

Denny H. Lee, MD

Phone: (949) 753-1663
dlee@irvineclinical.com

D. Lee

5/8/17



IRVINE
CLINICAL
RESEARCH

2515 McCabe Way, Suite 350
Irvine, CA 92614

PROFESSIONAL EXPERIENCE

President and Principal Investigator, 2005-Present
Irvine Center for Clinical Research, Irvine, CA

Principal and Sub-Investigator, 2005
Radiant Research Irvine, Irvine, CA

Medical Evaluator, 1999-2006
QTC Medical Group, Diamond Bar, CA

Private Practice, 1995-1999

Staff Physician, Ambulatory Care and Emergency Care, 1993-1994
Veterans Administration Hospital, Long Beach, CA

Course Director, Introduction to Medicine, 1991-1993
City University of New York, New York, NY

Instructor of Medicine, 1991-1993
Albert Einstein College of Medicine, New Hyde Park, NY

Attending Physician, Department of Internal Medicine, 1991-1993
Long Island Jewish Medical Center, New Hyde Park, NY

Attending Physician, Department of Internal Medicine, 1989-1991
Long Island Jewish Medical Center (Queens Hospital Center Affiliation), Jamaica, NY

Teaching Attending Physician, Department of Medicine, 1988-1989
Grant Hospital, Chicago, IL

CERTIFICATION AND LICENSURE

- Diplomate, American Board of Internal Medicine
- California Medical Board License #A44167 (Exp. 1/31/2019)
- DEA Certification (Exp. 3/31/2020)
- Good Clinical Practices: Compliance Annual Review and Investigator Meetings
- Human Participants Protection Education, HIPAA and OSHA Certificates

Denny H. Lee, MD

Phone: (949) 753-1663
dlee@irvineclinical.com



2515 McCabe Way, Suite 350
Irvine, CA 92614

EDUCATION AND TRAINING

Chief Medical Resident (PGY IV), 1987-1988

Grant Hospital, Chicago, IL

Department of Internal Medicine Resident (PGY I-III), 1984-1987

Grant Hospital, Chicago, IL

Internship, 1980-1981

Rangoon General Hospital, Burma

MD, 1980

Institute of Medicine (I), Rangoon, Burma

Pre-Medical Training, 1975

Institute of Medicine (I), Rangoon, Burma

AWARDS

Excellence in Teaching Award, Department of Medicine, 1990-1991

Long Island Jewish Medical Center, New Hyde Park, NY

Excellence in Teaching Award, Department of Medicine, 1989-1990

Long Island Jewish Medical Center, New Hyde Park, NY

Outstanding Medical Resident Award, 1986-1987

Grant Hospital, Chicago, IL

CLINICAL RESEARCH EXPERIENCE

Amgen

- 1 A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of xxxx in Migraine Prevention. (Protocol xxxx) Sub-Investigator. 6/15 to Present

Ardea Biosciences

- 2 Long Term Allopurinol Safety Study Evaluating Outcomes in Gout Patients (xxxx). (Protocol xxxx) Principal Investigator. 9/11 to 5/13
- 3 A Phase 3 Randomized, Double-Blind, Multicenter, Placebo-Controlled, Combination Study to Evaluate the Efficacy and Safety of xxxx and Allopurinol Compared to Allopurinol Alone in Subjects with Gout who have had an Inadequate Hypouricemic Response to Standard of Care Allopurinol. (Protocol xxxx) Principal Investigator. 12/11 to 8/14
- 4 A Phase 3 Randomized, Double-Blind, Multicenter, Placebo- Controlled Study to Assess the Efficacy and Safety of xxxx Monotherapy Compared to Placebo in Subjects with Gout and an Intolerance or Contraindication to a xxxx Inhibitor . (Protocol xxxx) Principal Investigator. 2/12 to 12/13
- 5 A Phase 3 Randomized, Double-Blind, Multicenter, Placebo-Controlled, Combination Study to Evaluate the Efficacy and Safety of xxxx and xxxx Compared to xxxx Alone at Lowering Serum Uric Acid and Resolving Tophi Subjects with Tophaceous Gout. (Protocol xxxx) Principal Investigator. 1/12 to 7/14

Denny H. Lee, MD

Phone: (949) 753-1663
dlee@irvineclinical.com



2515 McCabe Way, Suite 350
Irvine, CA 92614

- 6 A Long-Term Open Label Extension Study for Subjects Completing a Phase 3 Efficacy and Safety Study to Lesinurad Monotherapy in Subjects with Gout. (Protocol xxxx) Principal Investigator. 6/12 to 7/14
- 7 A Long-Term Extension Study of Lesinurad in Combination with Allopurinol for Subjects Completing an Efficacy and Safety Study of Lesinurad and Allopurinol. (Protocol xxxx) Principal Investigator. 1/13 to present
- 8 A Long-Term Extension Study of Lesinurad in Combination with Febuxostat for Subjects with Gout Completing an Efficacy and Safety Study of Lesinurad and Febuxostat. (Protocol xxxx) Principal Investigator 3/13 to present
- 9 A Phase 2, Randomized, Double-Blind, Multicenter, Placebo-Controlled Study to Evaluate the Efficacy and Safety of xxxx Monotherapy in Subjects with Gout. (Protocol xxxx) Principal Investigator 8/13 to 7/14
- 10 A Study to Determine the Presence and Volume of Monosodium Urate Crystals as Assessed by Dual-Energy Computed Tomography in Patients with Gout Treated with Allopurinol. (Protocol xxxx) Principal Investigator 4/15 to Present

