Beal G. Essink, M.D.
Oregon Center for Clinical Investigations, Inc.
905 SE 14th Avenue, Portland, OR 97214

CONTACT INFORMATION:

Site Selection and Information:
Bobbie Theodore, VP Sponsor Relations/BD
Apex Innovative Sciences, Alliance Division
Tel. 916-803-7149 (cell)
Email: bobbietheodore@apexsci.com

Site Contact:
Gina M Tiel, MS
Tel: 503-276-6224
Fax: 503-276-6225
Email: ginamtiel@gmail.com

AFFILIATIONS:

Oregon Center for Clinical Investigations, Inc.
702 Church Street NE
Salem, OR 97301

Oregon Center for Clinical Investigations, Inc.
572 W 11th Avenue
Eugene, OR 97401

Oregon Health & Science University
3181 SW Sam Jackson Park Road
Portland, OR 97239

EDUCATION:

08/92 – 05/96 MD
UNMC, Omaha, NE

08/92 – 05/94 BS, Premedical Sciences
UNMC, Omaha, NE

08/88 – 05/92 Undergraduate
University of Nebraska, Lincoln, NE

INTERNSHIP AND RESIDENCY:

07/99 – 06/00 Chief Resident
Dept. of Psychiatry, OHSU, Portland, OR

07/96 – 07/99 Psychiatry Resident
OHSU, Portland, OR

LICENSURE:

Oregon State Medical License, #MD22045, 1996 – Present

BOARD CERTIFICATION:

American Board of Psychiatry and Neurology – Psychiatry (recertification), 2012 – 2022
American Board of Psychiatry and Neurology – Sleep Medicine, 2010 – 2020
American Board of Psychiatry and Neurology – Psychiatry, 2002 – 2012

MEMBERSHIPS AND HONORS:

AOA member, 1996 – Present

Distinguished Service Award, June 2003

Elected Year 2000 Psychiatry Resident of the Year by Residency Training Committee, 2000

Selected as OHSU's resident representative for Resident Reporter Program at the APA in Toronto, Canada, 1998

PROFESSIONAL EXPERIENCE:

Research Investigator, 04/03 – Present
Oregon Center for Clinical Investigations, Inc., Portland, OR

Clinical Assistant Professor of Psychiatry, 10/04 – Present
Oregon Health & Science University, Portland, OR

Consulting Physician, 01/09 – 01/11
Pacific Northwest Sleep Centers, LLC, Salem, OR

Consulting Psychiatrist, 05/03 – 05/06
Dakota Exams, Vancouver, WA

Preceptor for Nurse Practitioner Program, 03/01 – 07/03
Portland VA Medical Center, Portland, OR

Director of the Intern Didactic Seminar, 01/01 – 07/03
Oregon Health and Sciences University, Portland, OR

Assistant Professor, 07/00 – 07/03
Oregon Health & Science University, Portland, OR

PROFESSIONAL EXPERIENCE (*continued*):

Leader of Medical Student Teaching Seminar, 07/00 – 07/03
Portland VA Medical Center, Portland, OR

Attending Physician of Psychiatry, 07/00 – 07/03
Portland VA Medical Center, Portland, OR

Principles of Clinical Medicine, 06/01 – 06/02
Oregon Health and Sciences University, Portland, OR

INVESTIGATOR EXPERIENCE:

Addiction • ADHD • Anxiety • Binge-eating Disorder • Bipolar Disorders • Celiac Disease
Chronic Pain • Depression • Erectile Dysfunction • Fibromyalgia • Hypertension • Insomnia
Irritable Bowel Syndrome - Diarrhea • Migraine • Opioid-induced Bowel Dysfunction
Oppositional Defiant Disorder • Seasonal Affective Disorder • Sexual Dysfunction
Sleep Disorders • Type 2 Diabetes Mellitus

CLINICAL TRIAL EXPERIENCE:

Addiction

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

A Phase III, Multicenter, Double-blind, Placebo-controlled, Randomized-withdrawal Study to Evaluate the Maintenance of Efficacy of *Drug* in Adults Aged 18-55 Years with Moderate to Severe Binge Eating Disorder. (SH.134) 2014

A Phase III, Multicenter, Open-label, 12-month, Extension, Safety, and Tolerability Study of *Drug* in the Treatment of Adults with Binge Eating Disorder. (SH.133) 2013

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Dose-optimization Study to Evaluate the Efficacy, Safety, and Tolerability of *Drug* in Adults Aged 18-55 Years with Moderate to Severe Binge Eating Disorder. (SH.132) 2013

A Phase III, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Dose-optimization Study to Evaluate the Efficacy, Safety, and Tolerability of *Drug* in Adults Aged 18-55 Years with Moderate to Severe Binge Eating Disorder. (SH.131) 2013

A Randomized, Double-blind, Placebo-controlled, Multi-center Study to Assess the Efficacy and Safety of *Drug* in the Treatment of Pathological Gambling. (SM.102) 2006

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 *Drug* 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

CLINICAL TRIAL EXPERIENCE (*continued*):

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

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

A Phase III, Randomized, Double-blind, Multicenter, Placebo-controlled, Forced-dose Titration, Safety and Efficacy Study of *Drug* in Adults Ages 18-55 Years with Attention-deficit/Hyperactivity Disorder (ADHD). (SH.136) 2015

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

A Phase III, Randomized, Double-blind, Multi-center, Placebo-controlled, Dose-Optimization, Safety and Efficacy Study of *Drug* in Children and Adolescents Aged 6-17 Years with Attention-Deficit Hyperactivity Disorder (ADHD). (SH.135) 2015

A Randomized, Double-blind, Multicenter, Placebo-controlled, Parallel-group, Efficacy and Safety Study of 2 Doses of *Drug* in Adults with Attention Deficit Hyperactivity Disorder (ADHD). (SU.105) 2015

A Phase III, 12-month, Multicenter, Open-label, Flexibly-dosed, Safety Study of *Drug* in Adults with Attention Deficit Hyperactivity Disorder (ADHD). (SU.104) 2014

