

Mira Baron, MD

Curriculum Vitae

Mira Baron MD
11/11/2011.

Palm Beach Research Center
1897 Palm Beach Lakes Blvd.
Suite 120
West Palm Beach, FL 33409
(561) 689-0606

EDUCATION	Doctor of Medicine University of Lvov Ukraine	1964-1970
LICENSURE	Ohio Medical License Florida Medical License	35-046478 ME 81958
CERTIFICATION	The International Society for Clinical Densitometry	October 2001
	Certified Principal Investigator (ACRP)	September 2009
QUESTIONNAIRE RATER TRAINING & EXPERIENCE	1. MINI 2. HAMD-17 3. SIGH-A	4. BDI 5. SIG-MA 6. BARS
11/3/2011 11/5/2011 11/10/2011	CITI Basic Training Ref#: 6929938 CITI GCP Training Ref#: 6929939 NIH Training Certification Number: 799212	
RESEARCH AFFILIATION	Investigator Palm Beach Research Center 1897 Palm Beach Lakes Blvd, Suite 120 West Palm Beach, Florida 33409	11/2011 - Current
	Medical Director Rapid Medical Research, Inc. 3619 Park East Drive, Suite 109 Cleveland, Ohio 44122	10/2006 – 9/2011
	Associate Medical Director Rapid Medical Research, Inc. 3619 Park East Drive, Suite 109 Cleveland, Ohio 44122	2000-10/2006

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PROFESSIONAL EXPERIENCE

Internal Medicine Practice (group practice) 26900 Cedar Road Beachwood, Ohio 44122	1999-2000
Primary Care Group (3 physician practice) 29001 Cedar Road Cleveland, Ohio 44124	1993-1999
Mira Baron, M.D., Inc. Solo practice : Internal Medicine 5 Severence Circle Cleveland Heights, Ohio 44118	1984-1993
Associate in a private practice 2460 Fairmount Blvd. Cleveland, Ohio 44106	1982-1984
Internal Medicine staff physician General City Hospital Lvov, Ukraine	1970-1976

POST GRADUATE TRAINING:

INTERNSHIP & RESIDENCY

Internal Medicine Mt. Sinai Medical Center Cleveland, Ohio	1979-1982
Visiting Fellowship Department of Allergy and Immunology Cleveland Clinic Foundation Cleveland, Ohio	1981-1982

PREVIOUS APPOINTMENTS

Clinical Instructor : Internal Medicine Medical Residency Program Mt. Sinai Medical Center Cleveland, Ohio	1982-1999
Clinical Instructor : Internal Medicine Medical Students Mt. Sinai Medical Center Cleveland, Ohio	1982-1999

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MEMBERSHIPS

American Medical Association 1982-Present

Academy of Medicine 1982-1998

COMMITTEES

Quality Assurance Committee 1993-1999
Mt. Sinai Medical Center
Cleveland, Ohio

Peer Review 1987-1989
Mt. Sinai Medical Center
Cleveland, Ohio

SPECIAL INTERESTS

1. Allergy and Immunology
2. Preventive Medicine
3. Women's Wellness
4. Hormone Replacement Therapy
5. Prevention of Osteoporosis
6. CAD in Women
7. Breast Cancer Prevention
8. Colon Cancer Prevention

PUBLICATIONS

Mira Baron, MD, Original Research: "A Patented Strain of Bacillus coagulans Increased Immune Response to Viral Challenge", Postgraduate Medicine, Volume 121. Issue 2, March 2009. ISSN-0032-5481. e-ISSN – 1941-9260

Mark H. Einstein, M.D., M.S.; Mira Baron; Myron Levin; Archana Chatterjee; Robert Edwards; Fred Zepp; Isabelle Carletti; Francis Dessy; Andrew Trofa; Anne Schuind; Gary Dubin. "Comparison of the Immunogenicity and Safety of Cervaris™ and Gardasil® Human Papillomavirus (HPV) Cervical Cancer Vaccines in Healthy Women Aged 18-45 Years". 2009

Labrie, F., Archer, D., Bouchard, C., Fortier, M., Cusan, L., Gomez, J-L., Girard, G., Baron, M., Ayotte, N., Moreau, M., Berger, L., Lavoie, L., Cote, I., Labrie, C., Dube, R., Balser, J. "Intravaginal DHEA, The Physiological Treatment of Vaginal Atrophy". EndoCeutics, Inc. July 2008

Einstein, M., Baron, M., Levin, M., Chatterjee, A., Edwards, R., Zepp, F., Carletti, I., Dessy, F., Trofa, A., Dubin, G., Schuind, A. "Immunogenicity and Safety of Cervarix™ and Gardasil™ Human Papillomavirus (HPV) Vaccines in Healthy Women Aged 18-45 Years; Results of an Observer-Blind, Randomized, Comparative Trial". Article, Nature Magazine

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CLINICAL TRIALS

Eli Lilly

Intermittent Dosing of XXX in the Treatment of Premenstrual Dysphoric Disorder: Luteal Phase Dosing

Eli Lilly

Pharmacological Treatment of XXX-Associated Sexual Dysfunction

Berlex Laboratories

A Multicentered Comparison of Continuous Transdermal XXX Combinations, Examining the Effect on the Endometrium, Bleeding Patterns in Previously Randomized Postmenopausal Women Who Have Completed 13 Cycles (1Year) of XXX Hormone Replacement Therapy

Endeavor Pharmaceuticals, Inc.

A Randomized, Double-Blind, Dose-Ranging, Parallel-Group Study to Compare the Safety and Efficacy of Synthetic 10-Component Conjugated Estrogens (XXX) (X.X, X.XXX, and X.XXmg Modified Release) with Placebo in Postmenopausal Women Suffering from Moderate to Severe Vasomotor Symptoms

Endeavor Pharmaceuticals, Inc.

A Randomized, Parallel-Group, 12 Week Study Comparing Bleeding Patterns Following the Administration of X mg of a Marketed Conjugated Estrogen Product in Combination with 2 Different Dose Combinations of a Marketed Progestin Product in Postmenopausal Women

Endeavor Pharmaceuticals, Inc.

A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of 3 Doses of Synthetic 10-Component Conjugated Estrogens (XXX) X.Xmg, X.XXmg, and X.XXX mg Modified Release Tablets) Compared to Placebo in Hysterectomized Postmenopausal Women for the Prevention of Osteoporosis

3-M

Principal Investigator

A Phase III, Randomized, Double-Blind Study of Topical XXX With and Without Anti-HSV Nucleoside Versus a Vehicle/Placebo Arm for the Treatment of Herpes Genitalis to Prevent Subsequent Recurrences

Barr Laboratories, Inc.

A Phase III, Parallel, Randomized, Multicenter, Open-Label Clinical Study to Evaluate the Efficacy and Safety of XXX Extended Oral Contraceptive Therapy- 84-Day Active Cycle

Barr Laboratories, Inc.

A Phase III/IV Extension- A Phase III, Parallel, Randomized, Multicenter, Open-Label Clinical Study to Evaluate the Efficacy and Safety of XXX Extended Oral Contraceptive Therapy- 84-Day Active Cycle

Berlex Laboratories, Inc.

A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy of a Monophasic Oral Contraceptive Preparation Containing XXX Xmg XXX XXg (as XXX), in the Treatment of Premenstrual Dysphoric Disorder (PMDD)

Berlex Laboratories, Inc.

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

Berlex Laboratories, Inc.

A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Effect of a Continuously Combined HRT Preparation Containing Xmg XXX and X mg XXX on Blood Pressure in Mildly Hypertensive Postmenopausal Women

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Bristol-Myers Squibb

A Randomized, Double-Blind, Dose Ranging, Dose Comparison-Controlled Trial to Determine the Safety and Efficacy of XXX in Subjects with Type 2 Diabetes

Bristol-Myers Squibb

Principal Investigator

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

Byk Gulden Pharmaceuticals

Principal Investigator

12 Weeks Treatment with XXX μ g XXX Versus XXX μ g XXX Versus Placebo in Patients with Asthma

Duramed Pharmaceuticals, Inc.