Astra-Zeneca LP

- 11 A multi-center, double-blind, randomized, parallel-group, placebo-controlled, Phase III study of the efficacy and safety of xxxx sustained release (xxxx SR) in combination with an antidepressant in the treatment of patients with Major Depressive Disorder with inadequate response to an antidepressant treatment (xxxx) Sub-Investigator. 12/06 to 9/07
- 12 A multi-center, randomized, placebo-controlled, double-blind, parallel group, Phase II study of 2 Oral dose groups of xxxx, with a xxxx arm, in subjects with Generalized Anxiety Disorder. (Protocol xxxx) Sub-Investigator. 1/09 to 5/09
- 13 A Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Phase III, Long-Term Safety and Tolerability Study of xxxx as a Adjunct to an Antidepressant in Patients with Major Depressive Disorder Who Exhibit an Inadequate response to Antidepressant Therapy. (Protocol xxxx) Sub-Investigator. 6/10 to 3/12
- 14 A Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Phase III, Efficacy and Safety Study of 3 Fixed Dose Groups of xxxx as an Adjunct to an Antidepressant in Patients with Major Depression Disorder Who Exhibit an Inadequate Response to Antidepressant Therapy. (Protocol xxxx) Sub-Investigator. 6/10 to 4/11
- 15 A Multinational, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Effect of xxxx 90 mg twice daily on the Incidence of Cardiovascular Death, Myocardial Infarction of Stroke in Patients with Type 2 Diabetes Mellitus [xxxx – effect of xxxx on Health outcomes in Diabetes Mellitus patients Intervention Study] Investigator. 7/14 to present

AR Scientific, Inc.

- 16 A multi-center, randomized, placebo-controlled, double-blind, parallel group, 1-week, dose-comparison study to evaluate the efficacy, safety and tolerability of xxxx in patients with an acute gout flare xxxx (Protocol xxxx) Principal Investigator. 6/07 to 11/07

Bayer Healthcare Pharmaceuticals

- 17 Pivotal Phase III trial to investigate the efficacy and safety of an Orodispersible tablet xxxx versus placebo in the treatment of men with erectile dysfunction (ED) – a fixed-dose, double-blind, randomized multicenter trial – xxxx. (Protocol xxxx) Sub-Investigator. 4/08 to 1/09
- 18 A multi-center, randomized, double-blind, active-controlled, parallel group, 2-arm study to show superiority of the oral contraceptive xxxx over xxxx on hormone withdrawal-associated symptoms after 6 cycles of treatment. (Protocol xxxx) Sub-Investigator. 8/08 to 10/09.

Denny H. Lee, MD

Phone: (949) 753-1663
dlee@irvineclinical.com



2515 McCabe Way, Suite 350
Irvine, CA 92614

BioCryst Pharmaceuticals, Inc.

- 19 A Phase 2, Randomized, Double-Blind, Dose Ranging, Two-Part, Multi-Center Study to Evaluate the Urate-Lowering Activity and Safety of Oral xxxx Administered in Subjects with Gout. (Protocol xxxx) Principal Investigator. 11/09 to 9/10
- 20 A Randomized, Double-Blind, Multi-Center Placebo Controlled, Combination Study to Evaluate the Urate Lowering Activity, Safety and Potential Pharmacokinetic Interaction of Oral xxxx and xxxx Administered in Subjects with Gout. (Protocol xxxx) Principal Investigator. 5/10 to 11/10
- 21 A Randomized, Double-Blind, Dose-Response Study of the Safety and Efficacy of Oral xxxx Added to xxxx in Subjects with Gout Who Have Not Adequately Responded to xxxx Monotherapy. (Protocol xxxx) Principal Investigator. 12/10 to 2/12
- 22 A Randomized, Double-Blind, Dose-Response Study of the Safety and Uric Acid Effects of Oral xxxx Added to xxxx in Subjects with Gout and Concomitant Moderate Renal Insufficiency. (Protocol xxxx) Principal Investigator. 9/11 to 8/12

Boehringer-Ingelheim Pharmaceuticals

- 23 A twenty-four week, randomized, double-blind, placebo-controlled, safety and efficacy trial of xxxx 50 milligrams daily and, with uptitration, 100 milligrams daily in post-menopausal women with hypoactive sexual disorder. (Protocol xxxx) Sub-Investigator. 7/06 to 4/08
- 24 A Twelve Month, Open-Label, Safety Trial of xxxx 50 Milligrams to 100 Milligrams Daily in Women with Hypoactive Sexual Desire Disorder. (Protocol xxxx) Sub-Investigator. 3/06 to 10/09
- 25 A twenty-four week, randomized, double-blind, placebo-controlled, safety and efficacy trial of xxxx (100 milligrams) administered orally once daily in naturally postmenopausal women in hypoactive sexual desire disorder in the United States. (Protocol xxxx) Sub-Investigator. 09/09 to 1/11
- 26 A twenty-four week, randomized, double-blind, placebo controlled, safety and efficacy trial of xxxx (100 milligrams) administered orally once daily in premenopausal women with hypoactive sexual desire disorder in the United States. (Protocol xxxx) Sub-Investigator. 09/09 to 3/11
- 27 Qualitative interview study to categorize men with low sexual desire and related distress. (Protocol xxxx) Sub-Investigator. 2/10 to 6/10.
- 28 A twenty-eight week, open-label, safety, extension trial of xxxx (100 milligrams) daily in premenopausal and naturally postmenopausal women with hypoactive sexual desire disorder in North America. (Protocol xxxx) Sub-Investigator. 2/10 to 1/11.
- 29 A randomized, double-blind, placebo-controlled parallel group efficacy and safety trial of xxxx (10 and 25 mg administered orally once daily) over 24 weeks in patients with type 2 diabetes mellitus with insufficient glycemic control despite a background therapy of xxxx alone or in combination with Metformin. (Protocol xxxx) Principal Investigator. 9/10 to 4/11