A Six-month, Open-label, Multi-center Study of the Safety and Efficacy of *Drug* in Adults and Adolescents with ADHD. (PU.102) 2014

A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel-arm, Multi-center Study Measuring the Efficacy and Safety of *Drug* in Adult ADHD Patients. (PU.101) 2014

A Randomized, Double-blind, Parallel-group, Multicenter Efficacy and Safety Study of *Drug* Versus Placebo in Adults with Attention-Deficit/Hyperactivity Disorder (ADHD). (SU.103) 2012

A Phase IV, Randomized, Double-blind, Multi-center, Parallel-group, Active-controlled, Forced-dose Titration, Safety and Efficacy Study of *Drug* Compared with *Drug* with a Placebo Reference Arm in Adolescents Aged 13-17 with Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.130) 2012

A Phase IV, Randomized, Double-blind, Multi-center, Parallel-group, Active-controlled, Dose-optimization Safety and Efficacy Study of *Drug* Compared with *Drug* with a Placebo Reference Arm in Adolescents Aged 13-17 with Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.129) 2012

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Double-blind, Randomized, Multi-center, Placebo-controlled, Dose-optimization Study Evaluating the Safety, Efficacy, and Tolerability of Once-daily Dosing with Extended-release *Drug* in Adolescents Aged 13-17 Years Diagnosed with Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.128) 2011

A 40-week, Phase IV, Double-blind, Placebo-controlled, Multi-center, Randomized-withdrawal Study to Evaluate the Long-term Efficacy and Safety of *Drug* Extended-Release in Children and Adolescents with Attention-Deficit/Hyperactivity Disorder (ADHD). (SO.101) 2011

A Phase II, Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of *Drug* as Adjunctive Therapy in the Treatment of Adult Attention-Deficit/Hyperactivity Disorder (ADHD). (OT.101) 2010

A Phase IV, Randomized, Double-blind, Multi-center, Placebo-controlled, Parallel-group Study Evaluating the Safety and Efficacy of *Drug* on Executive Function (Self-Regulation) Behaviors in Adults with Attention-Deficit/Hyperactivity Disorder (ADHD) Reporting Clinically Significant Impairment of Real-World Executive Function Behavior. (SH.127) 2010

A Phase III, Double-blind, Placebo-controlled, Multi-centre, Randomised-withdrawal, Long-term Maintenance of Efficacy and Safety Study of Extended-release *Drug* in Children and Adolescents Aged 6-17 with Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.126) 2010

A Double-blind, Randomized, Placebo-controlled, Multi-center, Fixed-dose, Titration Study to Assess Efficacy, Safety, and Tolerability of *Drug* in Adults with Attention-Deficit/Hyperactivity Disorder (ADHD). (TC.101) 2010

A Randomized, Double-blind, Placebo- and Active-controlled, Parallel-group, Multi-center Study of 3 Dosages of *Drug* in the Treatment of Adult Subjects with Attention-Deficit/Hyperactivity Disorder (ADHD). (JO.103) 2009

A Phase III, Open-label, Extension, Multi-center, Safety and Efficacy Study of *Drug* in Adolescents Aged 13-17 with Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.125) 2008

A Phase III, Randomized, Double-blind, Multi-center, Parallel-group, Placebo-controlled, Forced-dose-titration, Safety and Efficacy Study of *Drug* in Adolescents Aged 13-17 with Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.124) 2008

A Phase III, Double-blind, Randomized, Placebo-controlled, Multi-center, Dose-optimization Study Evaluating the Efficacy and Safety of *Drug* in Combination with Psychostimulants in Children and Adolescents Aged 6-17 with a Diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.123) 2008

CLINICAL TRIAL EXPERIENCE (*continued*):

The Long-term Safety and Tolerability of *Drug* in Adult with Attention-Deficit/Hyperactivity Disorder (ADHD): An Open-label Extension Study for Subjects Completing Study XXX. (AL.108) 2008

Maintenance of Response after Open-label Treatment with *Drug* in Adult Out-patients with Attention-Deficit/Hyperactivity Disorder (ADHD): A Placebo-controlled, Randomized Withdrawal Study. (EL.110) 2008

A Randomized, Double-blind, Placebo-controlled, Parallel-group, Phase II Study of the Safety and Efficacy of 40 mg QD and 80 mg QD of *Drug* in Adults with Attention-Deficit/Hyperactivity Disorder (ADHD). (AL.107) 2008

A Randomized, Double-blind, Placebo-controlled, Parallel-group, Phase II Study of the Safety and Efficacy of .07 mg/kg/day and 1.4 mg/kg/day of *Drug* in the Treatment of Children with Attention-Deficit/Hyperactivity Disorder (ADHD). (AL.106) 2008

A Multi-center, Double-blind, Placebo-controlled, Randomized, Parallel-group Study to Investigate the Safety and Efficacy of *Drug* in Adults with Attention-Deficit/Hyperactivity Disorder (ADHD). (JO.102) 2007

A Prospective, Open-label, Multi-center, Dose-optimization Study Evaluating the Efficacy, Safety, and Tolerability of *Drug* 20-70 mg in Children Aged 6-12 Diagnosed with Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.122) 2007

The Long-term Safety and Tolerability of *Drug* in Children with Attention-Deficit/Hyperactivity Disorder (ADHD): An Open-label Extension Study. (AL.105) 2007

A Randomized, Double-blind, Placebo-controlled, Parallel-group, Phase II, Dose-ranging Study of the Safety and Efficacy of *Drug* in Children with Attention-Deficit/Hyperactivity Disorder (ADHD). (AL.104) 2007

A Phase IIIb, Long-term, Open-label, Multi-center, Extension Study Designed to Evaluate the Safety and Efficacy of *Drug* in Adolescents Aged 13-17 Years with Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.121) 2007

A Phase IIIb, Randomized, Double-blind, Multi-center, Parallel-group, Placebo-controlled, Dose-optimization Study, Designed to Evaluate the Efficacy and Safety of *Drug* in Adolescents Aged 13-17 Years with Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.120) 2007

