice, 09/1995 - 10/1998
HealthFirst Medical Group, Tualatin, OR

Medical Consultant, Psychiatric Patients, 10/1994 - 06/1995
CareMark Behavioral Health, Emanuel Hospital, Portland, OR

Travel Medicine, 07/1993 - 06/1995
Travel Clinical & Urgent Care Clinic, Good Samaritan Hospital, Portland, OR

INVESTIGATOR EXPERIENCE:

ADHD • Alzheimer's Disease • Anorexia Nervosa • Anxiety
Binge Eating Disorder • Bipolar Disorder • Cholesterol • Chronic Bronchitis
Depression • Fibromyalgia • Hypertension • Insomnia • Men's Health
Migraine • Neuropathic Pain • Opioid Induced Bowel Dysfunction
Oppositional Defiant Disorder • Panic Disorder • Premenstrual Dysphoric Disorder • PTSD
Seasonal Affective Disorder • Sexual Functioning / Dysfunction

CLINICAL TRIAL EXPERIENCE:

ADHD

An Open-label, 52-Week, Multicenter Trial Evaluating the Long-term Safety and Tolerability of Drug Sustained-Release Tablets in Adults with Attention-Deficit/Hyperactivity Disorder. (OT.115) 2018

A Phase III, Randomized, Double-blind, Multicenter, Placebo-controlled, Parallel-group Trial Evaluating the Efficacy, Safety and Tolerability of Drug Sustained-release Tablets in Adults with Attention-deficit/Hyperactivity Disorder. (OT.114) 2018

A Phase III, Randomized, Double-blind, Multicenter, Placebo-controlled, Parallel-group Trial Evaluating the Efficacy, Safety and Tolerability of Drug Sustained-release Tablets in Adults with Attention-deficit/Hyperactivity Disorder. (OT.113) 2018

A Phase III, Multicenter, Dose-Optimized, Open-Label Safety Study with XXX in Children with Attention-Deficit/Hyperactivity Disorder. (KE.101) 2018

A Phase III, Evaluation of XXX 200 and 400 mg Efficacy and Safety in Adolescents with ADHD - A Double-Blind, Placebo-Controlled, Pivotal Trial. (SP.104) 2017

A Phase III, Evaluation of XXX 100 and 200 mg Efficacy and Safety in Children with ADHD - A Double-Blind, Placebo-Controlled, Pivotal Trial. (SP.103) 2017

A Phase II, Multicenter, Randomized, Double-blind, Active- and Placebo-controlled Trial of the Safety and Efficacy of XXX in the Treatment of Adult Attention-deficit/Hyperactivity Disorder. (OT.111) 2017

A Multicenter, 6-Week, Double-blind, Randomized, Placebo-controlled, Parallel-design Study to Assess the Efficacy and Safety of *Drug* in Adolescents (Ages 12-17 Years) with Genetic Disorders Impacting Metabotropic Glutamate Receptors and Attention Deficit Hyperactivity Disorder. (MG.102) 2016

A Noninterventional Genotype/Phenotype Study of mGluR Mutations in Children and Adolescents with Attention Deficit Hyperactivity Disorder (ADHD). (MG.101) 2016

CLINICAL TRIAL EXPERIENCE (*continued*):

Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Drug for the Treatment of Pediatric Patients with Attention Deficit/Hyperactivity Disorder (ADHD). (SP.102) 2016

Evaluation of Drug Efficacy and Safety in Children with ADHD - A Double-Blind, Placebo-Controlled, Dose-Ranging Study. (SP.101) 2016

A 6-Week, Double-Blind, Placebo-Controlled, Parallel-Group, Randomized-Withdrawal Study to Evaluate the Continued Efficacy of Drug Treatment at Dosages up to 425 mg/day in Patients with Attention-Deficit Hyperactivity Disorder Who are Responders to Drug Treatment, Followed by a 12-Month, Open-Label Extension Period. (CP.113) 2006

A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced-Dose Titration, Safety and Efficacy Study of Drug in Adults with Attention-Deficit Hyperactivity Disorder (ADHD). (SH.115) 2005