A Double-Blind, Randomized, Placebo-Controlled, Multicenter Trial to Demonstrate the Efficacy of 12 Weeks of Treatment with X.XX mg Synthetic Conjugated Estrogens, a (XX) on Vasomotor Symptoms in

Duramed Pharmaceuticals, Inc.

A Comparison of the Effects of XX and XX Versus XX on Brachial Artery Blood Flow Response

Forest Laboratories, Inc.

Principal Investigator

A 52-Week, Open-Label, Multicenter, Study of the Long-Term Safety and Efficacy of XXX XMG T.I.D. in Patients with Constipation-Predominant and Alternating-Type Irritable Bowel Syndrome

Forest Laboratories, Inc.

Principal Investigator

An Open-Label Extension of Study XXX to Investigate the Long-Term Safety and Efficacy of XXX XMG T.I.D. in Female Patients with Constipation-Predominant Irritable Bowel Syndrome

Forest Laboratories, Inc.

Principal Investigator

A 16 Week, Randomized, Double-Blind, Placebo-Controlled, Flexible-Dose, Parallel-Group, Multicenter Study with a Withdrawal Phase to Investigate the Safety and Efficacy of XXX XMG T.I.D. or XXMG B.I.D. in Female Patients with Constipation-Predominant Irritable Bowel Syndrome

Forest Laboratories, Inc.

Principal Investigator

A 52-Week, Open-Label, Multicenter Study of the Safety and Efficacy of XXX XMG T.I.D. in Patients with Constipation-Predominant and Alternating-Type Irritable Bowel Syndrome

Eli Lilly

Principal Investigator

Evaluation of the Dose Response Relationship of XXX on Fasting and Postprandial Blood Glucose and Tolerability in Patients with Type 2 Diabetes

Eli Lilly

Sequential Use of XXX and XXX in the Treatment of Postmenopausal Women with Osteoporosis

Eli Lilly

Study of Vasomotor Symptoms in Postmenopausal Women Receiving Combination XXX and Oral Estrogen

Eli Lilly

Principal Investigator

A Randomized, Double-Blind, 4-Week, 2 Period, Crossover Study to Evaluate Patient Preference for XX (X) Versus XXX During the Initial Treatment Period for Erectile Dysfunction

Eli Lilly

Principal Investigator

A Randomized, Double-Blind, 12-Week, 2 Period, Crossover Study to Evaluate Patient Preference for XX (X) Versus XXX During the Initial Treatment Period for Erectile Dysfunction

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Eli Lilly

Principal Investigator

Long Term Monitoring of Safety in Subjects Treated with XXX for Stress Urinary Incontinence

Eli Lilly

Principal Investigator

XXX Versus Placebo in the Treatment of Fibromyalgia Patients With or Without Major Depressive Disorder

Eli Lilly

XXX Comparison in Postmenopausal Women with Osteoporosis

MacroChem

Principal Investigator

A Randomized, Double-Blind, Placebo-Controlled, Dose-Finding Study of XX (Topical Gel Formulation of XXX and XX) For the Treatment of Male Erectile Dysfunction in an At-Home Setting

MacroChem

Principal Investigator

An Open-Label Continuation Trial of XX (Topical Gel Formulation of XXX and XX) In Male ED Patients Who Previously Participated In MacroChem Study XXX

Novo Nordisk

Principal Investigator

XXX XX-XXXX in Type 2 Diabetic Subjects: a 52 Week Double-blind, Parallel, Active-Controlled (Diabeta7 and Glucophage7) Study (Followed by a 52-Week Open-Label Extension) to Investigate Safety and Efficacy

Novo Nordisk

Principal Investigator

XXX XX-XXXX in Type 2 Hypertriglyceridemic Diabetic Subjects: a 12 Week Double-blind, Parallel, Placebo-Controlled Dose-Ranging Study with an Open XXX Arm to Investigate Safety and Efficacy

Novartis Pharmaceutical Corporation

Principal Investigator

A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XXX in the Treatment of Osteoporosis in Postmenopausal Women Taking Calcium and Vitamin D

Organon, Inc.

A Multinational, Multicenter, Randomized, Double-blind, Parallel-Group, Active Controlled, Comparative Trial to Assess the Endometrial Histological Profile Following Treatment with XXX (XX) Versus Conjugated Estrogen (CE) Plus Medroxyprogesterone Acetate (MPA) in Postmenopausal Women

Organon, Inc.

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Study of XXX in Women with Dysmenorrhea

Pfizer

A Double-Blind, Placebo-Controlled, Parallel Group Design Dose-Ranging Study of 3 Doses of XXX Versus Placebo for the Treatment of Sexual Dysfunction (Hypoactive Desire) in Postmenopausal Women

Pfizer

A Double-Blind, Placebo-Controlled, Parallel Group Design Dose Ranging Study of 3 Doses of XXX Versus Placebo for the Treatment of Sexual Dysfunction (Arousal Disorder) in Postmenopausal Women

Pfizer

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

Parke-Davis

A 12-Week, Randomized, Partially-Blinded, Active and Placebo-Controlled, Multicenter Study Assessing the Effect of XXX (XX) Plus XXX (XX) on Endothelial Dysfunction in Postmenopausal Women

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Pharmacia

Principal Investigator

A Multicenter, Randomized, Double-Blind, Parallel Group, Multiple Dose Comparison Study of XXX Xmg, XXX Xmg, XXX Xmg and Placebo in Patients with Moderate or Severe Acute Migraine Headache

Pharmacia

Principal Investigator

Clinical Protocol for a Multicenter Randomized, Double-Blind, Placebo-Controlled, Multiple Dose, Assessment of the Bone Resorption Activity of XXX XMG QD, XXX XMG QD, XXX XMG QD and XXX XMG QD, and Placebo in Women with Osteopenia

Pharmacia

Principal Investigator

A Phase III Multicenter, Randomized, Double-Blind, Parallel-Group Study of XXX Xmg, XXX Xmg and Placebo in Patients with Multiple Moderate or Severe Acute Migraine Headaches

Procter & Gamble

A Phase III, Multinational, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study to Evaluate Efficacy and Safety of Transdermal XXX (Xµg/day) for 24 Weeks and Safety for a Further 28-Week Open-Label Period in Women with Hypoactive Sexual Desire Disorder on Current Estrogen Replacement Therapy Who Have Undergone Hysterectomy and Bilateral Oophorectomy

Procter & Gamble

A Phase III, Multinational, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study to Evaluate Efficacy and Safety of Transdermal XXX (Xµg/day) for 24 Weeks and Safety for a Further 28-Week Open-Label Period in Naturally Menopausal Women with Hypoactive Sexual Desire Disorder on Concurrent Oral Hormone Replacement Therapy

Hoffmann-LaRoche

Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety of a Partial Alpha [IA/IL]-Adrenoceptor Agonist, XXX, in Women with Stress Urinary Incontinence or Mixed Urinary Incontinence

Hoffmann-LaRoche

Open-Label Extension for Treatment of Incontinent Patients Who Have Completed an XXX Study

Dimethaid Health Care Ltd

Principal Investigator

A Double-Blinded, Drug Controlled, Two-Way Parallel Clinical Trial to Confirm the Safety and Efficacy of XXX Topical Lotion in the Treatment of the Osteoarthritic Knee

Sepracor, Inc.

Principal Investigator

A Randomized, Double-Blind, Placebo-Controlled and Open-Label 12 Month Study of the Safety of (X)-XX in Adult Subjects with Insomnia

Parke-Davis/Pfizer

Beyond Endorsed Lipid Lowering with EBT Scanning (XXX)

Parke-Davis/Pfizer

A 20-Week Open-label Assessment of the Safety and Efficacy Profile of XXX When used to Optimally Control Dyslipidemia in Postmenopausal Patients (XXXX)

TAP Pharmaceutical Products, Inc.

A 12-Week Safety and Efficacy Study of Oral XXXXXXXX Versus Placebo in Subjects with Overactive Bladder

TAP Pharmaceutical Products, Inc.