A Randomized, Double-blind, Placebo-controlled, Phase II, Dose-ranging Study of the Safety and Efficacy of Multiple Doses of *Drug* in Adults with Attention-Deficit/Hyperactivity Disorder (ADHD). (AL.103) 2007

CLINICAL TRIAL EXPERIENCE (*continued*):

A Double-blind, Randomized, Multi-center, Flexible-dose Study Evaluating the Efficacy and Safety of *Drug* in Children Aged 6-12 with Symptoms of Oppositionality and a Diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.119) 2006

A Phase IV, Multi-center, Open-label Study of *Drug* to Characterize the Dermal Reactions in Pediatric Patients Aged 6-12 with Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.118) 2006

A Long-term, Open-label, and Single-arm Study of *Drug* 30 mg, 50 mg, or 70 mg Per Day in Adults with Attention-Deficit/Hyperactivity Disorder (ADHD). (NR.104) 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). (NR.103) 2006

A 6-week, Double-blind, Placebo-controlled, Parallel-group, Randomized-withdraw Study to Evaluate the Continued Efficacy of *Drug* Treatment at Dosages Up to 425 mg/day in Patients with Attention-Deficit/Hyperactivity Disorder (ADHD) who are Responders to Modafinil Treatment, Followed by a 12-month Open-label Extension Period. (CP.113) 2006

An Open-label, Dose-titration, Long-term, Safety Study to Evaluate *Drug* at Doses of 36 mg, 54 mg, 72 mg, 90 mg, and 108 mg Per Day in Adults with Attention-Deficit/Hyperactivity Disorder (ADHD). (MN.102) 2006

A Placebo-controlled, Double-blind, Parallel-group, Dose-titration Study to Evaluate the Efficacy and Safety of *Drug* in Adults with Attention-Deficit/Hyperactivity Disorder (ADHD) at Doses of 36 mg, 54 mg, 90 mg, or 108 mg Per Day. (MN.101) 2006

A Prospective, Open-label, Multi-center Study Evaluating the Safety and Tolerability of Converting Children Aged 6-12 From Extended Release *Drug* to *Drug* in Subjects Diagnosed with ADHD. (SH.117) 2005

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

An 8-week, Open-label Study to Characterize the Response to *Drug* (85 mg Film-coated Tablet) Treatment at Dosages up to 425 mg/day in Children and Adolescents with Attention-Deficit/Hyperactivity Disorder (ADHD) (With an Open-ended Extension Period). (CP.110) 2005

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Open-label Study of *Drug* in Children and Adolescents Aged 6-17 with Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.112) 2004

A Phase III, Randomized, Double-blind, Multi-center, Parallel-group, Placebo-controlled Safety and Efficacy Study of *Drug* in Children and Adolescents Aged 6-17 with Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.111) 2004

A Long-term, Open-label, and Single-arm Study of *Drug* 30 mg, 50 mg, or 70 mg Per Day in Children Aged 6-12 Years with Attention-Deficit/Hyperactivity Disorder (ADHD). (NR.102) 2005

A Phase II, Open-label, Co-administration Study of *Drug* and Psycho stimulants in Children and Adolescents Aged 6-17 with Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.114) 2004

A Phase III, Multi-center, Open-label Study of *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 Adults with Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.113) 2004

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 (ADHD) 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) (Followed by an Open-ended Extension). (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

CLINICAL TRIAL EXPERIENCE (*continued*):

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 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 Multi-center, Double-blind, Randomized, Placebo-controlled, Parallel-group, Study of the Efficacy and Safety of *Drug* at a Flexible Dose Administered Once Daily in Pediatric Patients 6-17 Years of Age with Attention-Deficit/Hyperactivity Disorder (ADHD). (NO.106) 2003

A 6-month, Open-label Extension to a 5-week, Multi-center, Randomized, Double-blind, Parallel-group, Placebo-controlled, Fixed-dose Study of the Efficacy and Safety of *Drug* Administered Once Daily in Adults with Attention-Deficit/Hyperactivity Disorder (ADHD). (NO.105) 2003

A 5-week, Multi-center, Randomized, Double-blind, Parallel-group, Placebo-controlled, Fixed-dose Study of the Efficacy and Safety of *Drug* Administered Once Daily in Adults with Attention-Deficit/Hyperactivity Disorder (ADHD). (NO.104) 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* to Placebo in Children and Adolescents Aged 6-17 with Attention-Deficit/Hyperactivity Disorder (ADHD). (SH.103) 2003

A One-year Extension to the Open-label Protocol. Extension Continuation, Long-term Evaluation, Open-label Study of *Drug* in Children with ADHD. (NP.105) 2002

Open-label Study of *Drug* in Children with ADHD. (NP.104) 2001

Anxiety

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

A Double-blind, Placebo-controlled, Flexible-dose Study of *Drug* in Patients with Generalized Anxiety Disorder. (FL.109) 2013

A Multi-center, Randomized, Placebo-controlled, Double-blind, Parallel-group, Efficacy and Safety Study of *Drug* in the Treatment of Generalized Anxiety Disorder (GAD). (AA.117) 2009

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multi-center, Randomized, Placebo-controlled, Double-blind, Parallel-group, Phase II Study of 2 Oral Dose Groups of *Drug*, with a *Drug* Arm, in Subjects with Generalized Anxiety Disorder (GAD). (AA.116) 2009

A 52-Week, Open-label, Safety Study of *Drug* in Subjects with Generalized Anxiety Disorder (GAD). (PR.104) 2008

A Randomized, Double-blind, Parallel-group, Placebo-controlled, Fixed-dose Study Comparing the Efficacy and Safety of a Single Dose of *Drug* in Acute Treatment of Adults with Generalized Anxiety Disorder (GAD). (TG.106) 2008

A Randomized, Double-blind, Parallel-group, Placebo-controlled, Active-referenced, Fixed-dose Study Comparing the Efficacy and Safety of 3 Doses of *Drug* in Acute Treatment of Adults with Generalized Anxiety Disorder (GAD). (TG.105) 2008

A Phase III, Randomized, Double-blind, Parallel-group, 10-week, Placebo-controlled, Fixed-dose Study of *Drug* and *Drug;* Evaluating the Efficacy and Safety of *Drug* for the Treatment of Generalized Anxiety Disorder (GAD). (PR.103) 2008