A Phase III, Multi-Center, 12-Month, Open-Label, Safety and Efficacy Study of Drug in Adults with Attention-Deficit Hyperactivity Disorder (ADHD). (SH.116) 2005

A Long-Term, Open-Label, and Single-Arm Study of Drug 30mg, 50mg, or 70mg per Day in Children Aged 6-12 Years with Attention Deficit Hyperactivity Disorder (ADHD). (NR.102) 2004

A Phase III, Multi-Center, Open-Label Study of Drug vs. Drug in Pediatric Patients Aged 6-13 with Attention-Deficit Hyperactivity Disorder (ADHD). (SH.110) 2004

A Phase III, Randomized, Multi-Center, Double-Blind, Parallel-Group, Placebo-Controlled Study of Drug in Children Aged 6-12 Years with Attention Deficit Hyperactivity Disorder (ADHD). (NR.101) 2004

A Phase III, Randomized, Double-Blind, Multi-Center, Parallel-Group, Placebo-Controlled, Dose-Optimization Study Designed to Evaluate the Safety and Efficacy of Drug vs. Drug in Pediatric Patients Aged 6-12 with Attention Deficit Hyperactivity Disorder (ADHD). (SH.109) 2004

A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Safety and Efficacy Study of Drug with an Open Label Extension in Adolescents with Attention-Deficit Hyperactivity Disorder (ADHD). (SH.111) 2004

A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Safety and Efficacy Study of Drug with an Open Label Extension in Adults with Attention-Deficit Hyperactivity Disorder (ADHD). (SH.113) 2004

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase IIIb, Open-Label, Multi-Center Study to Assess Safety, Tolerability, and Effectiveness Associated with the Use of Drug in Adults with Attention Deficit Hyperactivity Disorder and Evaluate an ADHD-specific Novel Quality of Life Measure. (SH.108) 2004

A 1-Year, Open-Label, Flexible-Dosage Study to Evaluate the Safety and Continued Efficacy of Drug (Film-Coated Tablet Formulation) in Children and Adolescents with Attention Deficit Hyperactivity Disorder (ADHD). (CP.106) 2003

A 9-Week, Randomized, Double-Blind, Placebo-Controlled, Fixed-Dosage (340 or 425 mg/day), Parallel-Group Study to Evaluate the Efficacy and Safety of Drug (Film-Coated Tablet) in Children and Adolescents with Attention Deficit Hyperactivity Disorder (ADHD), Including a 2-Week (Blinded) Withdrawal Period. (CP.104) 2003

A Phase III, Multi-Center, 18-Month, Open-Label Safety, Tolerability, and Efficacy Study of Drug in the Treatment of Adolescents Aged 13-18 with Attention Deficit Hyperactivity Disorder (ADHD). (SH.107) 2003

A Phase III, Randomized, Multi-Center, Double-Blind, Parallel-Group, Placebo-Controlled, Safety and Efficacy Study of Drug with an Open Label Extension, in the Treatment of Adolescents Aged 13-17 with Attention Deficit Hyperactivity Disorder (ADHD). (SH.106) 2003

A Phase II, Randomized, Multi-Center, Double-Blind, Parallel-Group, Placebo-Controlled Safety and Efficacy Study of Drug in Adults Aged 18-55 with Attention Deficit Hyperactivity Disorder (ADHD). (SH.105) 2003

A Phase III, Open-Label Study of Drug in Children and Adolescents (Aged 6-17) with Attention Deficit Hyperactivity Disorder (ADHD). (SH.104) 2003

A Phase III, Randomized, Multi-Center, Double-Blind, Parallel-Group, Placebo-Controlled, Safety and Efficacy Study of Drug in Children and Adolescents Aged 6-17 with Attention Deficit Hyperactivity Disorder (ADHD). (SH.103) 2003

A 4-Week, Double-Blind, Randomized, Placebo-Controlled, Parallel Study to Evaluate the Efficacy and Safety of Drug in Children and Adolescents with Attention-Deficit/Hyperactivity Disorder, Followed by an 8-Week, Open-Label Extension. (CP.101) 2002

A Multi-Center, Double-Blind, Placebo-Controlled Safety and Efficacy Study of Drug in Pediatric Patients with Attention Deficit Hyperactivity Disorder. (NP.103) 2001

