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Private Practice
Texas Medical Research Associates, L.L.C.
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Current Professional Experience

July 2001- Present	Texas Medical Research Associates LLC President and Principle Investigator
April 1997- Present	Patrick H. Peters Jr., MD PA Internal Medicine Physician
October 1980- Present	Air Force Village I / Attending Physician Health Care Center
November 1988- Present	Air Force Village II / Attending Physician Health Care Center
September 1996- Present	Air Force Village Freedom House /Attending Physician Alzheimer Research and Treatment Facility

Education

1970	Houston Baptist University B.A. with Double Majors: Biology and Chemistry
1975	University of Texas Medical School at San Antonio Medical Doctor Degree
1978	Bexar County Teaching Hospitals Internship
1978	Bexar County Teaching Hospitals Residency

LICENSURE: STATE OF TEXAS, Number E9334

CERTIFICATIONS:

1996-2006 Certified by the American Board of Internal Medicine, Number 100739

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Past Professional Experience

1980-2005	Air Force Village Foundation Air Force Villages I and II Medical Director
1998- 2000	San Antonio Center for Clinical Research Investigator
1996-1997	Pasteur Medical Associates San Antonio, Texas
1978-1996	Leon Valley Diagnostic Clinic, P.A. President and Founder
1988-1989	Bexar County Medical Foundation President

PUBLICATIONS

1999 PH Peters, Jr., P Norwood, V DeBoc, T Van Couter, M Gibbens, T Von Panta, P Ward. Oseltamivir is effective in the long-term prophylaxis of influenza in vaccinated frail elderly. *Late Breaker Presentation: II International Symposium on Influenza and Other Respiratory Viruses.* 1999

2000 NL Losben, PJ Drinka, PH Peters, Jr. Reducing Influenza Risks: New Treatment Options. *Supplement to Clinical Geriatrics,* 2000

2000 PH Peters, Jr. The Impact of Influenza on the Aging Population. *Annals of Long-Term Care,* 2000; 8:16-18.

2001 PH Peters, Jr. Influenza and Its Impact on the Elderly. *Clinical Geriatrics, 2001; 9(2):30-43*

2001 Peters, Patrick H., Gravenstein, Stefan, Norwood, Paul, DeBock, Veerle, Van Couter, Anthony, Gibbens, Michael, von Planta, Tonny-Andrea & Ward, Penelope (2001) Long-Term Use of Oseltamivir for the Prophylaxis of Influenza in a Vaccinated Frail Older Population. *Journal of the American Geriatrics Society* 49 (8), 1025-1031.

2008 Peters, Patrick H., Moscona, Anne, Schulman, Kathy L., Barr, Charles E. (2008) Study of the Impact of Oseltamivir on the Risk for Pneumonia and Other Outcomes of Influenza, 2000-2005. *Medscape Journal of Medicine* 10(6): 131.

2012 Joost N. Verneulen, Joep M.A. Lange, Stephen K. Tyring, Patrick H. Peters, Margaret Nunez, Gregory Poland, Myron J. Levin, Carrie Freeman, Ira Chalikonda, Jianjun Li, Jeffrey G. Smith, Michael J. Caulfield, Jon E. Stek, Ivan S.F. Chan, Rupert Vessey, Florian P. Schödel, Paula W. Annunziato, Katia Schlienger, Jeffrey L. Silber (2012) Safety, Tolerability, and Immunogenicity After 1 and 2 Doses of Zoster Vaccine in Healthy Adults ≥60 years of Age. *Journal of Vaccine,* Volume 30, Issue 5, Jan 2012, Pgs 904-910

CONSULTANT TO AND/OR PRESENTATIONS FOR PHARMACEUTICAL COMPANIES:

1. Merck Pharmaceuticals
   A. Hypertension
   B. Hyperlipidemia
   C. Benign Prostatic Hypertrophy
   D. Osteoporosis
   E. Shingle Vaccine
   F. Diabetes Mellitus Type II

2. Searle Pharmaceuticals
   A. Hypertension

3. Pfizer Pharmaceuticals
   A. Alzheimer's Disease
   B. Cardiac Arrhythmia
   C. Impotence
   D. Hyperlipidemia
   E. Herpes Simplex Treatment