A 52-Week Extension Study to Evaluate Long-Term Safety of Oral XXX in Subjects with Overactive Bladder

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Curriculum Vitae

Wyeth-Ayerst

A Double-Blind, Randomized, Placebo-and-Active-Controlled Safety and Efficacy Study of XXX Combinations in Postmenopausal Women

Wyeth-Ayerst

Fracture Incidence Reduction and Safety of XXX (XX) Compared to Placebo and XXX in Osteoporotic Postmenopausal Women

Wyeth-Ayerst

A Pilot Study of the Effect of Hormone Replacement Therapy in Recently Postmenopausal Women with Subjective Cognitive Complaints

Wyeth-Ayerst

A Double-Blind, Randomized, Placebo and Historical-Controlled Study of the Safety and Efficacy of XX for Postmenopausal Hormone Replacement Therapy

Wyeth-Ayerst

A Randomized, Double-Blind, Parallel, Multicenter Study to Evaluate the Effects on Cycle Control of 3 XX Regimens Versus an Open-Label XXX Treatment Arm

Wyeth-Ayerst

A Double-Blind, Placebo-Controlled, Randomized Trial of XXX on Serum Free Testosterone Concentrations in Healthy, Postmenopausal Women

Yamanouchi USA, Inc.

An Open-Label, Long-Term Tolerability Study of Daily Oral Administration of XMG (XXX) in Male and Female Subjects with Overactive Bladder

Yamanouchi USA, Inc

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose, Multicenter Study to Assess the Efficacy and Safety of Daily Oral Administration of XX mg XXXXX Versus Placebo in Male and Female Subjects with Overactive Bladder

Bristol-Myers Squibb

XXX Cardiovascular Treatment Assessment Versus XXX (XX)

Personal Products Company

Dose Ranging Study with Three Doses of a XXX Vaginal Suppository (CVS) Compared to XXX X Vaginal Cream XXX in the Treatment of Vulvovaginal Candidiasis

Novavax, Inc.

Evaluation of Daily Dose of XXX XMG Compared to Placebo in the Treatment of Symptomatic Post-Menopausal Women

Procter & Gamble

A Nonrandomized, Parallel-Group, Multicenter Validation Study of the Profile of Female Sexual Function⁸ and the Sexual Activity Log⁸ in Naturally and Surgically Menopausal Women with Low Libido, Compared with a Normal Libido Control Group

Bristol-Myers Squibb

A Multicenter, Randomized, Double-Blind, Active Control Trial to Evaluate the Safety and Efficacy of XXX Product as First Line Therapy in Patients with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control with Diet and Exercise

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Bristol-Myers Squibb

A Multicenter, Randomized, Double-Blind Clinical Trial Comparing the Safety and Efficacy of XXX Tablets to XXX Plus XXX Therapy in Patients with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control with XXX Monotherapy

Galen Ltd.

A Double-Blind, Randomized, Placebo-Controlled Clinical Trial in Postmenopausal Women to Demonstrate the Efficacy on Intravaginal Rings Releasing XXX with Respect to Postmenopausal Vasomotor Symptoms

Eli Lilly

Efficacy and Safety of AOn Demand@ Therapy with XXX (XX) Compared with Placebo in Subjects with Female Sexual Arousal Disorder

Solvay Pharmaceuticals, Inc.

Double-Blind Investigation of the Efficacy and Safety of Continuous Transdermal X% XXX in Combination with XXX Compared with Continuous Transdermal X% XXX Alone for the Prevention of Endometrial Hyperplasia in Postmenopausal Women

Solvay Pharmaceuticals, Inc.

Multicenter Efficacy Study Comparing XXX, a Once a Week XXX Combination Transdermal System (XXcm⁵ X% XXX/X% XXX TDS, XXcm⁵ X% XXX/X.XX% XXX TDS), with Placebo in the Treatment of Vasomotor Symptoms Associated with Menopause

Wyeth-Ayerst

A Prospective, Double Blind, Randomized Study of the Safety and Efficacy of Lower Doses of XXX and XXX in Postmenopausal Women

Amylin Pharmaceuticals, Inc.

Principal Investigator

A Phase 3, Randomized, Triple-Blind, Placebo-Controlled, Multicenter Study to Examine the Effect of Glucose Control (HbA_{1c}) of XXX Given Two Times a Day for 26 Weeks in Subjects With Type 2 Diabetes Mellitis Treated With Metformin Alone

Amylin Pharmaceuticals, Inc.

Principal Investigator

A Phase 3, Randomized, Triple-Blind, Long-Term, Placebo-Controlled, Multicenter Study to Examine the Effect of Glucose Control (HbA_{1c}) of XX Given Two Times a Day in Subjects With Type 2 Diabetes Mellitis Treated With Sulfonylurea Alone

Amylin Pharmaceuticals, Inc.

Principal Investigator

An Open-Label Extension of Protocol 2993-1133 to Examine the Long-Term Effect on Glucose Control (HbA_{1c}) and Safety and Tolerability of XXX Given Two Times a Day to Subjects Treated With Sulfonylurea Alone

Pharmacia

Principal Investigator

Open-Label, Long-Term Multi-Center Study of Safety and Tolerability of XXX XXmg in the Acute Treatment of Migraines in Adults

Eli Lilly

Principal Investigator

A Randomized, Double-Blind, Parallel, Placebo-Controlled Study in Men with Erectile Dysfunction to Evaluate the Efficacy and Safety of XXX When Sexual Attempts Occur at Specific Time Points After Dosing

Indevus Pharmaceuticals

Principal Investigator

A Double-Blind, Placebo Controlled Study of Urinary Frequency and Urgency Using XXX, 20 mg Tablets, Twice Daily, for 12 Weeks Followed by a 6- Month Open Label Treatment Phase in Patients with Overactive Bladder

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GlaxoSmithKline

Principal Investigator

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study Evaluating the Efficacy, Safety, and Reliability of 10mg XXX Administered for 12 Weeks Compared to Placebo in Subjects with Erectile Dysfunction and a Demonstrated Successful First Response to 10mg XXX

GlaxoSmithKline

Principal Investigator

An Open Label, Randomized Study to Evaluate the Safety of 4 mg XXX Lozenges in Comparison with 4 mg XXX Gum in Smokers with Certain Underlying Disease Restrictions Specified in the Label

Galen Ltd.

A Multicenter, Double-Blind, Controlled, Randomized Study to Compare the Efficacy in Relief of Hot Flashes in Women Receiving Oral XXX Acetate Tablets, Oral XXX Tablets or Oral Conjugated XXX

Barr Laboratories

Phase IIIB, Multicenter, Double-Blind Clinical Study to Evaluate the Safety and Tolerability of XXX Following a Run-In of XXX Extended Regimen Oral Contraceptive Therapy

Wyeth

A Phase 3, Multicenter, Open-Label, Study to Evaluate the Safety and Efficacy of XXX 90ug and XXX 20ug in a Continuous Daily Regimen for Oral Contraception

Pharmacia

Principal Investigator

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

Novartis

Principal Investigator

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Comparing XXX 150mg, 300mg, and 600 mg to Placebo and XXX 150 mg in Patients with Mild to Moderate Essential Hypertension

Neurocrine Biosciences

Principal Investigator

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

Neurocrine Biosciences

Principal Investigator

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

Neurocrine Biosciences

Principal Investigator

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

Neurocrine Biosciences

Principal Investigator

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

Solvay Pharmaceuticals

Principal Investigator

A Double-Blind, Placebo-Controlled, Randomized, Multicenter Study to Investigate the Safety and Efficacy of 2mg tid of XXX Over 12 Weeks in Diarrhea-Predominant Irritable Bowel Syndrome Subjects

Solvay Pharmaceuticals

Principal Investigator

An Open-Label, Multicenter Extension Study to Investigate the Long-Term Safety of 2mg tid of XXX in Diarrhea-Predominant Irritable Bowel Syndrome Subjects

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Eli/Lilly

Principal Investigator

A Non-Drug Study to Follow Patients who Participated in XXX

Barr Research

A Double-Blinded, Randomized, Parallel, Placebo-Controlled, Multicenter Trial to Compare the Effects of 12 Weeks of Treatment With Daily or Twice Weekly Doses of XXX Vaginal Cream Versus Daily Doses of XXX Cream on Vulvovaginal Atrophy in Healthy Postmenopausal Women

Novartis

Principal Investigator

A Randomized, Double-Blind, Multicenter, Multifactorial, Placebo-Controlled, Parallel-Group Study to Confirm the Efficacy and Safety of XXX Monotherapy, and Evaluate Efficacy and Safety of Combinations of XXX and XXX in Hypertensive Patients

ALZA Corporation

Principal Investigator

A Placebo-Controlled, Double-Blind, Randomized, Parallel Study of the Efficacy and Safety of XXX in the Treatment of Rapid Ejaculation

ALZA Corporation

Principal Investigator

An Open Label Study of the Long-Term Safety of XXX XXX in the Treatment of Rapid Ejaculation

Berlex Laboratories, Inc.