A Long-Term, Open-Label, Study of Drug in Pediatric Patients with Attention Deficit Hyperactivity Disorder. (NP.102) 2000

CLINICAL TRIAL EXPERIENCE (*continued*):

Alzheimer's Disease

A Double-Blind, Placebo-Controlled, Dose-Finding Study Evaluating the Safety and Efficacy of Drug, 80 m B.I.D., and 20 and 80 mg Q.D. in the Treatment of Mild to Moderate Alzheimer's Disease. (MI.101) 2003

A Long-Term, Open-Label Extension Study of Drug in Patients with Mild to Moderate Alzheimer's Disease. (FS.102) 2001

A Well-Controlled Safety and Efficacy Study of Drug in Patients with Mild to Moderate Alzheimer's Disease. (FS.101) 2001

Anxiety

A Phase III, Multicenter, Randomized, Double-Blind, Placebo Controlled Trial of XXX in Generalized Anxiety Disorder (BH.105) 2018

A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Drug in Patients with Generalized Anxiety Disorder (GAD). (PP.101) 2005

A 12-Month, Open-Label, Flexible-Dosage Study to Evaluate the Safety and Efficacy of Drug Treatment (up to 16mg/day) in Adults with Generalized Anxiety Disorder. (CP.112) 2005

A 10-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dosage Study to Evaluate the Efficacy and Safety of Drug (up to 16mg/day) in the Treatment of Adults with Generalized Anxiety Disorder. (CP.109) 2004

A Phase III, 10-Week, Double-Blind, Randomized, Placebo-Controlled Study of Drug 60 to 120 mg Once Daily (QD) or Placebo in Patients with Generalized Anxiety Disorder (GAD). (EL.105) 2004

An Open-Label Safety Study of Drug (4 to 16 mg BID) for Patients Completing Previous Drug Anxiety or Affective Disorder Studies. (EL.103) 2003

A Phase III, Randomized, Multi-Center, Double-Blind, Parallel, Placebo-Controlled, 6- to 10-Week Study Comparing the Efficacy and Safety of Drug (16 to 32 mg Once Daily [QD]) in Patients with Generalized Anxiety Disorder. (EL.102) 2003

A Four-Week, Double-Blind, Placebo- and Active-Controlled, Dose-Ranging Study of Drug 3 Doses (5, 15, 50 mg/day) and Drug (3 mg/day) in Out-Patients with General Anxiety Disorder (GAD). (SS.101) 2003

CLINICAL TRIAL EXPERIENCE (*continued*):

An 8-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dosage Study to Evaluate the Efficacy and Safety of Drug, at Dosages up to 16 mg/day, in the Treatment of Generalized Anxiety Disorder in Adults. (CP.103) 2003

Drug 60 mg (or 30 mg) Once Daily in the Treatment of Generalized Anxiety Disorder. An Open-Label, Multi-Center, Safety Study of 5 Months, including a 1-Month Drug-Free Follow-up Period. (PM.109) 2002

Drug 30 mg and Drug 60 mg Once Daily versus Placebo in Generalized Anxiety Disorder. A Randomized, Double-Blind, Placebo-Controlled, and Drug-Controlled, Fixed-Dose, Parallel-Group, Multi-Center Study of 10 Weeks (Including a 2-Week, Single-Blind Placebo Period). (PM.108) 2002

A 6-Week, Double-Blind, Randomized, Multi-Center, Fixed-Dose, Placebo-Controlled Study of Drug Dosed Twice a Day in Patients with Generalized Anxiety Disorder. (PR.101) 2001

A Randomized, Double-Blind, Placebo-Controlled, Flexible-Dosage Trial to Evaluate the Efficacy and Tolerability of Drug in Patients with Generalized Anxiety Disorder (GAD). (GK.105) 2001

A Placebo-Controlled Study of Drug Dosed BID and TID in Patients with Generalized Anxiety Disorder. (PD.103) 2000

Open-Label, Safety Study of Drug in Patients with Anxiety Disorders. (PD.104) 1999

Binge Eating Disorder

A Phase II study in patients with moderate to severe binge eating disorder (BED). The study will be a multi-center, double-blind, randomized, placebo-controlled design.