A Double-blind, Randomized, Placebo- and Active-controlled, Multi-center Study Examining the Efficacy and Safety of *Drug* in Subjects with Generalized Anxiety Disorder (GAD). (SE.103) 2008

A Multi-center, Randomized, Double-blind, Parallel-group, Placebo-controlled Study of the Efficacy and Safety of *Drug* Compared with Placebo as an Adjunct to Treatment in Patients with Generalized Anxiety Disorder (GAD) who Demonstrate Partial or No Response to a Selective Serotonin Reuptake Inhibitor or Serotonin-Norepinephrine Reuptake Inhibitor Alone or in Combination with a Benzodiazepine. (AA.115) 2007

An Eight-week, Multi-center, Double-blind, Placebo- and Paroxetine-controlled Study Evaluating the Efficacy and Tolerability of Two Fixed Doses of *Drug* (250 mg BID and 100 mg BID) in Out-patients with General Anxiety Disorder (GAD). (SV.105) 2007

A Multi-centre, Double-blind, Randomized, Parallel-group, Placebo-controlled, Phase III Study of the Efficacy and Safety of *Drug* as Monotherapy in the Treatment of Elderly Patients with Generalized Anxiety Disorder (GAD). (AA.113) 2007

A Multi-center, Randomized, Double-blind, Placebo- and *Drug*-controlled Trial of the Safety and Efficacy of *Drug* in the Treatment of Out-patients with Generalized Anxiety Disorder (GAD). (BS.101) 2007

A Multi-center, Randomized, Parallel-group, Placebo-controlled Study of the Efficacy and Safety of *Drug* Compared with Placebo in the Treatment of Generalized Anxiety Disorder (GAD). (AA.109) 2006

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multi-center, Randomized, Double-blind, Parallel-group, Placebo-controlled, Active-controlled Study of the Efficacy and Safety of *Drug* Compared with Placebo in the Treatment of Generalized Anxiety Disorder (GAD). (AA.106) 2006

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

A Randomized, Double-blind, Placebo-controlled, Multi-center 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 16 mg/day) in Adults with Generalized Anxiety Disorder (GAD). (CP.112) 2005

A Long-term, Open-label, Safety and Efficacy Study of *Drug* in Adults with General Anxiety Disorder (GAD). (JZ.102) 2004

A Randomized, Double-blind, Placebo- and Active-controlled, Parallel-group, Safety and Efficacy Study of *Drug* in Adults with Generalized Anxiety Disorder (GAD). (JZ.101) 2004

A 10-week, Randomized, Double-blind, Placebo-controlled, Parallel-group, Flexible-dosage Study to Evaluate the Efficacy and Safety of *Drug* (up to 16 mg/day) in the Treatment of Adults with Generalized Anxiety Disorder (GAD). (CP.109) 2004

A 10-week, Randomized, Double-blind, Placebo-controlled, Parallel-group, Flexible-dosage Study to Evaluate the Efficacy and Safety of *Drug* (up to 16 mg/day) in the Treatment of Adults with Generalized Anxiety Disorder (GAD). (CP.108) 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

Bipolar Disorders

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 Double-blind, Placebo-controlled Evaluation of the Safety and Efficacy of *Drug* in Patients with Bipolar Depression. (FL.108) 2013

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase II, Randomized, Double-blind, Placebo-controlled, Flexible-dose Study to Assess the Safety, Tolerability, and Efficacy of *Drug* in the Treatment of Bipolar I Depression. (RP.101) 2010

Randomized, Double-blind, Parallel-group, Placebo-controlled, *Drug*-referenced, Fixed-dose Study of *Drug* in the Treatment of Depression in Patients with Bipolar I or II Disorder. (LB.101) 2009

A Six-week Double-blind, Multi-center, Placebo-controlled Study Evaluating the Efficacy and Safety of Flexible Doses or Oral *Drug* as Add-On, Adjunctive Therapy with Lithium, Valproate, or Lamotrigine in Bipolar I Depression. (PR.102) 2008

An 8-Week, Double-blind, Placebo-controlled, Parallel-group, Fixed-dosage Study to Evaluate the Efficacy and Safety of *Drug* (150 mg/day) as Adjunctive Therapy in Adults with Major Depression Associated with Bipolar I Disorder. (CP.114) 2007

A Multi-center, Double-blind, Randomized, Parallel-group, Placebo-controlled, Phase III Study of the Efficacy and Safety of *Drug* as Monotherapy in Adult Patients with Acute Bipolar Depression. (AA.112) 2006

Multi-center, Randomized, Parallel-group, Double-blind, Placebo-controlled, Phase III Study of the Efficacy and Safety of *Drug* as Monotherapy for up to 104 Weeks Maintenance Treatment of Bipolar I Disorder in Adult Patients. (AA.111) 2006

Efficacy and Safety of *Drug* versus Placebo as Adjunct Therapy with Mood Stabilizers (Lithium or Divalproex) for the Treatment of Alcohol Dependence in Patients with Bipolar I Disorder. (AA.105) 2005

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 (Lithium or Valproate) in Maintenance Treatment of Bipolar I Disorder in Adult Patients. (AA.104) 2005

A Confirmatory, Multi-center, Double-blind, Randomized, Placebo-controlled, Study of the Use of *Drug* in the Treatment of Patients with Bipolar Depression. (AA.103) 2004

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 (Lithium or Divalproex) in the Maintenance Treatment of Bipolar Disorder in Adult Patients. (AA.102) 2003

A Multi-center, Double-blind, Placebo-controlled, Fixed-dose, 8-week Evaluation of the Efficacy and Safety of *Drug* in the Treatment of Major Depression in Patients with Type II Bipolar Disorder. (GK.120) 2003

CLINICAL TRIAL EXPERIENCE (*continued*):