Principal Investigator

A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Study Comparing 3 Continuous Oral Angeliq[®] (XX X mg/XXX Xmg, XX Xmg/XXX Xmg, XXX Xmg/XXX Xmg) Combinations and XXX (Xmg) with Placebo for a Treatment Period of 8 Weeks on Ambulatory and Office Cuff Blood Pressure in Postmenopausal Women with Stage I or Stage 2 Essential Hypertension

BioSante Pharmaceuticals

A Phase III, multi-Center, Double-Blind Study of the safety and Efficacy of XXX (Topical XX Gel) Versus Placebo for Treatment of Vasomotor Symptoms and Vulvovaginal Atrophy in Postmenopausal Females

Cypress Bioscience Inc.

Principal Investigator

A Phase III Pivotal, Multi-Center, Double-Blind, Randomized, Placebo-Controlled Monotherapy Study of XXX for Treatment of Fibromyalgia

Eli Lilly

Effects of XXX on Bone Mineral Density and Endometrial Histology in Postmenopausal Women

Pfizer

A Phase 3 Study of the Efficacy and Safety of XXX in the Treatment of Vaginal Atrophy in Postmenopausal Women

Sepracor, Inc.

Principal Investigator

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

Sepracor, Inc.

Principal Investigator

The Efficacy of XXX Xmg Compared to Placebo in the Treatment of Insomnia Secondary to Perimenopause or Menopause

Wyeth Research

A Phase 3, Multicenter Study to Evaluate the Return to Spontaneous Menses for Subjects Receiving Prior Treatment with a Continuous Daily Regimen of XXX and XXX for Oral Contraception

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GlaxoSmithKline

Principal Investigator

A randomized, double-blind, crossover study to evaluate the duration of erection following XXX (XXmg) administration for 4 weeks in a fixed-dose regimen compared to placebo in males with ED.

Sankyo Pharma Development

Principal Investigator

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of the Efficacy and Safety of XX® in Type 2 Diabetics with Inadequate Glycemic Control on XXX Monotherapy

Sankyo Pharma Development

Principal Investigator

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of XX® in Type 2 Diabetics with Inadequate Glycemic Control on XXX Monotherapy or XXX Therapy in Combination with Other Oral Anti-Diabetic Agents

Novartis

Principal Investigator

A 12-Week, Randomized, Double-Blind, Multi-Center, Vehicle-Controlled, Parallel Group Study to Assess the Efficacy and Safety of the XXX, 1% for the Relief of Signs and Symptoms in Patients with Osteoarthritis of the Knee

Novartis

Principal Investigator

An Uncontrolled Long Term Safety Trial of XX, 1% in Patients with Osteoarthritis of the Knee

Pfizer

Principal Investigator

A Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group Study Evaluating The Efficacy And Safety Of XXX For The Treatment Of Vasomotor Symptoms Of Menopause In Postmenopausal Women

Schwarz

Principal Investigator

A Phase 3, Parallel Group, Randomized, Double-Blind, Placebo Controlled Multicenter Trial to Investigate the Efficacy, Tolerability and Safety of XXX Sustained Release in Subjects with Overactive Bladder Syndrome

Schwarz

Principal Investigator

Long-Term Open-Label Extension Trial for Subjects Completing the Phase 3 Trial of XXX (XX) for the Treatment of Overactive Bladder Syndrome

Berlex Laboratories, Inc.

A Multicenter, Double-Blind, Double-Dummy, Randomized, Placebo-Controlled, Study Comparing a X.X mg XXX Xmg XXX Combination Transdermal Patch, and a XXX Transdermal Patch with a Placebo Patch in Postmenopausal Women to Determine the lowest Effective Dose of XXX for the Relief of Moderate to Severe Hot Flashes

Eli Lilly

Principal Investigator

Dose Response Study of XXX Versus Placebo in the Treatment of Fibromyalgia Syndrome

Eli Lilly

Principal Investigator

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

Novo Nordisk

A 12 Month Double-Blind, Randomized, Parallel-Group, Placebo-Controlled, Multi-Center Trial to Investigator the Efficacy and Safety of XXX Low Dose (XXX) for the Treatment of Postmenopausal Atrophic Vaginitis Symptoms

Novartis Pharmaceuticals

Principal Investigator

A 28-Week, Multicenter, Randomized, Active Controlled, Parallel Group Study to Evaluate the Effects of XXX (Xmg) in Comparison with XXX (XX mg) Monotherapy, for the Treatment of Patients with Hypertension, Uncontrolled by XXX (XX.X mg) Monotherapy

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Johnson & Johnson

A Randomized, Double-Blind, Two-Part, Parallel-Group, Comparative Study to Evaluate Blood Folate Levels in Women Taking Oral Contraceptive With and Without Folic Acid

Boehringer Ingelheim Pharmaceuticals Principal Investigator

A Double Blind, Placebo Controlled, Randomized, Parallel Group Study of the Efficacy and Safety of Oral Doses of XXmg XXX When Used On-demand for up to 7 Episodes Over a Period of 6 Weeks for the Treatment of Occasional Episodes of Self-Reported Abdominal Pain, Cramping and Discomfort in an OTC-Like Study Population

Procter & Gamble Principal Investigator

A Randomized Placebo Controlled Multi-Center Double Blind Parallel Study to Determine the Efficacy of a Novel Treatment for the Common Cold

Berlex, Inc.

A Multicenter, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled, 7 Cycle Duration (196 Days), Phase 3 Study of Oral XXX Tablets for the Treatment of Dysfunctional Uterine Bleeding

Eisai

Principal Investigator

Efficacy and Safety of XX mg XXX for treating Heartburn in Frequent Sufferers

Abbott

Principal Investigator

A Phase 3, Randomized, Multicenter, Double-Blind Study Comparing the Analgesic Efficacy of Extended Release XXX Tablets (XX) to Placebo in Subjects with Osteoarthritis Symptoms in Postmenopausal Women

Duramed

A Randomized, Multicenter, Double-Blind, Placebo-Controlled Trial to Demonstrate the Safety and Efficacy of Daily X.X mg XXX, A (XX) for the Treatment of Vasomotor

Ortho McNeil

Principal Investigator

XXX Intervention to Prevent Transformation of EPIsoDic Migraine : The XXX INTREPID Study

KOS Pharmaceuticals

Principal Investigator

An Open-Label Evaluation of the Safety and Efficacy of a Combination of XXX and XXX in Patients with Dyslipidemia

Pfizer

Principal Investigator

Double-Blind, Parallel-Group, Randomized, Study of the Efficacy and Safety of Continuous Use of XXX VS the "Usual Use" of XXX in the Treatment of Subjects with Chronic Osteoarthritis of the Hip or Knee Who Require an Anti-Inflammatory Medication for Control of their Pain

Pfizer

A Multicenter, Double-Phase, Randomized, Double-Blind, Placebo Controlled (12-Week Double-Blind Followed by 12-Week Open-Label) Study Evaluating the Effect of XXX on Urgency Urinary Incontinence (UI), Urgency, Frequency, Sexual Quality of Life and Sexual Function in Women with Overactive Bladder

Wyeth Research

A Phase 3, Randomized, Double-Blind, Placebo Controlled Study to Evaluate with Effect of X X μ g and XXX X μ g in a Continuous Daily Regimen on Cycle-Related Symptoms (CRS)

Wyeth Research

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of a Combination of XXX and XXX in a Continuous Daily Regimen in Subjects with Premenstrual Dysphoric Disorder

Mira Baron, MD

Curriculum Vitae

Abbott

Principal Investigator

An Open-Label Study Evaluating the Safety and Tolerability of Long Term Administration of XXX (XX) in Subjects with Moderate to Severe Chronic Non-Malignant Pain

Bristol-Myers Squibb

Principal Investigator

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 2 Trial to Evaluate the Safety and Efficacy of XXX as Monotherapy in Subjects with Type 2 diabetes Mellitus who are treatment Naive and have Inadequate Glycemic Control on Diet and Exercise

GlaxoSmithKline Biologicals'

Principal Investigator

A phase III, double-blind, randomized, controlled study to evaluate the safety, immunogenicity and efficacy of GlaxoSmithKline Biologicals' HPV-16/18 XX/XXXXX vaccine administered intramuscularly according to a three-dose schedule (0, 1, 6 month) in healthy adult female subjects aged 26 years and above

Somaxon

Principal Investigator

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Outpatient Study to Assess the Efficacy and Safety of XXX in Elderly Patients with Primary Sleep Maintenance Insomnia

Alcon Research, Ltd.