A 12-week, Randomized, Double-blind, Parallel-group, Placebo-controlled, Fixed-dosed, Multicenter Study to Evaluate the Efficacy, Safety, & Tolerability of Drug in Adults with Moderate to Severe Binge Eating Disorder. (SU.108) 2017

An Open-label, Flexibly-dosed, Multicenter, Extension Study of Drug to Evaluate Long-term Safety and Tolerability in Adults with Binge Eating Disorder. (SU.107) 2015

A 12-week, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexibly-dosed, Multicenter Study to Evaluate the Efficacy, Safety, & Tolerability of Drug in Adults with Moderate to Severe Binge Eating Disorder. (SU.106) 2015

CLINICAL TRIAL EXPERIENCE (*continued*):

Bipolar Disorder

A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter, Fixed-dose Clinical Trial Evaluating the Efficacy, Safety and Tolerability of Drug in Patients with Bipolar I Depression. (FL.111) 2016

A Multi-Center, Randomized, Parallel-Group, Double-Blind, Phase III Comparison of the Efficacy and Safety of Drug (oral tablets 400 mg to 800 mg daily in divided doses) to Placebo When Used as Adjunct to Mood Stabilizers (Drug or Drug) in the Maintenance Treatment of Bipolar I Disorder in Adult Patients. (AA.102) 2003

Cardiovascular

Follow-Up Serial Infusions of Drug for the Management of Patients with Heart Failure - STUDY II. 2004

Management of Patients with Congestive Heart Failure after Hospitalization, Follow-Up Serial Infusions of Drug, a pilot study. 2002

Depression

A Phase II, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study of the Safety and Efficacy of XXX in the Treatment of Adults with Major Depressive Disorder

A Randomized, Double-blind, Placebo-controlled Study of the Safety, Tolerability, and Efficacy of XXX Compared to Placebo in Adult Subjects with Comorbid Major Depressive Disorder and Insomnia (SA.103) 2018

A Phase III, Open-label, 1-year Study of the Safety, Tolerability, and Need for Re-treatment with XXX in Adult Subjects with Major Depressive Disorder (SA.102) 2018

A Double-Blind, Placebo-Controlled Study Of Drug As An Adjunct To Antidepressants In The Treatment Of Patients With Major Depressive Disorder Who Have Had An Inadequate Response To Antidepressants Alone. (AN.110) 2018

A Double-Blind, Placebo-Controlled Study Of Drug As An Adjunct To Antidepressants In The Treatment Of Patients With Major Depressive Disorder Who Have Had An Inadequate Response To Antidepressants Alone. (AN.109) 2018

A Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study Evaluating The Efficacy Of Drug In The Treatment Of Adult Subjects With Major Depressive Disorder. (SA.101) 2018

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy, Safety, and Tolerability of Drug as Adjunctive Therapy in the Maintenance Treatment of Adults With Major Depressive Disorder. (OT.112) 2018

A Phase IIb, Randomized, Double-Blind, Parallel-Group, Placebo Controlled Study to Evaluate the Efficacy and Safety of 2 Fixed Doses (5.0 mg or 2.5 mg) of XXX in Adult Patients with Major Depressive Disorder (MV.101) 2018

A Phase II, Depression Diagnostic Aid Confirmatory Performance Study - An Abbreviated Investigational Device Exemption Study (MB.101) 2017

A Double-Blind, Placebo- and Active-Controlled Evaluation of the Safety and Efficacy of *Drug* in Adolescent Patients with Major Depressive Disorder. (AN.105) 2017

A Randomized, Double-blind, Active-controlled Trial to Assess the Efficacy and Safety of Drug Administered Orally to Subjects with Treatment Resistant Major Depressive Disorder. (AS.101) 2016

A Randomized, Double-Blind, Placebo-Controlled, Phase 4, Relapse Prevention Study Evaluating the Efficacy and Safety of *Drug* (5, 10 and 20 mg) in Adults with Major Depressive Disorder (MDD). (TG.112) 2015