Bristol Myers Squibb Company

- 30 A multi-center, randomized, placebo-controlled, double-blind, parallel group, Phase 3 trial to evaluate the efficacy and safety of xxxx (xxxx) in combination with xxxx Therapy in subjects with Type 2 Diabetes who have inadequate glycemic control on xxxx therapy alone (Protocol xxxx) Principal Investigator. 2/06 to 6/06
- 31 A 4-week, multi-center, randomized, placebo-controlled, double-blind, parallel group, Phase 3 trial to evaluate the efficacy and safety of xxxx in comparison to Placebo as add-on treatment to Metformin XR in subjects with Type 2 Diabetes who have inadequate glycemic control with diet and exercise and as table dose of Metformin XR \geq 1500 mg/day. (Protocol xxxx) Principal Investigator. 11/08 to 10/09

Cephalon, Inc.

- 32 A 10-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-group Study to Evaluate the Efficacy and Safety of xxxx at 4, 8, and 12 mg/day in the treatment of Adults with Generalized Anxiety Disorder. (Protocol xxxx/US). Sub-Investigator. 8/05 to 4/06

Denny H. Lee, MD

Phone: (949) 753-1663

dlee@irvineclinical.com



2515 McCabe Way, Suite 350

Irvine, CA 92614

- 33 A 12-Month, Open-Label, Flexible-Dosage study to Evaluate the Safety Efficacy of xxxx Treatment (up to 16mg/day) in Adults with generalized anxiety Disorder. (Protocol xxxx/US) Sub-Investigator. 8/05 to 9/06

DOV Pharmaceuticals

- 34 A multi-center, standard of care-controlled study to evaluate the long-term safety of xxxx for the treatment of chronic low back pain. (Protocol xxxx) Sub-Investigator. 8/05 to 10/07

Duramed Research

- 35 A Randomized, Multi-center, Double-Blind, Placebo-Controlled Trial to Demonstrate the Safety and Efficacy of Daily 0.3mg Synthetic Conjugated xxxx, A (xxxx) for the Treatment of Vasomotor Symptoms in Postmenopausal Women. (Protocol xxxx) Sub-Investigator. 8/06 to 6/07
- 36 A prospective, multi-center, open-label study to evaluate the safety and efficacy of the 28-day oral contraceptive DR-1021 (Protocol xxxx). Sub-Investigator. 8/06 to 12/08

Eisai Medical Research, Inc.

- 37 A randomized, double-blind parallel study of xxxx Extended-release 50 mg versus xxxx 40 mg for healing and symptomatic relief of moderate to severe Erosive Gastroesophageal Reflux Disease (GERD). (Protocol xxxx) Principal Investigator. 3/08 to 10/09
- 38 A randomized, double-blind parallel study of xxxx Extended-release 50 mg versus xxxx 40 mg for healing and symptomatic relief of mild to moderate Erosive Gastroesophageal Reflux Disease (GERD) (Protocol xxxx) Principal Investigator. 3/08 to 10/09
- 39 A randomized, double-blind parallel study of xxxx Extended-release 50 mg versus xxxx 150 mg for maintenance of healed Erosive Gastroesophageal Reflux Disease (GERD). (Protocol xxxx) Principal Investigator. 3/08 to 10/09

Forest Research Institute

- 40 Fixed dose comparison of xxxx to active comparator in moderate-to-severely depressed patients. (Protocol xxxx) Sub-Investigator. 7/06 to 10/07
- 41 A double-blind, fixed-dose study of xxxx in adult patients with Major Depressive Disorder (Protocol xxxx) Sub-Investigator. 4/08 to 4/09
- 42 A long-term, open-label extension study of xxxx in adult patients with Major Depressive Disorder. (Protocol xxxx) Sub-Investigator. 4/08 to 9/09
- 43 A randomized, double-blind, placebo- and active-controlled study of the safety and efficacy of xxxx in patients with Diabetic Peripheral Neuropathic pain. (Protocol xxxx) Principal Investigator. 1/09 to 10/09
- 44 A double-blind, placebo-controlled study of xxxx (xxxx) as adjunctive therapy in Major Depressive Disorder. (Protocol xxxx) Sub-Investigator. 3/09 to 7/10