Principal Investigator

Safety Study of XXX Nasal Spray

Astellas

Principal Investigator

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

Boehringer-Ingelheim

Principal Investigator

A Twenty Four Week, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Trial of XXX XMilligrams Daily and, with Uptitration, XMilligrams Daily in Premenopausal Women with Hypoactive Sexual Desire Disorder

Bristol-Myers Squibb

Principal Investigator

A Multicenter, Randomized, Double-Blind, Placebo Controlled, Phase 3 Trial to Evaluate the Efficacy and Safety of XXX (XX) in Combination with XXX Therapy in Subjects with Type 2 Diabetes Who Have Inadequate Glycemic Control on XXX Therapy Alone

Daiichi Sankyo Pharma Development

Principal Investigator

A Randomized, Double-Blind, Placebo-and Active Comparator-Controlled, Parallel-Group Study of the Efficacy and Safety of XXX as Monotherapy Treatment of Type 2 Diabetes Mellitus

Duramed Research

Principal Investigator

A Prospective, Multicenter, Double-Blinded, Randomized Study to Evaluate Bleeding Patterns in Women Using One of Three Different Ascending XX Dose Extended Cycle (91-Day) Oral Contraceptive Regimens (XX) Compared To XXX ® Oral Contraceptive Regimen

Duramed Research

Principal Investigator

A Randomized, Multicenter, Double-Blind, Placebo-Controlled Trial To Compare the Effects of 12 Weeks of Treatment with XXX Vaginal Cream vs. Placebo Vaginal Cream on Vulvovaginal Atrophy in Healthy Postmenopausal Women

Forest Laboratories, Inc.

Principal Investigator

A Phase III Pivotal, Multi-Center, Double-Blind, Randomized, Placebo-Controlled Monotherapy Study of XXX for the Treatment of Fibromyalgia

Mira Baron, MD

Curriculum Vitae

Forest Laboratories, Inc.

Principal Investigator

A Phase III, Multi-Center, Open-Label, Extension Study of XXX for the Treatment of Fibromyalgia

Glenmark Pharmaceuticals, Inc.

Principal Investigator

A Randomized, Double-Blind, Placebo Controlled, Parallel Design, Multiple-Site Study to Evaluate the Clinical Equivalence of Two XXX X% Creams in Patients with Interdigital Tinea Pedis

MannKind Corporation

Principal Investigator

Pulmonary Outcomes Within a 2-Year Period in Subjects with Diabetes Mellitus Treated with XXX@/XX or Usual Antidiabetic Treatment and in Subjects without Abnormalities in Glucose Control

Novartis

Principal Investigator

A Phase III, Multi-Center, Randomized, Double-blind, Placebo-Controlled, Parallel Group Trial of Fourteen Day Treatment with XXX Xmg or XXmg One a Day in Frequent Nighttime Heartburn

Novo Nordisk

Principal Investigator

Inhaled Mealtime Insulin with the AERx® XXXX Versus Subcutaneous Injected XXX Both in Combination with XXX in Type I Diabetes: A 104 Week, Open Label, Multicenter, Randomized, Parallel Trial (Followed by a Twelve Week, Re-Randomized Extension) to Investigate Safety and Efficacy)

Novo Nordisk

Principal Investigator

XXX Effect and Action in Diabetes (LEAD-3): Effect on Glycemic Control of XXX Versus XXX in Type 2 Diabetes [A Fifty-Two Week (with Fifty-Two Week Open Label Extension), Double Blind, Multicenter, Randomized, Parallel Study to Investigate Safety and Efficacy]

Novo Nordisk

Principal Investigator

Inhaled Mealtime Insulin with AERx® XXX Plus XXX & XXX Versus XXX Plus XXX & XXX in Type 2 Diabetes: A 26-Week, Open-Label, Multicenter, Randomized, Parallel Trial to Investigate Safety and Efficacy

Novo Nordisk

Principal Investigator

Inhaled Mealtime Insulin with AERx® XXX Plus XXX Versus XXX Alone in Type 2 Diabetes: A 26-Week, Open-Label, Multicentre, Randomised, Parallel Trial to Investigate Safety and Efficacy

Pfizer

A Phase 2B Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging Study Evaluating the Efficacy and Safety of XXX for the Treatment of Moderate to Severe Vasomotor Symptoms Associated with Menopause

Sanofi Aventis

Principal Investigator

Efficacy and Safety Study of Oral Administration of XXX for the Relief of Abdominal Pain or Discomfort in Patients with Irritable Bowel Syndrome (IBS). A Randomized, Placebo-Controlled, Parallel Group, Dose-Ranging (Phase IIB) Trial

Schering Plough

Principal Investigator

A Clinical Study to Evaluate the Safety and Efficacy of XXX 12-Hour X mg XXX Tablet BID vs. Placebo Tablet in the Treatment of Allergic Rhinitis

Takeda

Principal Investigator

A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Demonstrate the Subjective Treatment Effects of XXX 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

Warner Chilcott

Principal Investigator

Open-Label Study of the Safety and Efficacy of a New Dose Oral Contraceptive Containing XXX

Mira Baron, MD

Curriculum Vitae

Watson Laboratories

Principal Investigator

A Multi-Center, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of Daily Dosing with XXX Topical Gel to Treat the Symptoms of Overactive Bladder with a 14-Week Open-Label Safety Extension

Wyeth Research

Principal Investigator

The Effect of Dose Titration and Dose Tapering on the Tolerability of XX in Women with Vasomotor Symptoms Associated with Menopause

Wyeth Research

A Double-Blind, Randomized, Placebo-Controlled, Efficacy and Safety Study of XXX Combinations for Treatment of Vasomotor Symptoms Associated with Menopause

Wyeth Research

A Double-Blind, Randomized, Placebo-and Active-Controlled, Efficacy and Safety Study of XXX Combinations for Treatment of Moderate to Severe Vulvar/Vaginal Atrophy in Postmenopausal Women

Wyeth Research

A Double-Blind, Randomized, Placebo-and Active-Controlled, Efficacy and Safety Study of XXX Combinations for Prevention of Endometrial Hyperplasia and Prevention of Osteoporosis in Postmenopausal Women

Wyeth Consumer Healthcare

Principal Investigator

A Study to Evaluate the Efficacy & Safety of an XXX Using Objective and Subjective Cough Assessments

Bayer Healthcare

Principal Investigator

A Multicenter, Double-Blind, Randomized Placebo-Controlled Study to Determine the Lowest Effective Dose of Oral XX (X X.Xmg/ XXX X.Xmg, XXX X.XX mg/XXX X.X mg, and XXX X.X mg) for the Relief of Moderate to Severe Vasomotor Symptoms in Postmenopausal Women Over a Treatment Period of 12 Weeks

Bayer Healthcare

Principal Investigator

A Double-Blind, Randomized, Multi-Center Study to Investigate the Endometrial Safety of a Continuous, Combined, Oral XXX Preparation (X.X mg XXX [XX] / XX [XXX] and to Compare the Bleeding Pattern of Subjects Treated with X.X mg XX / X.XX mg XXXX with the Bleeding Pattern of Subjects Treated with X.X mg XX / X.X mg XXX (XX) When Used for Hormone Therapy (HT) for 1 Year in Post-Menopausal Women