A Phase III, Multicenter Study of the Long-term Safety and Tolerability of Drug for the Adjunctive Treatment of Major Depressive Disorder in Adults Who Have an Inadequate Response to Antidepressant Therapy. (AK.103) 2014

A Multi-centre, Double-blind, Randomized-withdrawal, Parallel-group, Placebo-controlled, Phase III Study of Efficacy and Safety of *Drug* as Monotherapy in the Maintenance Treatment of Patients with Major Depressive Disorder (MDD) Following an Open-Label Stabilization Period (*XXX STUDY*). (AA.107) 2006

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Fixed-Dose Study Evaluating the Efficacy and Safety of Drug in Subjects with Major Depressive Disorder. (GK.122) 2004

A Phase III, 8-Week, Double-Blind, Randomized Study of the Efficacy and Safety of Drug plus Drug in Combination as Compared to Drug and Drug Monotherapies in Patients with Treatment Resistant Recurrent Major Depressive Disorder. (EL.106) 2004

A Double-Blind, Flexible-Dose Comparison of Drug, Drug, and Placebo in the Treatment of Major Depressive Disorder. (FL.103) 2003

A Double-Blind, Multi-Center, Placebo-Controlled Study of Drug in the Treatment of Patients with Major Depressive Disorder. (MC.103) 2003

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multi-Center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Flexible-Dose Study Evaluating Efficacy, Safety, and Tolerability of a Once-Daily Oral Drug (20-40-60 mg) versus Placebo in Subjects with Major Depressive Disorder Over an Eight-Week Treatment Period. (GK.114) 2003

An Open-Label, Extension Trial in Children and Adolescents with Major Depressive Disorder Who Participated in One of the Short-Term Drug Safety and Efficacy Trials. (OG.102) 2003

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Fixed-Dose, Safety and Efficacy Trial of Drug in Outpatient Children and Adolescent with Major Depressive Disorder. (OG.101) 2003

An 8-Week, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Multi-Center, Fixed-Dose Study Comparing the Efficacy and Safety of Drug or Drug to Placebo in Moderately to Severely Depressed Patients with Major Depressive Disorder. (GK.107) 2002

A Study to Evaluate the Efficacy, Safety, and Maintenance Effect of Drug Augmentation of Drug Monotherapy in Young and Older Adult Patients with Unipolar Treatment-Resistant Depression. (JN.101) 2002

A Double-Blind, Multi-Center, Placebo- and Active-Controlled, Acute and Extension Study of Two Doses of Drug in the Treatment of Patients with Major Depressive Disorder. (MC.101) 2001

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study Evaluating Efficacy and Safety of Three Doses of Drug versus Placebo in Patients with Major Depressive Disorder. (SB.108) 2001

A Double-Blind, Placebo-Controlled, Fixed-Dosage Study Comparing the Efficacy and Tolerability of Drug and Drug to Placebo in the Treatment of Major Depressive Disorder with Anxiety. (GK.104) 2001

Fibromyalgia

A Multicenter, Randomized, Double-blind, Placebo-controlled, Proof of Concept Study of the Efficacy and Safety of XXX for Treatment of Patients with Fibromyalgia (TV.104) 2019

A Multicenter, Randomized, Double-blind, Placebo-controlled, Proof of Concept Study of the Efficacy and Safety of XXX for Treatment of Patients with Fibromyalgia (TV.104) 2019

A Phase IIa, Randomized, Double-Blind Placebo-controlled, Parallel-group Study to Assess the Analgesic Efficacy and Safety of XXX in Patients with Fibromyalgia (AT.101) 2017

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Double-blind, Randomized, Multicenter, Placebo-controlled Study to Evaluate the Efficacy and Safety of Drug Tablets Taken Daily at Bedtime in Patients with Fibromyalgia. (TX.101) 2016

An Open-label Extension Study of Drug for 52 Weeks in Pain Associated with Fibromyalgia. (DS.103) 2015

Hypertension

A Randomized, Double-blind, Placebo-controlled, Forced-titration, Phase IV Study Comparing Drug 80 mg + Drug 25 mg versus Drug 160 mg + Drug 25 mg Taken Orally for Eight Weeks in Patients with Stage I or Stage II Hypertension. (BI.102) 2005