GlaxoSmithKline

- 45 A randomized, double-blind, parallel group study to investigate the efficacy and safety of treatment with xxxx (0.5mg) and xxxx (0.4mg), administered once daily for 4 years, alone and in combination on the improvement of symptoms and clinical outcome in men with moderate to severe symptomatic benign prostatic hyperplasia. (Protocol xxxx) Principal Investigator. 8/05 to 4/09
- 46 A multi-center, randomized, double-blind, double-dummy, parallel group, placebo-controlled study to investigate the efficacy, safety and tolerability of Oral xxxx capsules (2.5, 5, 10, 15 and 20 mg once a day) as monotherapy (diet and / or exercise treated) or as an add-on to Metformin for 16 weeks duration in subjects with Type 2 Diabetes Mellitus. (Protocol xxxx) Principal Investigator. 3/06 to 12/06
- 47 A randomized, double-blind, single migraine attack, placebo-controlled, parallel group, multi-center study to evaluate the efficacy and tolerability of xxxx (xxxx / xxxx) tablets vs placebo when administered during the mild pain phase of menstrual migraine in women with dysmenorrhea. (Protocol xxxx) Sub-Investigator. 3/06 to 12/06

Denny H. Lee, MD

Phone: (949) 753-1663

dlee@irvineclinical.com



2515 McCabe Way, Suite 350

Irvine, CA 92614

- 48 A Randomized, Double-Blind, Multi-Center, placebo-controlled, cross-over study to determine the consistency of response for xxxx (xxxx 85 mg / xxxx 500 mg) administered during the mild pain phase for the acute treatment of multiple migraine attacks. (Protocol xxxx) Sub-Investigator. 11/05 to 9/06
- 49 A Long-Term Safety Study of a Combination Product Containing xxxx and xxxx and for the Treatment of Migraine in Adolescents. (Protocol xxxx) Sub-Investigator. 10/07 to 3/09
- 50 A Randomized, Double-Blind, Multi-Center Study Comparing the Effects of xxxx Modified Release Formulation (xxxx) with xxxx (xxx-XL) on the Lipid Profile in Normolipidemic, or Mildly Dyslipidemic Hypertensive Patients. (Protocol xxxx) Principal Investigator. 5/06 to 6/08
- 51 A randomized, open-label, parallel-group, multicenter study to determine the efficacy and long term safety of xxxx compared with insulin subjects with Type 2 Diabetes Mellitus. (Protocol xxxx) Principal Investigator. 7/09 to 6/11
- 52 A randomized, double-blind, placebo-controlled, parallel-group, multicenter study to determined the efficacy and safety of xxxx when used in combination with xxxx with or without Metformin in subjects with Type 2 Diabetes Mellitus (Protocol xxxx) Principal Investigator. 7/09 to 6/11
- 53 A randomized, double-blind, placebo-controlled, parallel-group, multicenter study to determine the efficacy and safety of two dose levels of xxxx compared with placebo in subjects with Type 2 Diabetes Mellitus. Principal Investigator. 7/09 to 2/10
- 54 A Randomized, Open-Label, Parallel-Group, Multicenter Study to Determine the Efficacy and Safety of xxxx as Compared with xxxx in Subjects with Type 2 Diabetes Mellitus. (Protocol xxxx) Principal Investigator 7/10 to 1/12

Integrium

- 55 A randomized, double-blind, placebo-controlled study comparing the efficacy and safety of xxxx 75 mg bid to Placebo in patients with Stage I or Stage II Hypertension (xxxx study) Principal Investigator 2/07 to 5/07

Lilly

- 56 Long-Term Open-Label, Safety Study of xxxx HCL in Patients, 6 Years and Older, with Attention Deficit Disorder. (Protocol xxxx) Sub-Investigator. 8/05 to 3/08
- 57 A Randomized, Double-Blind Comparison of Placebo and xxxx Given Once a Day in Adults with Attention-Deficit/Hyperactivity Disorder: with a Secondary Examination of Impact of Treatment on Family Function. (Protocol xxxx) Sub-Investigator. 7/06 to 7/07
- 58 TRY FIRST: A 12-week, randomized, open-label trial of xxxx versus Generic SSRIs in the treatment of a severe Depressive episode (Protocol xxxx) Sub-Investigator. 3/08 to 6/09
- 59 A Double-Blind, Efficacy and Safety Study of xxxx versus Placebo in the Treatment of Children and Adolescents with Major Depressive Disorder. (Protocol xxxx) Sub-Investigator 3/10 to 12/11
- 60 A Study of xxxx in the Treatment of Men with Erectile Dysfunction. (Protocol xxxx) Principal Investigator. 11/10 to 1/12
- 61 A Randomized, Placebo-Controlled, Double-Blind Study of xxxx Fixed Dose 12 mg and 18 mg Once Daily as Adjunctive Treatment for Patients with Major Depressive Disorder Who Are Partial Responders to Selective xxxx Reuptake Inhibitor Treatment . (Protocol xxxx) Principal Investigator. 1/12 to 1/14
- 62 A Randomized, Double-Blind, Placebo-Controlled, Proof-of-Concept Study to Explore the Impact of Testosterone Solution 2% on Symptoms of Ejaculatory Dysfunction in Men with Testosterone Deficiency. (Protocol xxxx) Principal Investigator. 5/12 to 4/14
- 63 A Randomized, Double-Blind, Placebo-Controlled Parallel Study with an Open-Label Extension to Assess the Impact of Testosterone Solution on Total Testosterone, Sex Drive and Energy in Hypogonadal Men. (Protocol xxxx) Principal Investigator. 3/13 to 7/15
- 64 The Addition of Evacetrapib to Atorvastatin Compared to Placebo, High Intensity Atorvastatin with Exetimibe to Evaluate LDL-C Lowering in Patients with Primary Hyperlipedemia (Protocol xxxx) Principal Investigator. 9/14 to Present

Denny H. Lee, MD

Phone: (949) 753-1663
dlee@irvineclinical.com



2515 McCabe Way, Suite 350
Irvine, CA 92614

Merck & Co., Inc.