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 Phase III, Multicenter, Double-blind, Randomized, Placebo-controlled Study Evaluating the Efficacy of XXX in the Treatment of Adult Subjects with Major Depressive Disorder (SA.101) 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, 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 Phase II, Randomized, Double-blind, Placebo-Controlled, Parallel-groups Safety and Efficacy Study of XXX Administered Once Daily in Patients with Major Depressive Disorder with or without Anhedonia 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

CLINICAL TRIAL EXPERIENCE (*continued*):

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 Non-Interventional Study of Subjects Who Have Participated in *Study*, a Study of Adjunctive Treatment of Major Depressive Disorder. (AK.104) 2015

A Randomized, Double-Blind, Placebo-Controlled, Phase IV, 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 Multicenter, Randomized, Double-blind, Placebo-Controlled, Relapse-Prevention Study With *Drug* in Patients With Major Depressive Disorder. (FL.110) 2014

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of the Safety and Efficacy of Fixed-dose *Drug* as Adjunctive Therapy in the Treatment of Adults with Major Depressive Disorder with and Without Anxious Distress. (OT.109) 2014

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 Phase III Efficacy and Safety Study of *Drug* for the Adjunctive Treatment of Major Depressive Disorder. (AK.102) 2014

A Phase III Efficacy and Safety Study of *Drug* for the Adjunctive Treatment of Major Depressive Disorder. (AK.101) 2014

A Phase IIIb, Multicenter, Open-label Exploratory Trial to Evaluate the Efficacy, Safety, and Subject Satisfaction of *Drug* as Adjunctive Therapy in the Treatment of Adults with Major Depressive Disorder and an Inadequate Response to Previous Adjunctive Therapy. (OT.108) 2014

An Exploratory, Multicenter, Open-label, Flexible-dose Trial of *Drug* as an Adjunctive Treatment in Adults with Major Depressive Disorder and Anxiety Symptoms. (OT.107) 2014

A Phase III, Multicenter, Randomized, Double-blind, Placebo- and Active Comparator-controlled Trial of Flexible-dose *Drug* as Adjunctive Therapy in the Treatment of Adults with Major Depressive Disorder. (OT.106) 2013

A Phase IIb, Randomized, Double-blind, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Study to Assess the Safety and Efficacy of 2 Fixed Dose Groups of *Drug* as Monotherapy Treatment in Patients with Major Depressive Disorder with an Inadequate Response to Antidepressant Therapy. (AA.121) 2012

CLINICAL TRIAL EXPERIENCE (*continued*):

A Double-blind, Placebo-controlled Study of *Drug* as Adjunctive Therapy in Major Depressive Disorder (MDD). (FL.107) 2011

A Phase IV, Multi-center, Randomized, 8-week, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy of 2 Fixed Doses (50 and 100 mg/day) of *Drug* Sustained-release Formulation in Adult Outpatients with Major Depressive Disorder (MDD). (PR.105) 2011

A Long-term, Phase III, Multicenter, Open-label Trial to Evaluate the Safety and Tolerability of Oral *Drug* as Adjunctive Therapy in Adults with Major Depressive Disorder, the *X* Trial. (OT.105) 2011

A Phase III, Randomized, Double-blind, Parallel-group, Placebo-controlled, *Drug*-Referenced, Fixed-dose Study Comparing the Efficacy and Safety of 2 Doses (15 and 20 mg) of *Drug* in Acute Treatment of Adults with Major Depressive Disorder. (TG.111) 2011

A Multicenter, Double-blind, 58-week, Rollover Study to Assess the Safety and Tolerability of *Drug* in Patients with Treatment Resistant Major Depression. (BS.104) 2011

A Randomized, Double-blind, Parallel-group, Active-controlled, Flexible-dose Study Evaluating the Effect of *Drug* vs. *Drug* on Sexual Functioning in Adults with Well-Treated Major Depressive Disorder Experiencing Selective Serotonin Reuptake Inhibitor-Induced Sexual Dysfunction. (TG.110) 2011

A Phase III, Multi-center, Randomized, Double-blind, Placebo-controlled Trial of the Safety and Efficacy of Fixed-dose *Drug* as Adjunctive Therapy in the Treatment of Adult with Major Depressive Disorder, the *Y* Trial. (OT.103) 2011

A Phase III, Multi-center, Randomized, Double-blind, Placebo-controlled Trial of the Safety and Efficacy of Two Fixed Doses of *Drug* as Adjunctive Therapy in the Treatment of Adult with Major Depressive Disorder, the *X* Trial. (OT.104) 2011

A Double-blind, Placebo-controlled, Fixed-dose Study of *Drug* in Patients with Major Depressive Disorder (MDD). (FL.106) 2011

A Multi-center, Randomized, Double-blind, Active-controlled Study of the Efficacy and Safety of Flexibly-dosed *Drug* in Patients with Treatment Resistant Major Depression. (BS.103) 2011

A Phase II, Multi-center, Open-label Study to Assess the Safety and Tolerability of Oral *Drug* as Adjunctive Therapy in Adult Patients with Major Depressive Disorder (MDD). (OT.102) 2011

A Randomized, Double-blind, Placebo-controlled, Parallel-group Assessment of the Efficacy, Safety, and Tolerability of *Drug* Modified Release Tablet, 125 mg Twice Per Day, in Subjects with Treatment Resistant Depression. (CB.101) 2011

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase III, Randomized, Double-blind, Parallel-group, Placebo-controlled, Fixed-dose Study Comparing the Efficacy and Safety of 2 Doses (10 and 15 mg) of *Drug* in Acute Treatment of Adults with Major Depressive Disorder (MDD). (TG.109) 2011

A Multi-center, Randomized, Double-blind, Parallel-group, Placebo-controlled, Phase III Efficacy and Safety Study of *Drug* in Flexible Doses as an Adjunct to an Antidepressant in Patients with Major Depressive Disorder (MDD) Who Exhibit an Inadequate Response to Antidepressant Therapy. (AA.120) 2011

A Multi-center, Randomized, Double-blind, Parallel-group, Placebo-controlled, Phase III, Efficacy and Safety Study of 3 Fixed Dose Groups of *Drug* as an Adjunct to an Antidepressant in Patients with Major Depressive Disorder Who Exhibit an Inadequate Response to Antidepressant Therapy. (AA.119) 2011