A Multi-Center, Double-Blind, Randomized, Parallel-Group Study to Evaluate the Effects of Drug and Drug on Microalbuminuria in Mild to Moderate Hypertensive Subjects with Type 2 Diabetes Mellitus. (NO.107) 2003

Drug Cardiovascular Treatment Assessment Versus Drug (Study). (BS.105) 2000

Insomnia

Multi-center, double-blind, parallel-group, randomized, placebo-controlled, three doses, 40-week extension to studies XXX and XXX to assess the long-term safety and tolerability of Drug in adult and elderly subjects with insomnia disorder. (ID.102) 2018

A Phase III, Multi-center, double-blind, randomized, placebo-controlled, parallel-group, polysomnography study to assess the efficacy and safety of XXX in adult and elderly subjects with insomnia disorder AND Extension (ID.101) 2018

Efficacy and Safety of Drug 5mg/day for Sleep Maintenance Insomnia: a 12-week, Multi-center, Randomized, Double-blind, Placebo-controlled Study Followed by an Open-treatment, Phase Extension with Drug for a 40-week Period. (SV.102) 2006

The Efficacy of Drug 3mg as Adjunctive Therapy in Subjects with Insomnia Related to Generalized Anxiety Disorder (GAD). (SE.102) 2005

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 8-Week, Safety and Efficacy Study of Drug 3 mg Compared to Placebo in Subjects with Insomnia Related to Major Depressive Disorder. (SE.101) 2003

CLINICAL TRIAL EXPERIENCE (*continued*):

Irritable Bowel Syndrome

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, 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 (AR.101) 2019

A Phase II, Randomized, Double-blind, Placebo-controlled, Parallel-group, Dose-range-finding Study of XXX Administered Orally for 12 Weeks to Treat Abdominal Pain in Patients With Diarrhea-predominant Irritable Bowel Syndrome (IR.101) 2019

A Phase IV Multicenter, Multinational, Prospective, Randomized, Placebo-Controlled, Double-Blinded Parallel Group Study to Assess Efficacy of *Drug* in the Treatment of Irritable Bowel Syndrome with Diarrhea (IBS-D) in Patients Who Report Inadequate Control of IBS-D Symptoms with Prior Loperamide Use. (AN.106) 2017

Men's and Women's Health

A Placebo-Controlled, Double-Blind, Randomized, Parallel Study of the Withdrawal Effects of Chronic Daily and As Needed Dosing with Drug in the Treatment of Premature Ejaculation. (JO.101) 2005

A 12-Week, Multi-Center, Randomized, Double-Blind, Double-Dummy, Parallel-Group, Active-Controlled, Escalating-Dose Study to Compare the Effects on Sexual Functioning of Drug (150-450 mg/day) and Drug (75-225 mg/day) in Subjects with Major Depressive Disorder. (GK.121) 2004

A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy of a Monophasic Oral Contraceptive Preparation, Containing Drug, in the Treatment of Premenstrual Dysphoric Disorder (PMDD). (BX.101) 2000

A Double-Blind, Placebo-Controlled, 3-Arm, Fixed-Dose Study of Drug Continuous Treatment (12.5 mg and 25 mg/day) for Premenstrual Dysphoric Disorder. (SB.102) 2000

Genital Herpes Oral Suppression Trial of Drug vs. Placebo. 1999

Drug vs. Placebo to Assess Efficacy and Safety in Patients with Recurrent Herpes Labialis. 1999

Drug vs. Placebo to Assess Safety and Efficacy in Patients with Recurrent Genital Herpes. 1999

CLINICAL TRIAL EXPERIENCE (*continued*):

A Comparison of the Efficacy and Safety of Oral Drug for the Treatment of Pyelonephritis or Complicated Urinary Tract Infections. 1999

A Comparison of the Efficacy and Safety of Drug Given Either as a Single Oral Dose of 640 mg or as 320 mg Twice Daily vs. Oral Drug 250 mg Twice Daily for the Treatment of Uncomplicated Urinary Tract Infections in Females. 1999

Migraine

A Phase IV, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Followed by an Open-Label Extension to Evaluate the Efficacy and Safety of XXX for Preventive Treatment of Migraine in Patients with Major Depressive Disorder (TV.105) 2019