- 65 A Double-Blind, Randomized, Multi-Center, Placebo-Controlled, Parallel-Group Efficacy and safety extension study of xxxx 15 mg and 10 mg in the Treatment of Adult Outpatients with Primary Insomnia. (Protocol xxxx) Sub-Investigator. 8/05- to 10/06
- 66 A Phase IIa, multi-center, randomized, placebo-controlled clinical trial to study the safety and efficacy of xxxx for Migraine Prophylaxis in patients with episodic migraine. (Protocol xxxx) Sub-Investigator. 11/08 to 5/09
- 67 A Phase 3, Safety and Efficacy Study of xxxx/xxxx xxxx/xxxx in Chronic HCV Genotype 1 IL28BCC Subjects. (Protocol xxxx) Principal Investigator. 3/13 to 11/13

Novartis Pharmaceuticals Co.

- 68 A 52-week, international, multi-center, randomized, double-blind, double-dummy, parallel-group clinical trial to compare retention on treatment, safety, tolerability and efficacy of xxxx 100mg od, xxxx 100mg od and xxxx 200 mg od in patients with primary osteoarthritis of hip, knee, hand or spine. (Protocol xxxx) Principal Investigator. 8/05 to 7/06
- 69 An 8-week, randomized, double-blind, fixed dosage, placebo-controlled, parallel-group, multi-center study of the efficacy, safety and tolerability of xxxx 25 mg and 50 mg in the treatment of Major Depressive Disorder (MDD) followed by a 52-week, open-label extension. (Protocol xxxx and xxxxE) Sub-Investigator. 11/06 to 3/09
- 70 An 8-week, double-blind, multi-center, randomized, multi-factorial, placebo-controlled, parallel-group study to evaluate the efficacy and safety of xxxx administered alone and in combination with xxxx in patients with essential hypertension. (Protocol xxxx) Principal Investigator. 1/09 to 2/09
- 71 A multi-center, randomized, double-blind study to evaluate the efficacy and long-term safety of xxxx modified release (MR) as add-on therapy to metformin in patients with type 2 diabetes. (Protocol xxxx) Principal Investigator. 02/09 to 1/12

Ortho McNeal Neurologics, Inc.

- 72 Long-term, open-label safety study of oral xxxx 12.5 mg in the treatment of Migraine in adolescents. (Protocol xxxx) Sub-Investigator. 1/06 to 6/06

Otsuka Maryland Research Institute

- 73 xxxx Ophthalmic Suspension in the Treatment of Dry Eye: A Multi-center, Phase 3, Randomized, Double-Masked, Placebo-Controlled, Parallel-Group, 52-week Study. (Protocol xxxx) Sub-Investigator. 7/05 to 4/07
- 74 A Multicenter, Randomized, Double-Blind Study to Evaluate the Efficacy, Safety and Tolerability of an Oral xxxx/xxxx Combination Therapy in Patients With Major Depressive Disorder. (Protocol xxxx) Sub-Investigator. 7/10 to 2/12
- 75 A Multicenter, 52-week, Open-Label Study to Assess the Safety and Tolerability of an Oral xxxx/xxxx Combination Therapy in Patients With Major Depressive Disorder. (Protocol xxxx) Sub-Investigator. 8/10 to 2/12
- 76 A Phase 3, Multicenter, Randomized, Double-blind, Placebo and Active Comparator-controlled Trial of Flexible-dose xxxx (xxxx) as Adjunctive Therapy in the Treatment of Adults with Major Depressive Disorder. (Protocol xxxx) Sub-Investigator. 3/13 to present
- 77 A Long-term, Phase 3, Multicenter, Open-label Trial to Evaluate the Safety and Tolerability of Oral xxxx as Adjunctive Therapy in Adults with Major Depressive Disorder. (Protocol xxxx) Sub-Investigator. 4/13 to Present

Pfizer, Inc.

- 78 Prospective randomized evaluation of xxxx integrated safety vs. Ibuprofen or Naproxen – A Randomized, double-blind, parallel-group study of cardiovascular safety in osteoarthritis or rheumatoid arthritis

Denny H. Lee, MD

Phone: (949) 753-1663

dlee@irvineclinical.com



2515 McCabe Way, Suite 350

Irvine, CA 92614

patients with or at high risk for cardiovascular disease comparing xxxx with Naproxen and Ibuprofen. (Protocol xxxx) Principal Investigator. 11/06 to 6/07

79 An 8-week, Randomized, Phase 2, Double-Blind, Sequential, Parallel-Group, Comparison Study of Two Dose Levels of xxxx Compared to Placebo as an Adjunctive Treatment in Outpatients with Inadequate Response to Standard of Care for Generalized Anxiety Disorder. (Protocol xxxx) Sub- Investigator. 10/14 to present

80 A Phase 3 Randomized, Double-Blind, Placebo-Controlled Multicenter Study of the Analgesic Efficacy and Safety of a Dose Titration Regimen for the Subcutaneous Administration of XXXX in Subjects with Osteoarthritis of the Hip or Knee. (Protocol xxxx) Investigator. 4/2016 to Present

Procter & Gamble Pharmaceuticals Inc.