A Phase III, Long-term, Open-label, Flexible-dose, Extension Study Evaluating the Safety and Tolerability of *Drug* (15 and 20 mg) in Subjects with Major Depressive Disorder (MDD). (TG.108) 2010

A Phase III, Randomized, Double-blind, Parallel-group, Placebo-controlled, Fixed-dose Study Comparing the Efficacy and Safety of 2 Doses (10 and 20 mg) of *Drug* in Acute Treatment of Adults with Major Depressive Disorder (MDD). (TG.107) 2010

A 52-week, Multi-center, Open-label Study of the Safety and Tolerability of *Drug* Sublingual Tablets in Patients with Major Depressive Disorder (MDD). (NO.108) 2010

A Multi-center, Randomized, Double-blind, Parallel-group, Placebo-controlled, Phase III, Long-term Safety and Tolerability Study of *Drug* as an Adjunct to an Antidepressant in Patients with Major Depressive Disorder Who Exhibit an Inadequate Response to Antidepressant Therapy. (AA.118) 2010

Phase IV, Double-blind, Randomized, Placebo-controlled, 8-week Study Evaluating the Efficacy of *Drug* 60 mg Once Daily in Adult Outpatients with Major Depressive Disorder and Associated Painful Physical Symptoms. (EL.113) 2010

A Double-blind, Efficacy and Safety Study of *Drug* versus Placebo in the Treatment of Children and Adolescents with Major Depressive Disorder (MDD). (EL.112) 2010

A Long-term, Open-label Extension Study of *Drug* in Adult Patients with Major Depressive Disorder (MDD). (FL.105) 2009

A Double-blind, Placebo-controlled, Flexible-dose Study of *Drug* in Patients with Major Depressive Disorder (MDD). (FL.104) 2009

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multi-center, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of 2 Fixed Doses (10 and 50 mg/day) of *Drug* Tablets in Adult Out-patients with Major Depressive Disorder (MDD). (WR.101) 2009

A Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of *Drug* in Subjects with Major Depressive Disorder (MDD). (GK.130) 2009

Randomized, Double-blind, Parallel-group, Placebo-controlled, *Drug*-referenced, Fixed-dose Study Comparing the Efficacy and Safety of *Drug* in Acute Treatment of Major Depressive Disorder (MDD) in Elderly Patients. (LB.102) 2009

A Randomized, Double-blind Comparison of *Drug* and Placebo and Long-Term Treatment with *Drug* in Adult Patients with Major Depressive Disorder (MDD). (EL.111) 2008

A Randomized, Double-blind, Parallel-group, Placebo-controlled, Fixed-dose Study Comparing the Efficacy and Safety of *Drug* Versus Placebo in Acute Treatment of Adults with Major Depressive Disorder (MDD). (TG.104) 2008

An Eight-week, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of *Drug* 100 mg Once Daily in Combination with *Drug* 10 mg Once Daily in Patients with Major Depressive Disorder (MDD). (SV.104) 2007

A Multi-center, Randomized, Double-blind, Placebo- and *Drug*-controlled Trial of the Safety and Efficacy of *Drug* in the Treatment of Out-patients with Major Depressive Disorder (MDD). (BS.102) 2007

A Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Safety and Efficacy of *Drug* in Patients with Recurrent Major Depressive Disorder (MDD). (OP.101) 2007

A Multi-center, Double-blind, Randomized, Parallel-group, Placebo-controlled, Phase III Study of the Efficacy and Safety of *Drug* as Monotherapy in the Treatment of Elderly Patients with Major Depressive Disorder (MDD). (AA.114) 2007

A Multi-center, Randomized, 24-52-week, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of *Drug* 100 mg Once Daily in the Prevention of Relapse of Depressive Symptoms in Out-patients with Major Depressive Disorder (MDD) Who Achieved an Initial Response to 12 Weeks of Open-label Treatment with *Drug* 100 mg Once Daily. (SV.103) 2006

A Multi-center, Double-blind, Randomized, Parallel-group, Placebo-controlled, Phase III Study of the Efficacy and Safety of *Drug* as Monotherapy in Treatment of Patients with Major Depressive Disorder (MDD). (AA.110) 2006

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multi-center, Double-blind, Randomized, Parallel-group, Placebo-controlled and Active-controlled, Phase III Study of the Efficacy and Safety of *Drug* as Monotherapy in the Treatment of Patients with Major Depressive Disorder (MDD). (AA.108) 2006

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. (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 (MDD). (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 (TR MDD). (EL.106) 2004

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 (MDD). (GK.121) 2004

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 (MDD). (SE.101) 2003

A Double-blind, Flexible-dose Comparison of *Drug*, *Drug*, and Placebo in the Treatment of Major Depressive Disorder (MDD). (FL.103) 2003

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 (MDD) over an Eight-week Treatment Period. (GK.114) 2003

An Open-label, Extension Trial in Children and Adolescents with Major Depressive Disorder (MDD) 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 Out-patient Children and Adolescent with Major Depressive Disorder (MDD). (OG.101) 2003

A Double-blind, Placebo-controlled Evaluation of the Safety and Efficacy of *Drug* in Pediatric Depression. (FL.101) 2003

CLINICAL TRIAL EXPERIENCE (*continued*):

A Multi-center, Double-blind, Placebo-controlled, Fixed-dose, 8-week Evaluation of the Efficacy and Safety of *Drug* in the Treatment of Bipolar Disorder Patients Currently Experiencing a Major Depressive Episode. (GK.115) 2003

A 7-month, Multi-center, Parallel, Double-blind, Placebo-controlled Comparison of Two Doses of *Drug* and Placebo for the Prevention of Seasonal Depressive Episodes in Subjects with a History of Seasonal Affective Disorder (SAD) Followed by an 8-week Observational Follow-up Phase. (GK.111) 2003

A Multi-center, Randomized, Double-blind, Parallel-group, Placebo-controlled, Fixed-dose Study Evaluating the Efficacy, Safety, and Tolerability of Two Doses of *Drug* in Subjects with Major Depressive Disorder (MDD) for a Treatment Period of Eight Weeks. (GK.110) 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 (MDD). (GK.107) 2002