4. Novartis Pharmaceuticals
   A. Hypertension
   B. Alzheimer's type Dementia

5. Hoffmann-LaRoche
   A. Treatment of Infuenza

6. Glaxo-Wellcome
   A. Treatment of Influenza
   B. Treatment of Irritable Bowel Syndrome

7. Oscient Pharmaceuticals
   A. Antibiotic Therapy
   B. Hyperlipidemia

8. Sanofi-Aventis Pharm
   A. Antibiotic Therapy
   B. Allergic Rhinitis

9. Ortho-McNeill
   A. Myelodysplastic Anemia
   B. Anemia of Chronic Renal Failure

10. Boehringer-Ingelheim
   A. Anti-hypertensive Medications
   B. Stroke Prevention in Atrial Fibrillation

Research Experience

1989

1. Phase III - U.S. Multicenter Phase III: Study of a Novel NSAID in Osteoarthritis

1998

2. U.S. Multicenter Osteoporosis Trial.

3. Tricor U.S. Multicenter Physician Experience Trial: NSAID A Novel Compound in Patients with Type II Hyperlipidemia.

4. Phase III - Northern Hemisphere Multicenter, Double Blind, Randomized Placebo Controlled Study of a Novel Compound for Prevention of Clinical Influenza in Elderly Subjects.

1999

5. Multicenter Trial of a Novel Compound for the Treatment of Osteoarthritis of the Hip and Knee.

6. Phase III - Multicenter Double-Blind Study of a Novel Compound in Patients with Chronic, Moderate to Severe Pain.

7. Phase III - Multicenter Open Extension Study of a Novel Compound in Patients with Chronic, Moderate to Severe Pain.

7. Phase III - Study of A Novel Compound in the Therapy of Hypercholesterolemia.

8. Microbiology Surveillance Study of Community-Acquired Respiratory Tract Infections.

9. Open Label Multicenter Non-Comparative Study of a Novel Compound in the Treatment of Community-Acquired Respiratory Tract Infections.

10. Phase III - Double-Blind, Randomized Placebo-Controlled, Parallel Group, Multicenter Study to Investigate the Efficacy and Safety of an Inhaled Novel Compound. Administered Twice Daily for Five Days in the Treatment of Symptomatic Influenza A and B Viral Infections in Subjects Ages Greater than or Equal to 65.

11. A Multicenter Treatment of Osteoarthritis of the Hip/Knee Hypertension Study Using a Novel Compound.

12. An Open-Label Evaluation of the Effectiveness of a Novel Compound in the Treatment of Hypertension.

13. A Multicenter, Open-Label Clinical Hypertension Trial Using a Novel Compound.

14. Phase III - Open-Label Study Multicenter Trial of a Novel Compound in the Treatment of Moderate to Severe Pain.

2000

15. A Double-Blind Randomized Study to Evaluate the Effects of Fixed Combination Therapy in Subjects with type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Half-Maximum to Maximum of the Labeled Doses of Sulfonylurea Monotherapy

16. Phase III - Double-Blind Efficacy and Safety Study of One Dose Novel Compound Compared to Placebo in Subjects with Primary Hypercholesterolemia

17. Phase III - Comparison of Analgesic Efficacy and Safety of a Novel Compound vs. Placebo for the treatment and Signs and Symptoms of Osteoarthritis in Subjects Receiving a Cox-2 Selective Inhibitor.

18. Phase III - Double-Blind Efficacy and Safety Study of a Novel Compound in Addition to Simvastatin Compared to Placebo in Subjects with Primary Hypercholesterolemia

19. Multicenter Open Label Trial of a Novel Compound for Treatment of Post-Herpetic Neuralgia

20. Multicenter Open Label Trial of a Novel Compound for Treatment of Hypertension

21. Multicenter Open Label Trial of a Novel Compound in Treatment of Respiratory Tract Infections

22. A Comparative Study of the Safety and Efficacy of a Novel Compound QD vs. 150mg BID for the Treatment of Acute Sinusitis.