81 A Phase III multinational, Randomized, Double-Blind, Placebo-Controlled Multi-Center study to Evaluate the Efficacy and safety of transdermal xxxx 300 mcg/day for 24 weeks and safety for a further 28 week Open-label period in Women with hypoactive sexual desire disorder on concurrent estrogen replacement therapy who have undergone hysterectomy and bilateral oophorectomy. (Protocol xxxx) Sub-Investigator. 7/05 to 9/07

82 A randomized, double-blind, placebo-controlled, parallel-group, multi-center, 52-week study to evaluate the efficacy and safety of transdermal patches delivering 150 or 300 mcg/day xxxx in menopausal women with low libido not receiving systemic estrogen or estrogen progestin therapy. (Protocol xxxx) Sub-Investigator. 7/05 to 9/07

Daiichi Sankyo Pharma Development

83 A multi-center, randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of xxxx in type 2 diabetes with inadequate glycemic control on Sulphonylurea Monotherapy or Sulphonylurea therapy in combination with other oral anti-diabetic agents. (Protocol xxxx) Principal Investigator. 7/05 to 12/06

84 A multi-center, randomized, double-blind, placebo-controlled, parallel-group study of the efficacy and safety of xxxx in type 2 diabetes with inadequate Glycemic Control on Metformin Monotherapy or Metformin in combination with other oral anti-diabetic agents. (Protocol xxxx) Principal Investigator. 7/05 to 12/06

85 A multi-center, 52-week, open-label extension study to evaluate the long-term safety and tolerability of xxxx in type 2 diabetic patients. (Protocol xxxx) Principal Investigator. 7/05 to 12/06

86 A randomized, double-blind, placebo-controlled, parallel-group study of the efficacy and safety of xxxx as monotherapy for Type 2 Diabetes Mellitus. (Protocol xxxx) Principal Investigator. 2/09 to 6/11

Sanofi Aventis US Inc.

87 An eight-week, multi-center, randomized, double-blind, placebo-controlled study with xxxx as an active control, to evaluate the efficacy, safety and tolerability of a xxxx 100 mg dose once daily, in patients with Generalize Anxiety Disorder(Protocol xxxx) Sub-Investigator. 9/06 to 1/07

88 A multi-center, randomized, 24-52 week, double-blind, placebo-controlled study to evaluate the efficacy, safety and tolerability of xxxx 100 mg once daily in the prevention of relapse of depressive symptoms in out-patients with Major Depressive Disorder who achieved an initial response to 12 weeks of open-label treatment with xxxx 100 mg once daily dosing. (Protocol xxxx) Sub-Investigator. 12/05 to 5/08

89 A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, multi-center 12-week Study assessing the efficacy and safety of xxxx in patients with Type 2 Diabetes not treated with anti-diabetic agents. (Protocol xxxx) Principal Investigator. 8/08 to 12/09

90 A Randomized, Open-label, Active-Controlled, 2-arm Parallel-Group, multi-center 24-week Study followed by an extension assessing the efficacy and safety of xxxx versus xxxx on top of Metformin in patients with Type 2 Diabetes not adequately controlled with Metformin. (Protocol xxxx) Principal Investigator. 8/08 to 3/11

Denny H. Lee, MD

Phone: (949) 753-1663
dlee@irvineclinical.com



2515 McCabe Way, Suite 350
Irvine, CA 92614

- 91 A multi-center, Randomized, Placebo-Controlled, “factorial” design, 12-month Study to evaluate the efficacy and safety of xxxx 25 mg/day and 50 mg/day co-administered with all registered xxxx strengths ranging from 10 mg to 80 mg in patients with primary hypercholesterolemia. (Protocol xxxx) Principal Investigator. 8/08 to 6/09

Schering-Plough

- 92 A phase 2 randomized, double-blind, dose-response efficacy and safety study of xxxx compared to placebo in subjects with primary Hypercholesterolemia (familial and nonfamilial) or mixed hypercholesterolemia. (Protocol xxxx) Principal Investigator. 09/09 to 7/10

Sepracor Inc.

- 93 The efficacy of xxxx 3 mg as adjunctive therapy in subjects with insomnia related to Generalized Anxiety Disorder. (Protocol xxxx) Sub-Investigator. 8/05 to 11/06
- 94 Double-blind, randomized, placebo-controlled study examining the safety, efficacy and tolerability of xxxx in subjects with Major Depressive Disorder (including Atypical and Melancholic features). (Protocol xxxx) Sub-Investigator. 11/07 to 6/09.