A 6 ½-month, Multi-center, Randomized, Double-blind, Placebo-controlled Comparison of 300 mg/day of Extended-Release *Drug* and Placebo for the Prevention of Seasonal Affective Disorder in Subjects with a History of Seasonal Affective Disorder (SAD). (GK.106) 2002

An Open-label Extension to 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 (MDD). (MC.102) 2001

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 (MDD). (MC.101) 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 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

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-blind, Placebo- and Active-controlled Study of *Drug* in Subjects with Pain Associated with Fibromyalgia. (DS.102) 2015

A Randomized, Double-blind, Placebo- and Active-controlled Study of *Drug* in Subjects with Pain Associated with Fibromyalgia. (DS.101) 2015

A Multi-center, Multiple-dose, Double-blind, Randomized, Placebo-controlled, Parallel-group Study of the Safety and Efficacy of *Drug* in Female Patients with Fibromyalgia Syndrome. (AN.101) 2007

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

A Randomized, Double-Blind, Placebo-Controlled, Phase III Study to Evaluate the Efficacy, Safety, and Tolerability of *Drug* in the Treatment of Patients with Diarrhea-Predominant Irritable Bowel Syndrome. (FX.101) 2012

Men's and Women's Health

A Randomized, Double-Blind, Parallel Group, Placebo- and Active-Controlled, Phase 4 Study Evaluating the Effect of *Drug* 10 and 20 mg/day vs *Drug* 20 mg/day on Sexual Functioning in Healthy Subjects. (TG.113) 2016

A Prospective, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multi-center Study of the Efficacy and Safety of *Drug* in Men with Premature Ejaculation and Concomitant Erectile Dysfunction Treated with a Phosphodiesterase-5 Inhibitor. (JO.104) 2010

CLINICAL TRIAL EXPERIENCE (*continued*):

An Open-label Study of the Long-term Safety of *Drug* in the Treatment of Rapid Ejaculation. (AC.102) 2004

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) 2004

A Placebo-controlled, Double-blind, Randomized, Parallel Study of the Efficacy and Safety of *Drug* in the Treatment of Rapid Ejaculation. (AC.101) 2003

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 Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy, Safety, and Tolerability of Oral XXX for the Prevention of Migraine in Participants 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

CLINICAL TRIAL EXPERIENCE (*continued*):

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)

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, Double-Blind, Randomized, Placebo Controlled, Safety, Efficacy, Trial of XXX for the Acute Treatment of Migraine (BH.101) 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 Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Single Attack Study to Evaluate the Efficacy, Safety and Tolerability of Oral XXX in the Acute Treatment of Migraine (AN.102) 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 Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Comparing the Efficacy and Safety of 2 Dose Regimens of Subcutaneous Administration of *Drug* Versus Placebo for the Preventive Treatment of Episodic Migraine. (TV.102) 2016

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Comparing the Efficacy and Safety of 2 Dose Regimens of Subcutaneous Administration of *Drug* Versus Placebo for the Preventive Treatment of Chronic Migraine. (TV.101) 2016

CLINICAL TRIAL EXPERIENCE (*continued*):

An Open-label, Long-term, Safety Study of *Drug* (100 mg and 200 mg) in the Acute Treatment of Migraine. (CO.102) 2015

A Study of Two Doses of *Drug* (100 mg and 200 mg) Compared to Placebo in the Acute Treatment of Migraine: A randomized, double-blind, placebo-controlled parallel group study. (CO.101) 2015

A Worldwide, Open-label, Clinical Trial to Examine the Long-term Safety and Tolerability of *Drug* in Pediatric Migraineurs for the Treatment of Migraine with or without Aura. (MC.107) 2010

A Worldwide, Randomized, Double-blind, Placebo-controlled, Parallel-group Clinical Trial to Evaluate the Safety and Efficacy of *Drug* for the Acute Treatment of Migraine in Children and Adolescents. (MC.106) 2010

A Randomized, Multi-center, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of a Combination Product Containing *Drug* for the Acute Treatment of Migraine in Adolescents (12-17). (GK.129) 2008

A Six-week, Double-blind, Multi-center, Placebo-controlled, Parallel-group, Phase III Study of *Drug* in Adult Migraineurs for a Single Migraine Followed by Open-label Extensions to 26/52 Weeks. (MP.101) 2008

A Long-term, Safety Study of a Combination Product Containing *Drug* for the Treatment of Migraine in Adolescents. (GK.128) 2007

A Randomized, Double-blind, Single Migraine Attack, Placebo-controlled, Parallel-group, Multi-center Study to Evaluate the Efficacy and Tolerability of *Drug* Tablets vs Placebo When Administered During the Mild Pain Phase of Menstrual Migraine in Women with Dysmenorrhea. (GK.127) 2006

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

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

Open-label, Long-term, Multi-center Study of Safety and Tolerability of *Drug* in the Acute Treatment of Migraines in Adults. (PM.111) 2002

CLINICAL TRIAL EXPERIENCE (*continued*):

Pain

A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multi-center, Phase III Study to Evaluate the Long-term Safety of *Drug* for the Treatment of Opioid-induced Constipation in Subjects with Non-malignant Chronic Pain Receiving Opioid Therapy. (SO.102) 2013

A Randomized, Double-blind, Placebo-controlled, Multi-center, Phase III Study to Evaluate the Long-term Safety of *Drug* 0.5 mg 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, Multi-center, Phase III Study to Evaluate the Efficacy and Safety of *Drug* 0.5 mg Once Daily and 0.5 mg 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 Randomized, Double-blind, Placebo-controlled, Multi-center, Phase III Study to Evaluate the Efficacy and Safety of *Drug* 0.5 mg Once Daily and 0.5 mg Twice Daily for 12 Weeks for the Treatment of Opioid-induced Bowel Dysfunction in Adults Taking Therapy for Persistent Non-cancer Pain. (GK.123) 2005