An Open-Label Study to Assess the Long-term Safety of XXX for the Acute Treatment of Migraine in Adults (AS.103) 2019

A Phase II: Double-Blind, Randomized, Placebo Controlled, Dose-Ranging Trial of XXX for the Acute Treatment of Migraine (BH.106) 2019

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 Randomized, Double-blind, Single-dose, Placebo-controlled Study to Assess the Efficacy and Safety of Drug for the Acute Treatment of Migraine in Adults with Inadequate Response to Prior Acute Treatments. (AS.102) 2018

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy, Safety, and Tolerability of oral Drug for the Prevention of Migraine in Participants with Episodic Migraine. (AN.108) 2018

A Phase III, Multicenter, Randomized, Open-Label Study to Evaluate the Long-term Safety and Tolerability of Oral Drug for the Prevention of Migraine in Patients with Episodic Migraine. (AN.107) 2018

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety and Efficacy of Drug for the Acute Treatment of Episodic Migraine With or Without Aura in Adolescents. (AV.101) 2018

A Phase III, Randomized, Double blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of XXX in Migraine Prevention. (BH.104) 2018

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multicenter, Open Label, Long-Term Safety Study of XXX in Patients with Acute Migraines (BH.103) 2017

A Phase III, Double-Blind, Randomized, Placebo Controlled, Safety, Efficacy, Trial of XXX for the Acute Treatment of Migraine (BH.102) 2017

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Efficacy, Tolerability and Safety Study of XXX in Episodic Migraine with or Without Aura (DL.101) 2017

A Phase IIb, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Multiple Dosing Regimens of Oral XXX in Episodic Migraine Prevention (AN.104) 2016

A Multicenter, Randomized, Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of Oral XXX in the Acute Treatment of Migraine With or Without Aura (AN.103) 2016

A Multicenter, Randomized, Double-Blind, Parallel-Group Study Evaluating the Long-Term Safety, Tolerability, and Efficacy of Subcutaneous Administration of *Drug* for the Preventive Treatment of Migraine. (TV.103) 2016

A Randomized, Double-blind, Multi-center, Placebo-controlled, Cross-over Study to Determine the Consistency of Response for Drug Administered During the Mild Pain for the Acute Treatment of Multiple Migraine Attacks. (GK.126) 2005

Drug Intervention to Prevent Transformation of Episodic Migraine: The Drug XXX Study. (OM.104) 2005

A Randomized, Double-blind, Placebo-controlled, Single-attack, Parallel-group Evaluation of the Efficacy of Drug 100 mg Tablets versus Placebo in the Treatment of Subjects Who Affirm Tension, Tension-type, or Stress Headaches and Who Meet International Headache Society Criteria for Migraine. (GK.113) 2003

A Randomized, Double-Blind, Placebo-Controlled, Single-Attack, Parallel-Group Evaluation of the Efficacy of Drug 100 mg Tablets versus Placebo in the Treatment of Subjects Who Affirm Tension, Tension-type, or Stress Headaches, and Who Meet International Headache Society Criteria for Migraine. (PM.113) 2003

Open-Label, Long-Term, Multi-Center Study of Safety and Tolerability of Drug in the Acute Treatment of Migraines in Adults. (PM.111) 2002

A Phase III, Multi-Center, Randomized, Double-Blind, Parallel Group Study of Drug and Placebo in Patients with Multiple Moderate or Severe Acute Migraine Headaches. (PM.110) 2002

CLINICAL TRIAL EXPERIENCE (*continued*):

Multi-Center, Randomized, Double-Blind, Parallel-Group, Multiple-Dose Comparison Study of Drug, Drug, and Placebo in Patients with Moderate to Severe Acute Migraine Headache. (PM.106) 2001

Oppositional Defiant Disorder

A Phase III, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Safety and Efficacy Study of Drug in Children and Adolescents Aged 6-17 with Oppositional Defiant Disorder (ODD). (SH.102) 2003