2001

23. Phase III - A Phase III Double-Blind Efficacy and Safety Study of a Novel Compound (10mg) in Addition to a Novel Compound Compared to Placebo in Subjects with Primary Hypercholesterolemia

24. Long-Term, Open-Label, Safety and Tolerability Study of a Novel Compound in Addition to a Novel Compound in Subjects with Primary Hypercholesterolemia who have Previously Completed the 12 Week Double-Blind Study

25. Long-Term, Safety and Tolerability Study of a Novel Compound or Placebo in Addition to a Novel Compound in Subjects with Primary Hypercholesterolemia

26. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of a Novel Compound in the Treatment of Acute Influenza A and B Infections in Healthy Adults

27. Clinical Protocol for a Randomized Double-Blind Placebo-Controlled Study of a Novel Compound as Monotherapy in Patients with Primary Hypercholesterolemia (Monotherapy Assessment of Reduction Cholesterol)

28. A Double-Blind Placebo Controlled Dose-Finding Trial to Evaluate the Efficacy and Safety of a Novel Compound in Gastroesophageal Reflux Disease (GERD)

29. A Double-Blind Placebo-Controlled Dose-Finding Trial to Evaluate the Efficacy and Safety of a Novel compound in Diabetic Subjects with Symptoms of Gastroparesis

30. A Randomized, Double-Blind, Placebo-Controlled and Open Label Twelve Month Study of the Safety of a Novel Compound in Adult Subjects with Insomnia

31. Phase III - Beyond Endorsed Lipid-Lowering with EBT Scanning (BELLES)

32. A Novel Compound Cardiovascular Treatment Assessment Versus a Novel Compound (OCTAVE)

33. Phase III - A Randomized, Double-Blind, Multicenter, Comparative Phase III Study of a Novel Compound vs. Oral Novel Compound in the Treatment of Community-Acquired Pneumonia

34. Efficacy and Safety of a Flexible Dose of a Novel Compound versus Placebo in the Treatment of Psychosis of Alzheimer's Disease.

35. Double Blind, Placebo-Controlled, Randomized Study to Evaluate Safety, Tolerability and Immunogenicity After 1 and 2 Doses of PHN/Zoster Vaccine

36. An Open-Label, Multicenter, Single Group Study to Assess the Bacteriological Eradication, Clinical Efficacy, and Safety of Oral Novel Compound 320 mg Given Once Daily for Five Days in the Treatment of Acute Bacterial Sinusitis (ABS).

37. A Multicenter, Randomized, Double-Blinded Placebo-Controlled Study to Assess the Efficacy and Safety of a Novel Compound in the Treatment of Acute Influenza A and B Infections in Healthy Adults.

2002

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

39. A Comparative Efficacy and Safety Study of a Novel Compound Delayed-Release Capsules (40 mg qd and 20 mg qd) Versus Novel Compound (150 mg BID) for the Healing of NSAID-associated Gastric Ulcers When Daily NSAID Use is Continued

40. Phase III - A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of a Novel Compound added to a Novel Compound in Patients with Inadequately Controlled Type 2 Diabetes Mellitus

41. Phase III - A Randomized, Double-Blind, Active-Comparator-Controlled, Parallel-Group Study to Evaluate the Safety of a Novel Compound in Patients with Osteoarthritis or Rheumatoid Arthritis.

42. Phase IIIb - An Open-Label Comparison Study to Evaluate the Role of a Novel Compound Versus a Novel Compound in Combination with a Novel Compound in Type 2 Diabetes Mellitus Subjects Not Responding Adequately to a Novel Compound Monotherapy

43. Phase III - A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of a Novel Compound added to Sulfonylurea in Patients with Inadequately Controlled Type 2 Diabetes Mellitus

44. Phase III - A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of a Novel Compound added to Patients with Type 2 Diabetes with Inadequate Glycemic Control on Combined Novel Compound and Novel Compound Therapy

45. Phase IV - Impact of Point-of-Care VS. Laboratory Testing of Hemoglobin A1C (HbA1c), and Intense VS. Standard Monitoring of Titration Algorithm Adherence on Glycemic Control in type 2 Diabetes Subjects, Who are Inadequately Controlled on Oral Anti-Hyperglycemic Therapy, and Starting Novel Compound (Insulin Glargine (rDNA Origin Injection): A 2X2, Randomized, Open-Label Trial.

2003

46. Phase II - A Multicenter, Double-Blind, Randomized Comparison of the Efficacy and Safety of a Novel Compound and Placebo in the Treatment of Agitation Associated with Dementia

47. Phase IV - An Open-Label, Randomized Study to Evaluate the Safety of 4 MG a Novel Compound in Comparison with 4 MG Novel Compound in Smokers with Certain Underlying Disease Restrictions Specified in the Label.

48. Phase IV - A Prospective, 26-week, Open-Label, Single-arm, Multi-center study Evaluating the Efficacy and Safety of a Novel Compound in Patients with Mild to Moderate Alzheimer's Disease who are Responding Poorly to Novel Compound Treatment.