Shire

- 95 A Phase 2, Multicenter, Double-blind, Paralled-group, Randomized, Placebo-controlled, Forced-dose Titration, Dose-ranging Efficacy and Safety Study of xxxx in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant. (Protocol xxxx) Sub-Investigator. 12/11 to 3/14
- 96 A Phase 3, Open-label Multicenter, 12-month Extension Safety and Tolerability Study of xxxx in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Residual Symptoms or Inadequate Response Followi9ng Treatment with an Antidepressant. (Protocol xxxx) Sub-Investigator. 12/11 to 5/14
- 97 A Phase 2, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Assess the Safety and Tolerability of xxxx in Subjects Aged 6-17 years with Generalized Anxiety Disorder (GAD), Separation Anxiety Disorder (SAD), or Social Phobia (SoP). (Protocol xxxx) Principal Investigator, 10/12 to 4/13

TAP Pharmaceuticals Inc.

- 98 A phase 3, open-label, randomized, Allopurinol-controlled study to assess the long-term safety of Oral xxxx in subjects with gout. (Protocol xxxx) Principal Investigator. 8/05 to 4/07
- 99 A Phase 3 Study to Evaluate the Efficacy and Safety of xxxx (60 mg QD and 90 mg QD) Compared to Placebo on Symptom Relief in Subjects with Symptomatic Non-Erosive Gastroesophageal Reflux Disease (GERD). (Protocol xxxx) Principal Investigator. 11/05 to 10/06
- 100 A Phase 3, Open-Label Study to Assess the Long-Term Safety of xxxx (60mg QD and 90mg QD). (Protocol xxxx) Principal Investigator. 11/05 to 10/06
- 101 A Phase 3 study to Evaluate the Efficacy and Safety of xxxx (60mg QD and 90 mg QD) and an Active Comparator, xxxx (30 mg QD) on Healing of Erosive Esophagitis. (Protocol xxxx) Principal Investigator. 11/05 to 3/07
- 102 A Phase 3 Study to Evaluate the Safety and Efficacy of xxxx (60mg QD and 90mg QD) Compared to Placebo in Maintenance of Healing in Subjects with Healed Erosive Esophagitis. (Protocol xxxx) Principal Investigator. 11/05 to 10/06
- 103 A Phase 3 Study to Evaluate the Safety and Efficacy of xxxx (30 mg QD and 60 mg QD) Compared to Placebo in Maintenance of Healing in Subjects with Healed Erosive Esophagitis. (Protocol xxxx) Principal Investigator. 4/06 to 3/07
- 104 A Phase 3 Study to Evaluate Efficacy and Safety of xxxx (30 mg QD and 60 mg QD) Compared to Placebo on Symptom Relief in Subjects with Symptomatic Non-Erosive Gastroesophageal Reflux Disease. (Protocol xxxx) Principal Investigator. 4/06 to 3/07

Denny H. Lee, MD

Phone: (949) 753-1663

dlee@irvineclinical.com



2515 McCabe Way, Suite 350

Irvine, CA 92614

105 A Phase III, Randomized, Multi-center, Double-blind, Allopurinol-controlled Study Assessing the Efficacy and Safety of Oral xxxx in Subjects with Gout. (Protocol xxxx) Principal Investigator. 12/06 to 4/08.

Takeda Global Research & Development Center, Inc.

106 A multi-center, randomized, double-blind, placebo-controlled study to determine the efficacy and safety of the combination of xxxx (xxxx) and Pioglitazone HCL (Actos) in subjects with Type 2 Diabetes. (Protocol xxxx) Principal Investigator. 4/06 to 11/07

107 A multi-center, double-blind study to determine the efficacy and safety of the combination of xxxx plus Pioglitazone HCL (Actos), SYR-322 alone or Pioglitazone HCL alone in subjects with Type 2 Diabetes. (Protocol xxxx) Principal Investigator. 4/06 to 4/08

108 A long-term, open-label extension study to investigate the durability of response and long-term safety of xxxx (xxxx) in subjects with Type 2 Diabetes. (Protocol xxxx) Principal Investigator. 4/06 to 3/09

109 A randomized, double-blind, placebo-controlled, parallel group study to demonstrate the subjective treatment effects of xxxx on sleep using a post-sleep questionnaire-interactive voice response system (PSQ-IVRS) in an "at-home setting" in an adult population with chronic insomnia. (Protocol xxxx) Sub-Investigator. 4/07 to 9/07

110 A randomized, double-blind, parallel-group, placebo-controlled, active-referenced, fixed-dose study comparing the efficacy and safety of 2 doses of xxxx in acute treatment of adults with Major Depressive Disorder. (Protocol xxxx) Sub-Investigator. 4/08 to 3/10

111 A long-term, open-label, flexible-dose, extension study evaluating the efficacy and safety of xxxx in acute treatment of adults with Major Depressive Disorder. (Protocol xxxx) Sub-Investigator. 4/08 to 7/09

112 A randomized, double-blind, parallel-group, placebo-controlled, fixed-dose study comparing the efficacy and safety of single dose of xxxx in acute treatment of adults with Generalized Anxiety Disorder. (Protocol xxxx) Sub-Investigator. 5/08 to 7/09

113 A phase 3, double-blind, randomized, factorial, efficacy and safety study of xxxx plus xxxx fixed-dose combination in subjects with moderate to severe Hypertension (Protocol xxxx) Principal Investigator. 1/09 to 6/10

114 A Multicenter, Randomized, Double-Blind, Phase 2 Study to Evaluate the Effect of xxxx versus Placebo on Renal Function in Gout Subjects with Hyperuricemia and Moderate to Severe Renal Impairment. (Protocol xxxx) Principal Investigator. 2/10 to 2/12