Boehringer Ingelheim

Principal Investigator

A Twelve Month, Open-label, Safety Trial of XX XXMilligrams to XXXMilligrams Daily in Women with Hypoactive Sexual Desire Disorder

GlaxoSmithKline

Principal Investigator

A Parallel-Group, Double-Blind, Randomized, Placebo-Controlled, Active Comparator, Multicenter Study to evaluate the Efficacy, Safety, Tolerability and Pharmacokinetics of Two Dosed of XXX Administered Orally as Monotherapy for 12 Weeks in Healthy Postmenopausal Women with Moderate to Extremely Severe Vasomotor Symptoms

GlaxoSmithKline

Principal Investigator

A Phase IIIB, Observer-Blind, Randomized, Multicenter Study with Two Parallel Groups to Compare the Immunogenicity of GlaxoSmithKline Biological's HPV-16/18 XXX Vaccine Versus XXXXX's XXX@ Vaccine when Administered Intramuscularly According to a 3-Dose Schedule in Healthy Adult Females 18-45 Years of Age

GlaxoSmithKline

Principal Investigator

A 16-Week, Parallel-Group, Double-Blind, Randomized, Placebo-Controlled, Multicenter, Dose-Ranging Study to Evaluate the Efficacy, Safety and Tolerability of Multiple Doses and Multiple Treatment Regimens of XXX, with XX as an Open-Label Active Reference, in Subjects with Type 2 Diabetes Mellitus

Mira Baron, MD

Curriculum Vitae

Jazz Pharmaceuticals

Principal Investigator

A Randomized, Double-Blind, Placebo Controlled, Safety and Efficacy Study of XX® (XXX) in Subjects with Fibromyalgia

Jazz Pharmaceuticals

Principal Investigator

A Long-Term, Open-Label Safety and Efficacy Study of XX® (XXX) in Subjects with Fibromyalgia

KV Pharmaceuticals

Principal Investigator

A Phase 2 Clinical Study Evaluating the Safety and efficacy of Two Regimens of XXX Administered Intravaginally for Three Months in Women with Moderate-to-Severe Pain Associated with Endometriosis

MannKind Corporation

Principal Investigator

A 2-Month Safety Follow-up Trial of Subjects from MannKind Protocols XXX, XX and XXX

Microbia

Principal Investigator

A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Dose-Range-Finding, Parallel-Design, Phase 2 Trial of Oral XXX Administered to Patients with Irritable Bowel Syndrome with Constipation

Neurocrine Biosciences

Principal Investigator

A Phase II, Randomized, Double-Blind, Active-Controlled Study to Assess the Safety and Efficacy of XX in Subjects with Endometriosis

NicOx S.A.

Principal Investigator

A 13-Week, Phase 3, Multicenter, Randomized, Parallel-Group, Double-Blind, Placebo bid and XX Xmg bid, Controlled Study on the Efficacy on Signs and Symptoms, and Safety of XXX (XX) XXmg bid, in Patients with Osteoarthritis of the Hip

Novartis

Principal Investigator

A 12-Week, Randomized, Double-Blind, Multi-Center, Vehicle-Controlled, Parallel Group Study to Assess the Efficacy and Safety of the XXX X% for the Relief of Signs and Symptoms in Patients with Osteoarthritis of the Knee

Procter & Gamble

Principal Investigator

A Randomized, Double-Blind, Placebo-Controlled, Multicenter, 52-Week Study to Evaluate the Endometrial Safety of XXX (XXmcg/day) in Naturally Postmenopausal Women with Hypoactive Sexual Desire Disorder

Sanofi Aventis

Principal Investigator

Efficacy and Safety of XX Xmg/day on Sleep Maintenance Insomnia: a 12 Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Followed by an Open Treatment Phase Extension with XXX for 40 Weeks Period

Schwarz Pharma

Principal Investigator

A Parallel, Randomized, Double-Blind, Placebo-Controlled, Multicenter Proof of Concept Trial to Assess the Efficacy and Safety of 2 Different Transdermal Doses of XXX in Subjects with Signs and Symptoms Associated with Fibromyalgia Syndrome

Sciele Pharma, Inc.

Principal Investigator

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

Shionogi

Principal Investigator

A Double Blind, Multi-Center, Randomized, Parallel-Group, Yearlong Study to Assess the Efficacy and Safety of X, XXX, or XXX mg/day of S-XXX Administered Orally Once Daily with a Reduced Calorie Diet in Obese Males and Females

Mira Baron, MD

Curriculum Vitae

Strakan Pharmaceuticals Ltd. Principal Investigator
An Open Label Phase 3 Study of XXX X% in Hypogonadal Males

Takeda Principal Investigator
An 8-Month Phase 3, Open-Label Study with a Blinded Reversal Phase to Evaluate the Safety and Tolerability of XXX in Subjects with Essential Hypertension

TAP Pharmaceutical Products, Inc. Principal Investigator
A Phase 3, Randomized, Multicenter, Double-Blind, XXX-Controlled Study Assessing the Efficacy and Safety of Oral XXX in Subjects with Gout

Warner Chilcott Principal Investigator
An Open Label Study of the Contraceptive Efficacy of an Extended Regimen of XXX and XXX

Xanodyne Pharmaceuticals, Inc. Principal Investigator
A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multicenter Study to Evaluate Efficacy and Safety of a X.X G Oral Dose of XXX TID Administered During Menstruation for the Treatment of Menorrhagia

Antares Pharma AG Principal Investigator
A Double-Blind, Randomized, Parallel, Placebo-Controlled, Multicenter Study Evaluating the Effect of Treatment with Topically Administered XXX Gel in Patients with Urinary Frequency, and Urge and Mixed Urinary Incontinence with a Predominance of Urge Incontinence Episodes

Arena Pharmaceuticals Principal Investigator
A 52-Week, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Assess the Safety and Efficacy of XXX in Overweight and obese Patients with Type 2 Diabetes Mellitus Managed with Oral Hypoglycemic Agent(s)

Nastech Pharmaceutical Company, Inc. Principal Investigator
A 24-Week, Blinded, Randomized, Placebo-Controlled Dose-Ranging Trial of XXX for Weight Loss in Healthy Obese Patients

NicOx S.A. Principal Investigator
A Phase 3, 53 Week Study on Analgesic Efficacy and Safety of XXX (XX): 26-Week, Randomized Parallel-Group, Double-Blind, Placebo (13 Weeks)- and XXX (26 Weeks)- Controlled, Multicenter Study of XXX (Xmg bid and Xmg bid) with a 26-Week XXX-Controlled Safety Follow-Up in Subjects with Osteoarthritis of the Knee, and a 1-Week Post-Treatment Safety Follow-Up

Forest Research Institute Principal Investigator
A Double-Blind, Randomized, Placebo-Controlled Dose Escalation Study of XXX XMG and XXMG Daily in Patients with Fibromyalgia: Effects on 24-Hour Ambulatory Blood Pressure Monitoring

Orexigen Therapeutics, Inc. Principal Investigator
A Multicenter, Randomized, Double Blind, Placebo Controlled Study Comparing the Safety and Efficacy of Two Doses of XXX (XX)/ XXX (SR) and Placebo in Obese Subjects

EndoCeutics, Inc. Principal Investigator
XXX Against Vaginal Atrophy (3-Month Placebo-Controlled Double-Blind Randomized Phase III Study)

VIVUS, Inc. Principal Investigator
A Phase III, Randomized, Double-Blind, Parallel-Design Study Comparing Multiple Doses of XXX to Placebo and Their Single-Agent XXX and XXX Constituents for the Treatment of Obesity in Adults

Mira Baron, MD

Curriculum Vitae

Bayer Health Care

Principal Investigator

A Multicenter, Open-Label, Single-Arm Study to Assess the Efficacy and Safety of the Oral Contraceptive XXX (X.XX mg XXX as XXX and X mg XXX) in a Flexible Extended Regimen in 1356 Healthy Females for 1 Year.