Pain

A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Phase III Study to Evaluate the Long-Term Safety of Drug 0.5mg Twice Daily for 12 Months for the Treatment of Opioid-Induced Bowel Dysfunction in Adults Taking Opioid Therapy for Persistent Non-Cancer Pain. (GK.125) 2005

A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Phase III Study to Evaluate the Efficacy and Safety of Drug 0.5mg Once Daily and 0.5mg Twice Daily for 12 Weeks for the Treatment of Opioid-Induced Bowel Dysfunction in Adults Taking Opioid Therapy for Persistent Non-Cancer Pain. (GK.124) 2005

A 12-Week, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Study to Evaluate the Efficacy and Safety of Flexible Dosing of Drug at 500 mg to 1500 mg B.I.D. in the Treatment of Subjects with Painful Diabetic Neuropathy. (UP.101) 2001

Post-Traumatic Stress Disorder

A Phase II, Multicenter, Randomized, Double-blind, Placebo- and Active-controlled Trial of Drug (1 - 3 mg/day) as Monotherapy or as Combination Therapy in the Treatment of Adults with Post-traumatic Stress Disorder. (OT.110) 2017

A 12-Month, Open-Label, Flexible-Dosage Study to Evaluate the Safety of Drug at Dosages up to 16 mg/day in Adults with Chronic Post Traumatic Stress Disorder. (CP.107) 2003

A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dosage Study to Evaluate the Efficacy and Safety of Drug, at Dosages up to 16 mg/day in the Treatment of Chronic Post-Traumatic Stress Disorder (PTSD) in Adults. (CP.102) 2003

Respiratory

A Comparison of the Efficacy and Safety of Drug Given Either as Drug or Drug for the Treatment of Acute Bacterial Sinusitis. 1999

CLINICAL TRIAL EXPERIENCE (*continued*):

A Comparison of the Efficacy and Safety of Oral Drug for the Treatment of Acute Exacerbation of Chronic Bronchitis. 1999

Drug vs. Placebo to Assess the Efficacy and Safety of Drug (nasal spray), 5%, for the Prevention of Recurrent Acute Bacterial Sinusitis. 1999

Other Indications

A 6 ½-Month, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Comparison of Drug and Placebo for the Prevention of Seasonal Affective Disorder in Subjects with a History of Seasonal Affective Disorder. (GK.106) 2002

The Effect of Drug on Bone Mineral Density in Pediatric Patients with Anorexia Nervosa: A Double-Blind, Placebo-Controlled Study. (OM.101) 2002

A Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dose Study of Drug in Adolescent Outpatients with Panic Disorder. (WA.101) 2001

A Randomized, Double-Blind, Placebo-Controlled Study of Drug as Mono-Therapy Assessment of Reducing Cholesterol (STUDY). (PM.105) 2001

A Comparison of Drug vs. Drug in Patients Undergoing PCI (Percutaneous Coronary Intervention) Who Are at High Risk for Bleeding Complications. 2002

CLINICAL TRIALS TRAINING:

05/23/19	Syneos Health-GCP Training: Refresher Course, including ICH E6, Revision 2 Changes Version 1 Jan 2018
05/29/18	National Institutes of Health (NIH) Office of Extramural Research - Protecting Human Research Participants Training Course
04/04/18	ProHIPAA - HIPAA Training Program - Recertification
06/21/17	INC Research - ICH/GCP Training: Refresher Course, including ICH E6, Revision 2 Changes
06/19/17	INC Research - ICH/GCP Training: Review of ICH E6, Revision 2 Changes
04/13/16	The HIPAA Group - HIPAA Training Program
04/13/16	Collaborative Institutional Training Initiative (CITI)- Good Clinical Practice & ICH (GCP)
01/04	Good Clinical Practice Training

COMMITTEES:

Medication Oversight Committee, 01/2009 - Present
Willamette Valley Hospice, Salem, OR

Quality Assurance and Performance Improvement Committee (QAPI), 01/2010 - 01/2013
Willamette Valley Hospice, Salem, OR

RESEARCH AND PUBLICATIONS:

Potential of Infection by Epinephrine, Journal of Plastic and Reconstructive Surgery,
December, 1985. Presented at the Annual Plastic and Reconstructive Surgery National Meeting,
Detroit, MI, April, 1984.