49. Phase IV - A Randomized, Placebo-Controlled, Parallel-Group, Double Blind Study to evaluate the Safety and Efficacy of Novel Compound 12.2 mg and Novel Compound 200 mg in Patient with Osteoarthritis of the knee.

50. Phase III - A Multicenter, Double-Blind, Randomized, Active Controlled, Parallel, Group Study to Evaluate the Lipid-Altering Efficacy of a Novel Compound in Patients with Type 2 Diabetes and Dyslipidemia.

51. Phase III - An Investigator-Blinded, Parallel Group to Compare the Safety, Therapeutic Efficacy, and Vulvovaginal Symptomatic Relief of Novel Compound Vaginal Ointment Plus Novel Compound External Vulvar Cream to Monistat 7 Vaginal Cream in the Treatment of Vulvovaginal Candidiasis.

52. Phase III - A Multicenter, Double-Blind, Randomized, Parallel Group, 6-Week Study to Evaluate the Efficacy and Safety of Novel Compound Versus Atorvastatin in Patients with Hypercholesterolemia.

53. Phase IIb - A Multicenter, Double-Blind, Randomized, Placebo and Active-Controlled Dose-Range Finding Study of Novel Compound in Patients with Type 2 Diabetes Mellitus who have Inadequate Glycemic control.

54. Phase IV - A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Group, 6-Week Study to Evaluate the Efficacy and Safety of a Novel Compound When Added to Ongoing Therapy with a Statin Therapy Alone, in Patients with Hypercholesterolemia Who Have Not Reached National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III Target LDL-Cholesterol Level.

55. Phase III - A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Effects of a Novel Compound in Decreasing the Risk of Prostate Cancer.

56. Phase IV - A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Forced-Titration, Comparison of Novel Compound HT versus Novel Compound HCT using Seated Trough Cuff Blood Pressure in Patients with Stage 1 and Stage 2 Hypertension.

57. Phase IIIb - A Six Month, Chronic Efficacy and Safety Study of Novel Compound in Adult Subjects with Primary Insomnia: A Randomized Double-Blind, Placebo-Controlled Study.

58. Phase III - Evaluation of the Safety and Tolerability of a Higher Potency Dose of Varicella Zoster Virus Vaccine Live Among Adults 50 Years of Age and Older.

59. Phase IV - A Multicenter, Randomized, double-Blind, Placebo-Controlled Parallel Study to Determine the Efficacy and Safety of Novel Compound Administered Once Daily to Hypercholesterolemia Subjects with Chronic, Well Compensated Liver Disease.

2004

60. Phase III - A 26-week, Randomized, Placebo- and Active-Comparator-Controlled, Parallel-Group, Double-Blind, 2-Part Study to assess the Safety and Efficacy of Novel Compound 30 mg Versus Novel Compound 200mg in patients with Osteoarthritis

61. Phase II - A Randomized, Double-Blind, Placebo-Controlled Multicenter Study to Assess the Efficacy, Safety, and Tolerability of Novel Compound Alone and in Combination with Novel Compound Given Orally in Patients Suffering from Symptomatic (non-erosive) Gastroesophageal Reflux Disease (sGERD)

62. Phase III - A Multicenter, Randomized, Double-Blind, Active and Placebo-Controlled, Phase III, Efficacy and Safety Study of Novel Compound HCl and Low-Dose Novel Compound HCl in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the hip on knee.

63. Phase IIIb - An open-label Multicenter study to assess the efficacy and safety of daily oral administration of XXXXX in patients who wish to switch from XXXX for the treatment of overactive bladder symptoms

64. Phase IIa - A Multicenter, Randomized, Double-Blind, Placebo controlled Study to Assess the efficacy of Novel Compound Monotherapy in Patients with Type 2 Diabetes Mellitus and Metabolic Syndrome.

65. Phase III - A Randomized, Double-Blind, Active Controlled, Multicenter study that Employs a Parallel Group Design to Compare Novel Compound 20 or Novel Compound IR to Novel Compound 5 in Subjects with Moderate to Severe Osteoarthritic Pain of the Hip or Knee.