Pfizer

Principal Investigator

XXX Dose-Ranging Trial: A Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multicenter Outpatient Trial of XXX in Adults with Primary Insomnia

Xanodyne Pharmaceuticals, Inc.

Principal Investigator

A Randomized, Double-Blind Placebo Controlled, Parallel Group, Multicenter Study to Evaluate Efficacy and Safety of X.XX G and X.X G Oral Doses of XXX TID During Heavy Menstruation for the Treatment of Menorrhagia

Duramed Research, Inc.

Principal Investigator

A Phase 4, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Effects of XXX on Nocturnal Vasomotor Symptoms in Postmenopausal Women

Orexigen Therapeutics, Inc.

Principal Investigator

A Multicenter, Randomized, Double Blind, Placebo Controlled Study Comparing the Safety and Efficacy of Multiple Doses of XXX (SR)/XXX (XX) and Placebo in Obese Subjects with Type 2 Diabetes

Pfizer

Principal Investigator

A Phase II Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel Group, Proof of Concept Study of the Analgesic Effects of XXX in Adult Patients with Post-Herpetic Neuralgia

NicOx S.A.

Principal Investigator

A 7-Week, Phase 2, Multicenter, Double-Blind, Randomized, Parallel-Group Study to Evaluate the Effects of XXX (XXmg, bid), and XXX (XXX mg, tid) on Arterial Blood Pressure as Measured by Ambulatory Blood Pressure Monitoring in Osteoarthritis Patients with Controlled Essential Hypertension

MannKind Corporation

Principal Investigator

Evaluation of the Effect of Symptomatic Upper Respiratory Infections on Pharmacological Characteristics of XXX® / XXX in Subjects with Diabetes Mellitus After a Meal Challenge

Dynogen Pharmaceuticals, Inc.

Principal Investigator

A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Effectiveness of XXX in Female Patients with Irritable Bowel Syndrome with Constipation

GlaxoSmithKline

Principal Investigator

A Phase 3, Observer-Blind, Randomized, Placebo-Controlled, Multi-Center Trial to Evaluate the Safety and Immunogenicity of a Two-Dose Series of XXX vaccine in Association with XXX in Adults Aged ≥ 18 Years

Repros Therapeutics Inc.

Principal Investigator

A Phase II, Three-Arm, Parallel Design, Dose-Ranging Placebo-Controlled, Randomized, Double-Blind, Multicenter Study Evaluating the Safety and Efficacy of the Selective Progesterone Receptor Modulator XXX (XX) in the Treatment of Premenopausal Women with Symptomatic Endometriosis

MAP Pharmaceuticals, Inc.

Principal Investigator

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 3 Study of XXXX In Adult Migraineurs for a Single Migraine Followed by Open-Label Extensions to 26/52 weeks

Wyeth Research

Principal Investigator

A Phase 3, Randomized, Active-Controlled, Modified Double-Blind Trial to Evaluate the Safety, Tolerability, and Immunogenicity of XXX vaccine When Administered Over 12 Months Either as a 2-Dose Regimen or With XXX in Health Adults 60-64 Years of Age Who Are Naive to XXXXX

Mira Baron, MD

Curriculum Vitae

Wyeth Research

Principal Investigator

A Phase 3, Randomized, Double-Blind Trial to Evaluate the Safety, Tolerability, and Immunogenicity of a XXX vaccine when administered concomitantly with XXX in Healthy Adults 50-59 Years of Age Who are Naive to XXX and to Evaluate the Immune Response of a Second Dose of XXX Administered 5 Years After Initial XXX

GlaxoSmithKline

Principal Investigator

A Study to Evaluate the Potential Incidence of Orthostatic Hypotension in Elderly Hypertensive Patients Following Administration of a Combination of XX and XXX

NicOx S.A.

Principal Investigator

A 12-Week, Phase 1, Multicenter, Double-Blind, Randomized, Forced Titration, XXX-Controlled, Parallel-Group Pharmacodynamic Study to Assess the Effects of XXX (in doses ranging from XXX XX to XXXX mg, bid), and XX (in doses ranging from XXX mg to XXX mg, bid) on Arterial Blood Pressure as Measured by Ambulatory Blood Pressure Monitoring in Osteoarthritis Patients with Controlled Essential Hypertension

BioSante Pharmaceuticals, Inc.

Principal Investigator

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of the Long-Term Safety and Efficacy of XXX® for the Treatment of Hypoactive Sexual Desire Disorder in Postmenopausal Women

BioSante Pharmaceuticals, Inc.

Principal Investigator

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of the Long-Term Safety and Efficacy of XXX® for the Treatment of Hypoactive Sexual Desire Disorder in Surgically Menopausal Women

Daiichi-Sankyo

Principal Investigator

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

Duramed

Sub- Investigator

A Multicenter, Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Two Doses of XXX Versus Placebo in Women with Overactive Bladder

Forest Research Institute

Principal Investigator

A Multicenter, Randomized, Open-Label, Controlled Study to Evaluate the Safety, Tolerability, and Efficacy of XXX When Added to XXX in the Treatment of Fibromyalgia

Astellas

Principal Investigator

A Phase III, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Multicenter Study to Assess the Efficacy and Safety of the Beta-3 Agonist XXX in Subjects with Symptoms of Overactive Bladder

Astellas

Principal Investigator

A Randomized, Double-Blind, Parallel-Group, Active-Controlled, Multicenter Long-Term Study to Assess the Safety and Efficacy of the Beta-3 Agonist XXX (XX mg qd and 100 mg qd) in Subjects with Symptoms of Overactive Bladder

Pfizer

Principal Investigator

A Multicenter, Long-Term, Open-Label Extension Study of XX Administered Once Daily in Patients with Fibromyalgia

Wyeth Research

Principal Investigator

A Double-Blind, Randomized, Placebo-Controlled Study Assessing the Safety and Efficacy of XXX XX for the Treatment of Vasomotor Symptoms Associated with Menopause

Eli Lilly

Principal Investigator

A Phase 2, Randomized, Double-Blind, Placebo-and-Active-Comparator-Controlled Study of the Safety and Efficacy of XXX in Outpatients with Insomnia

Mira Baron, MD

Curriculum Vitae

Pozen**Principal Investigator**

Randomized, Double-Blind, Parallel Group, Placebo-Controlled Multi-Center Study Evaluating the Efficacy of XXX BID and XXX Xmg QD in Patients with Osteoarthritis of the Knee

Pharmos**Principal Investigator**

A Double-Blind, Randomized, Placebo-Controlled Phase 2b Study of XXX, XXX, and XXX mg BID XXX in Female Outpatients with Irritable Bowel Syndrome

InteKrin Therapeutics**Principal Investigator**

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

Pfizer**Principal Investigator**

A Long-Term, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Radiographic Study to Investigate the Safety and Efficacy of Orally Administered XX in Subjects with Symptomatic Osteoarthritis of the Knee

IDEA AG**Principal Investigator**

Multicentre, Randomized, Double-blind, Placebo-Controlled Study of Safety and Efficacy of Epicutaneously Applied X® (XX in XX® gel) for the Treatment of Osteoarthritis of the Knee

Sanofi Aventis**Principal Investigator**

A Double-Blind, Randomized, 12-Month, Placebo-Controlled, Parallel group, Fixed-Dose Study to Evaluate the Efficacy and Safety of X Xmg/day and XX XXmg/day in Patients with Primary Hypercholesterolemia

Quatrx Pharmaceuticals**Principal Investigator**

Efficacy and Safety of XXX in the Treatment of Moderate to Severe Vaginal Dryness and Vaginal Pain Associated with Sexual Activity, Symptoms of Vulvar and Vaginal Atrophy (VVA), Associated with Menopause: A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Comparing Oral XXX XMG Daily Dose with Placebo in Postmenopausal Women

Quatrx Pharmaceuticals**Principal Investigator**

Open-Label Study of XX, XX mg Oral Daily Dose, in the Treatment of Moderate to Severe Vaginal Dryness and Pain Associated with Sexual Activity, Symptoms of Vulvar and vaginal Atrophy (VVA) Associated with Menopause: A Follow-Up to Protocol XXX