Sleep Disorders

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 (ID.101) 2018

A Randomized, Placebo-controlled, Double-blind, Fixed-dose Study of the Efficacy and Safety of *Drug* in Children and Adolescents 6 through 17 Years of Age with Attention-Deficit/Hyperactivity Disorder- (ADHD) Associated Insomnia. (SE.106/SU.101) 2010

A Long-term, Open-label, Safety Study of *Drug* in Children (6 to 11 years) and Adolescents (12 to 17 years) with Attention-Deficit/Hyperactivity Disorder- (ADHD) Associated Insomnia. (SE.107/SU.102) 2010

A Safety, Tolerability, Pharmacokinetic and Pharmacodynamic Evaluation of Single Oral Doses of *Drug* in Adolescents 6 to 11 Years of Age with Attention-Deficit/Hyperactivity Disorder (ADHD) and Insomnia. (SE.105) 2008

CLINICAL TRIAL EXPERIENCE (*continued*):

A Safety, Tolerability, Pharmacokinetic and Pharmacodynamic Evaluation of Single Oral Doses of *Drug* in Adolescents 12 to 17 Years of Age with Attention Deficit Hyperactivity Disorder and Insomnia. (SE.104) 2008

A Phase II, Randomized, Double-blind, Placebo-and-Active-comparator-controlled Study of the Safety and Efficacy of *Drug* in Out-patients with Insomnia. (EL.109) 2008

A Randomized, Double-blind, Placebo-controlled, Parallel, Proof of Concept Study to Evaluate the Effectiveness of *Drug* to Advance the Timing of Sleep in Individuals with Delayed Sleep Phase Syndrome (DSPS). (TG.103) 2007

A Two-week, Double-blind, Placebo-controlled, Randomized, Parallel-group, Efficacy and Safety, Out-patient Trial with *Drug* in Patients with Chronic Primary Insomnia. (OG.103/SP.101) 2007

Fifty-two-weeks, Open-label Extension Trial to Evaluate Safety and Efficacy or *Drug* in Out-patients with Chronic Primary Insomnia who Completed Clinical Trial Protocol *X* and *Y*. (OG.104/SP.102) 2007

A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multi-center, Out-patient Study to Assess the Efficacy and Safety of *Drug* in Elderly Patients with Primary Sleep Maintenance Insomnia. (SM.101) 2006

Efficacy and Safety of *Drug* 5 mg/day on 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

Other Indications

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 Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Different Doses of *Drug* for the Treatment of Celiac Disease. (AB.101) 2012

6-Month, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of *Drug* and *Drug* both in combination with oral anti-hyperglycemic drug(s) in Patients with Type 2 Diabetes Mellitus with a 6-month Safety Extension Period. (SV.106) 2012

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

CLINICAL TRIAL EXPERIENCE (*continued*):

A Randomized, Double-blind, Parallel-group, Placebo-controlled, Safety and Efficacy Study of *Drug* to Placebo in Children and Adolescents Aged 6-17 with Oppositional Defiant Disorder (ODD). (SH.102) 2003

CLINICAL TRIALS TRAINING:

07/26/18	ProHIPAA - HIPAA Training program - Recertification
01/05/18	INC Research - ICH/GCP Training: Refresher Course, including ICH E6, Revision 2 Changes
06/24/17	INC Research - ICH/GCP Training: Review of ICH E6, Revision 2 Changes
04/26/17	Medidata Rave - Certified Principal Investigator
07/27/16	ProHIPAA - H|PM Training program – Recertification
01/07/16	Collaborative Institutional Training Initiative (CITI) – Good Clinical Practice & ICH (GCP)
08/28/14	The HIPAA Group – HIPAA Training Program
01/19/14	Collaborative Institutional Training Initiative (CITI) – Good Clinical Practice & ICH (GCP)
02/20/13	Otsuka Good Clinical Practices and Clinical Drug Safety Training
11/14/12	Collaborative Institutional Training Initiative (CITI) – Good Clinical Practice & ICH (GCP)
05/14/12	The HIPAA Group – HIPAA Training Program
08/30/11	Pfizer GCP for Investigational Site Staff Version 1.2
11/05/10	Collaborative Institutional Training Initiative (CITI) – Good Clinical Practice & ICH (GCP)
03/09/10	The HIPAA Group – HIPAA Training Program
10/24/08	Collaborative Institutional Training Initiative (CITI) – Good Clinical Practice & ICH (GCP)
03/21/08	Good Clinical Practices (GCP) Training (sponsor-provided)
03/14/08	NIH Human Participant Protections: Education for Research Teams
03/08/04	Human Subject Assurance Training

COMMITTEES:

2003	Root Cause Analysis Committee
2003	Dialectical Behavioral Therapy Treatment Team
2002 – 2003	Medical Student Education Committee

RESEARCH AND PUBLICATIONS:

Lankford, A., R. Rogowski, Beal Essink, E. Ludington, H. Heith Durrence, and T. Roth. "Efficacy and Safety of Doxepin 6 mg in a Four-week, Outpatient Trial of Elderly Adults with Chronic Primary Insomnia." Sleep Med 2012: Feb;13(2):133-8. doi: 10.1016/j.sleep.2011.09.006. Epub 2011 Dec 24.

Pangallo, B., Mary Ann Dellva, Deborah N. D'Souza, Beal Essink, James Russell, and Celine Goldberger. "A Randomized, Double-blind Study Comparing LY2216684 and Placbeo in the Treatment of Major Depressive Disorder." Journal of Psychiatric Research 2011: doi: 10.1016/j.jpsychires.2011.03.014

Hansen, T., Beal Essink, and W. Hoffman. "Metabolic and Cardiac Changes with Ziprasidone Treatment." American Psychiatric Association Poster Presentation, 2003.

Hoffman, W., Beal Essink, and T. Hansen. "Use of the Clinical Laboratory in the Diagnosis and Treatment of Depression." Laboratory Medicine 2002: 7,33:2-5.

Susman, J., B. Crabtree, and Beal Essink. "Depression in Rural Family Practice: Easy to Recognize, Difficult to Diagnose." Archives of Family Medicine 1995: 4:427-431.