115 A Multicenter, Randomized, Double-Blind, Phase 2 Study to Evaluate the Effect of xxxx versus Placebo in Joint Damage in Hyperuricemic Subjects with Early Gout. (Protocol xxxx) Principal Investigator. 2/10 to 12/13

116 A Multicenter, Randomized, Active-Control, Phase 3B Study to Evaluate the Cardiovascular Safety of xxxx and xxxx in Subjects With Gout and Cardiovascular Comorbidities. (Protocol xxxx) Principal Investigator. 4/10 to Present

117 A Phase 3, Randomized, Double-Blind, Parallel-Group, Placebo Controlled, Fixed-Dose Study Comparing the Efficacy and Safety of 2 Doses (10 and 20 mg) of xxxx in Acute Treatment of Adults with Major Depressive Disorder. (Protocol xxxx) Sub-Investigator. 7/10 to 4/12

118 A Phase 3, Long-Term, Open-Label, Flexible-Dose, Extension Study Evaluating the Safety and Tolerability of xxxx (15 and 20 mg) in Subjects With Major Depressive Disorder. (Protocol xxxx) Sub-Investigator. 8/10 to 9/13

119 A Phase 2, Randomized, Placebo-Controlled, Factorial, Double-Blind, Double-Dummy, Parallel-Group, Multicenter Study to Determine the Efficacy and Safety of 25 mg and 50 mg of xxxx in Combination with xxxx 100 mg in Subjects with Type 2 Diabetes Mellitus. (Protocol xxx) Principal Investigator. 7/11 to 11/12

Denny H. Lee, MD

Phone: (949) 753-1663

dlee@irvineclinical.com



2515 McCabe Way, Suite 350

Irvine, CA 92614

- 120 A Phase 2, Double-Blind, Placebo-Controlled Study to Assess the Effect of xxxx 80 mg Once Daily Compared to Placebo on Ambulatory Blood Pressure in Subjects with Hyperuricemia and Hypertension. (Protocol xxxx) Principal Investigator. 2/12 to 10/14
- 121 A Phase 3, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, xxxx-Referenced, Fixed-Dose Study Comparing the Efficacy and Safety of 2 Doses (15 and 20 mg) of xxxx in Acute Treatment of Adults with Major Depressive Disorder. (Protocol xxxx) Sub-Investigator. 11/11 to 4/12
- 122 A Randomized, Double-Blind, Parallel-Group, Active-Controlled, Flexible-Dose Study Evaluating the Effect of xxxx vs xxxx on Sexual Functioning in Adults With Well-Treated Major Depressive Disorder Experiencing Selective xxxx Reuptake Inhibitor–Induced Sexual Dysfunction. (Protocol xxxx) Sub-Investigator. 5/11 to 2/14
- 123 A Phase 3, Randomized, Double Blind, Multicenter, Placebo Controlled Study to Evaluate the Efficacy and Safety of xxxx 40mg XR, 80 mg XR, 40 mg IR and 80 mg IR in Subjects with Gout. (Protocol xxxx) Sub-Investigator. 4/2014 to present
- 124 A Phase 2, Randomized, Double Blind, Multicenter, Placebo Controlled Study to Evaluate the Efficacy and Safety of xxxx 40 mg XR, 80 mg XR, 40 mg IR and 80 mg IR in Subjects with Gout and Moderate Renal Impairment. (Protocol xxxx) Sub-Investigator. 12/2014 to present

Teva Women’s Health Research

- 125 A multicenter, open-label study to evaluate the efficacy and safety of a combination oral contraception regimen (xxxx) for the prevention of pregnancy in women. (Protocol xxxx)Sub-Investigator. 09/09 to 12/11

Tioga Pharmaceutical

- 126 A 12-Week, Randomized, Double-Blind, Dose-Ranging, Placebo-Controlled Study of xxxx in Subjects with Irritable Bowel Syndrome. (Protocol xxxx) Principal Investigator. 3/06 to 10/07

Transcept Pharmaceuticals inc.

- 127 A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of Efficacy and Safety of xxxx Lozenge in Adult Subjects with Insomnia Characterized by Difficulty Returning to Sleep after Awakening in the Middle-of-the-Night (MOTN). (Protocol xxxx) Sub-Investigator. 4/07 to 12/07

Vivus Inc.

- 128 A double-blind, randomized, 6-month evaluation of the safety and efficacy of topical xxxx in hysterectomized women with female sexual arousal disorder (Protocol xxxx) Sub-Investigator. 8/05 to 9/06

Watson Laboratories Inc.

- 129 A multi-center, randomized, double-blind, placebo-controlled, parallel evaluation of the efficacy and safety of xxxx in the treatment of the signs and symptoms of benign prostatic hyperplasia. (Protocol xxxx) Principal Investigator. 8/05 to 6/06

Wyeth Research

- 130 A Multicenter, Randomized, 8-Week Double-Blind Acute Phase Followed by a 6-Month Continuation Phase (Open-Label or Double-Blind) Study to Evaluate the Efficacy, Safety, and Tolerability of xxxx versus xxxx in Postmenopausal Women with Major Depressive Disorder. (Protocol xxxx) Sub-Investigator. 8/07 to 4/08