Sanofi Aventis**Principal Investigator**

A Randomized, Double-Blind, Placebo-Controlled, 2-Arm Parallel-Group, Multicenter Study with a 24-Week Main Treatment Period and an Extension Assessing the Efficacy and Safety of XXX on Top of XXX in Patients with Type 2 Diabetes Not Adequately Controlled with XXX

Graceway Pharmaceuticals LLC**Principal Investigator**

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Efficacy and Safety Study of XXX Creams in the Treatment of External Genital Warts

Depomed, Inc.**Principal Investigator**

A Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Safety and Efficacy of XXX Extended Release (G-ER) Tablets in the Treatment of Vasomotor Symptoms in Postmenopausal Women

GlaxoSmithKline**Principal Investigator**

A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Crossover Study to Evaluate with efficacy of XXX™ (XX + XX) versus XXX-Containing Combination Medications (BCM) for the Acute Treatment of Migraine When Administered During the Moderate-Severe Pain Phase of the Migraine (Study 2 of 2)

Mira Baron, MD

Curriculum Vitae

Takeda**Principal Investigator**

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

Forest Research Institute**Principal Investigator**

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Trial of XXX Administered Orally for 12 Weeks in Patients with Chronic Constipation

Forest Research Institute**Principal Investigator**

An Open-Label, Long-Term Safety Study of Oral XXX Administered to Patients with Chronic Constipation or Irritable Bowel Syndrome with Constipation

GlaxoSmithKline**Principal Investigator**

Assessment of the Effect of XXX and XXX Combination Tablet, XXX Tablet, and XXX Tablet Treatment on Blood Pressure when Administered Intermittently for Six Months for the Acute Treatment of Migraine attacks, With or Without Aura, in Adults

VIVUS, Inc.**Principal Investigator**

A Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XX (XX) in the Treatment of Erectile Dysfunction in Diabetic Men

Eli Lilly**Principal Investigator**

XXX X.X mg and X mg Once a Day Compared to Placebo in Day of Onset of Efficacy

Daiichi Sankyo Pharma Development**Principal Investigator**

A Prospective, Open-Label, Titration Study to Evaluate the Efficacy and Safety of XXXX™ in Multiple Subgroups of Hypertensive Subjects who are Non-Responders to Anti-Hypertensive Monotherapy

GlaxoSmithKline**Principal Investigator**

A Randomized, Double-Blind, Parallel-Group, 24-Week Study to Evaluate the Efficacy and Safety of XX (XXX Combination Product XXX/XX mcg Inhalation Powder) BID Plus XXX (XX Inhalation Powder XX mcg) QD Versus XXX QD Plus Placebo XX BID in Subjects with Chronic Obstructive Pulmonary Disease (COPD)

Hoffman LaRoche**Principal Investigator**

Influenza Resistance Information Study (IRIS)

GlaxoSmithKline**Principal Investigator**

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

GlaxoSmithKline**Principal Investigator**

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

GlaxoSmithKline**Principal Investigator**

A Phase II, Observer-Blind, Randomized, Placebo-Controlled, Adjuvant-Dose Selection, Multicenter Prophylactic Vaccination Study to Evaluate the Immunogenicity and Safety of GSK Biologicals' Herpes Zoster vaccine, XXX, in Comparison to XX Combined with 1/2/ Dose XXX Adjuvant (XX), to Unadjuvanted XX (XX), and Saline (Placebo) When Administered Twice in Subjects Aged 50 Years and Older

GlaxoSmithKline**Principal Investigator**

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

Mira Baron, MD

Curriculum Vitae

GlaxoSmithKline

Principal Investigator

A Randomized, Open-Label, Parallel-Group, Multicenter Study to Determine the Efficacy and Long Term Safety of XXX Compared With XXX in Subjects with Type 2 Diabetes Mellitus

GlaxoSmithKline

Principal Investigator

A Randomized, Double-Blind, Placebo-and Active Controlled, Parallel-Group, Multicenter Study to Determine the Efficacy and Safety of XXX Administered in Combination with XXX and XXX Compared with XXX Plus XXX and Placebo and with XX Plus XXX and XX in Subjects with Type 2 Diabetes Mellitus

Sanofi Aventis

Principal Investigator

A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of XXX when added to Ongoing Stable XX Therapy at High Doses in Patients with Severe Primary Hypercholesterolemia

Pfizer

Principal Investigator

A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of XXX to Evaluate the Ability to detect Change and Estimate the Minimum Important Difference in a Daily Diary of Fatigue Symptoms for use with Fibromyalgia Subjects

GlaxoSmithKline

Principal Investigator

A Phase IIIb, Prospective, Observer-Blind, Randomized, Controlled, Multicenter Study to Evaluate the Immunogenicity and Safety of GlaxoSmithKline (GSK) Biologicals' Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed [XXX®] compared to XX's Tetanus and Diphtheria Toxoid Adsorbed Vaccine [XX™], When Administered to Adults Aged 65 Years or Older

Wyeth Research

Principal Investigator

A Double-Blind, Randomized, Placebo-and Active-Controlled Efficacy and Safety Study of the Effects of XXX Combinations on Endometrial Hyperplasia and Prevention of Osteoporosis in Postmenopausal Women

Repros Therapeutics Inc.

Principal Investigator

A Multi-Center, Placebo Controlled, Safety and Efficacy Study of the Selective Progesterone Receptor Modulator XXX® (XXX) in Anemic, Pre-Menopausal Women with Symptomatic Uterine Fibroids Requiring Hysterectomy

Repros Therapeutics Inc.

Principal Investigator

A Phase III, Three-Arm, Parallel Design, Placebo-Controlled, Randomized, Double-Blind, Multicenter Study Evaluating the Safety and Efficacy of XXX® (XXX) in the Treatment of Premenopausal Women with Symptomatic Uterine Fibroids

Regeneron Pharmaceuticals, Inc.

Principal Investigator

A Multi-Center, Randomized, Double-Blind, Placebo Controlled Trial of the Safety of XXX for the Prophylaxis of Gout Flares in Patients on Urate Lowering Therapy

Forest Research Institute

Principal Investigator

A Randomized, Double-Blind, Placebo and Active Controlled, Study of the Safety and Efficacy of XXX in Patients with Diabetic Peripheral Neuropathic Pain

Daiichi Sankyo Pharma Development

Principal Investigator

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of XX® as Add-On to XXX Therapy for Type 2 Diabetes Mellitus

Daiichi Sankyo Pharma Development

Principal Investigator

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

Mira Baron, MD

Curriculum Vitae

Surface Logix, Inc.

Principal Investigator

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of Different Doses of XX in Combination with a XXX vs. XX Mono-Therapy in Patients with Hyperlipidemia

Takeda

Principal Investigator

A Phase 3, Double-Blind, Randomized, Factorial, Efficacy and Safety Study of XXX Plus XXX Fixed-Dose Combination in Subjects with Moderate to Severe Hypertension

Bayer Health Care

Principal Investigator

A Multicenter, Open-Label, uncontrolled study to investigate the efficacy and safety of the transdermal contraceptive patch containing X.XX mg XXX and X.X mg XX (XXX) in a 21 day regimen for 13 cycles in 1650 healthy females subjects.

Boehringer Ingelheim

Principal Investigator

A Double-Blind, Placebo-Controlled, Randomized, Parallel-Group pilot study of the Safety and Efficacy of oral doses of XX mg XXX when used on demand for treatment of self-reported functional abdominal pain associated with cramping

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AC# 183294

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
12/11/2010	ME 81958	333988

The MEDICAL DOCTOR

named below has met all requirements of the laws and rules of the state of Florida.

Expiration Date: **JANUARY 31, 2013**

MIRA V BARON
3619 PARK EAST DRIVE
SUITE 300
CLEVELAND, OH 44122

STATE OF FLORIDA
AC# 4183294

DIVISION OF MEDICAL QUALITY ASSURANCE

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MIRA V BARON

LICENSEE SIGNATURE

Charlie Crist

Charlie Crist
GOVERNOR

Ara M. Viamonte Ros

Ara M. Viamonte Ros, M.D., M.P.H.
STATE SURGEON GENERAL