66. Phase II - A Multicenter, Randomized, Parallel-group, Investigator-blinded Study to Compare the Safety, Therapeutic Efficacy and Vulvovaginal Symptomatic Relief of a Single Vaginal Dose of Novel Compound 500 mg Suppository Compared to a 7 Day Dose of Novel Compound Vaginal Cream in the Treatment of Vulvovaginal Candidiasis.

67. Phase III - A Multicenter, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of the Addition of Novel Compound to Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Metformin Therapy.

68. Phase IV - A Randomized, Double-blind, Double-Dummy, Placebo-Controlled, Forced-Titration, Comparison of Novel Compound HCT versus Novel Compound HCT.

69. Phase III - A Randomized, Double-blind, Multicenter, Positive-controlled, Parallel Group Study to Evaluate the Safety and Efficacy of Novel Compound and Novel Compound administered in Combination to Novel Compound Monotherapy in Hypertensive Patients Not Adequately Controlled Alone.

70. Phase IV - An Open-label, Randomized, Multicenter, Clinical Study to Compare the Effects of Novel Compound and Novel Compound on the Penicillin or Macrolide Resistance of Streptococcus Pneumonia in Patients with Acute Exacerbation of Chronic Bronchitis

71. Phase III - A Trial to Reduce Cardiovascular Events with Novel Compound Therapy.

72. Phase III - A Randomized, Double-blind, Parallel Group Study to Compare the Effect of the Novel Compound Diskus Combination product 250/50 mg BID with Novel Compound Diskus 50 mcg BID on the Annual Rate of Moderate/Severe Exacerbations in Subjects with Chronic Obstructive Pulmonary Disease (COPD).

73. Phase III – A Multicenter, Randomized, Double-Blind, Active Comparator Study to Determine the efficacy and Safety of Novel Compound 20 and Novel Compound versus Novel Compound 5 in subjects with Moderate to Severe Osteoarthritis (OA) Pain

2005

74. Phase II – A Multicenter, Randomized, Double-Blind, Placebo-controlled, Phase II Study of the Efficacy and Safety of Novel Compound in Subjects With Mild to Moderate Alzheimer's Disease.

75. Phase III – A Phase III, Multicenter, Double-blinded, Parallel Group, Placebo-controlled trial to compare the effects of Novel Compound With Placebo on the Time to the First Incidence of Primary Cardiovascular Events.

76. Phase III – A Placebo-controlled, Double-blind, Parallel Arm Trial to Assess the Efficacy of Novel Compound 400mg BID for the Prevention of Cardiovascular Hospitalization or Death From Any Cause in Patients with Atrial Fibrillation/Atrial Flutter (AF/AFL).

77. Phase III – To Assess the Effect of Anemia Therapy with Novel Compound on the Composite Event Comprising All-Cause Mortality and CV Events in Subjects with Both Type II Diabetes and Renal Dysfunction.

78. Phase III – An Open-label, Multicenter Study to Determine the Level of Adherence to Monthly Oral or Every Three Month IV Novel Compound Treatment in Postmenopausal Women with Osteoporosis or Osteopenia, Who Are GI Intolerant of Daily and/or Weekly Novel Compound or Novel Compound.

79. Phase III – The Safety and Efficacy of a Combination of Novel Compound ER and Novel Compound in Patients with Dyslipidemia: A Dose Ranging Study

80. Phase III – A Randomized, Double-blind, Placebo-controlled, Multicenter Phase 3 Study to Evaluate the Long-term Safety of Novel Compound 0.5 mg Twice Daily for 12 Months for the Treatment of Opioid-Induced Bowel Dysfunction in Adults Taking Opioid Therapy for Persistent Non-Cancer Pain.

81. Phase III – A Randomized, Double-blind, Placebo-controlled, Multicenter Phase 3 Study to Evaluate the Safety and Efficacy of Novel Compound 0.5 mg Once Daily and 0.5 mg Twice Daily for 12 Weeks for the Treatment of Opioid-Induced Bowel Dysfunction in Adults Taking Opioid Therapy for Persistent Non-Cancer Pain.

2006

82. Phase III – A Randomized Evaluation of Long Term Anticoagulant Therapy Comparing the Efficacy and Safety of Two Blinded Doses Novel Compound with Open Label Novel Compound for the Prevention of Stroke and Systemic Embolic Events in Patients with Non-valvular Atrial Fibrillation. A Prospective, Randomized Open Label, Active Controlled, Multicenter, Parallel-group Non-inferiority Trial.

83. Phase III – A Worldwide, Multicenter, Double-blind, Randomized, Parallel, Placebo-controlled Study to Evaluate the Lipid-Altering Efficacy, Safety and Tolerability of Novel Compound in Patients With Primary Hypercholesterolemia or Mixed Hyperlipidemia.

84. Phase III – A Phase 3 Study to Evaluate the Efficacy and Safety of a Novel Compound (60 mg QD and 90 mg QD) and an Active Comparator, Novel Compound (30 mg QD) on Healing of Erosive Esophagitis.

85. Phase III – A Multicenter, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Novel Compound / Novel Compound and Niacin (Extended Release Tablet) Co-Administered in Patients with Type IIa or Type IIb Hyperlipidemia.

86. Phase III - A Long-Term Safety and Efficacy Study of Novel Compound in Elderly Subjects With Primary Chronic Insomnia.

2007

87. Phase III – Follow up of Clinical Outcomes: The Long-term Novel Compound plus Usual Care Study.

88. Phase III - A Randomized Double-Blind, Placebo- and Active-Control, Parallel-arm, Phase III Trial with Controlled Adjustment of Dose to Evaluate the Efficacy and Safety of Novel Compound Extended-Release (ER) in Subjects with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee.

89. Phase III - A Randomized Double-Blind, Placebo- and Active-Control, Parallel-arm, Phase III Trial with Controlled Adjustment of Dose to Evaluate the Efficacy and Safety of Novel Compound Extended-Release (ER) in Subjects with Moderate to Severe Chronic Low Back Pain.

90. Phase III – Open Label Extension, Single-Arm, Flexible-Dosing, Phase III Trial with Novel Compound Extended-Release (ER) in Subjects with Moderate to Severe Chronic Pain.

91. Phase III - A Multi-Center, Prospective, Longitudinal, Randomized, Double-Blind, Phase III Study to Evaluate the Efficacy and Safety of Daily Administration of Novel Compound or Novel Compound or Novel Compound (combination of Novel Compound and Novel Compound) for 12 weeks Followed by a 52-Week Open-Label Safety Phase of the Novel Compound alone in the Treatment of Combined Hyperlipidemia.

92. Phase IV – A 6-Week, Prospective, Randomized, Double-Blind, Double-Dummy Phase IV Clinical Trial Designed to Evaluate the Efficacy of an Aggressive Multi-Risk Factor Management Strategy with Novel Compound versus a Guideline-Based Approach in Achieving Blood Pressure and Lipid Goals in Hypertensive Subjects with Additional Risk Factors.

93. Phase IIIB – A Phase IIIB, 12 Month, Double-blind, Double-dummy, Randomized, Parallel-group, Multicenter Exacerbation Study of Novel Compound x 2 actuations Twice-daily and Novel Compound x 2 actuations Twice-daily Compared to Novel Compound x 2 inhalations Twice-daily in COPD Subjects.

94. Phase III – A Multicenter, Randomized, Double-blind, Titration Study to Evaluate and Compare the Efficacy and Safety of Novel Compound Added On to Novel Compound Versus Up Titration to Novel Compound in Hypercholesterolemia Patients at High Risk for Coronary Heart Disease Not Adequately Controlled on Novel Compound.

95. A Randomized, Double-blind, Placebo-controlled, Parallel Group Study of the Efficacy and Safety of TransOral Novel Compound in Adult Subjects with Insomnia Characterized by Difficulty Returning to Sleep after Middle-of-the-Night (MOTN) Awakening.

96. Phase III – A Phase III Randomized, Placebo-Controlled Clinical Trial to Assess the Safety and Efficacy of Novel Compound to Reduce the Risk of Fracture in Osteoporotic Postmenopausal Women Treated With Vitamin D and Calcium.

97. Gastrointestinal (GI) Randomized Event and Safety Open-Label NSAID Study (GIREASONS): A Randomized, Open-Label, Blinded-Endpoint, Parallel-Group Trial of GI Safety of Novel Compound Compared with Non-Selective Nonsteroidal Anti-inflammatory Drugs (NSAID) in Osteoarthritis Patients.

2008

98. Phase II – The investigation of the efficacy and pharmacokinetics of Novel Compound in subjects with neuropathic pain associated with post-herpetic neuralgia (PHN) who have had an inadequate response to Novel Compound treatment.

99. Phase II – A dose-response study of Novel Compound, compared with concurrent placebo control and Novel Compound, in subjects with neuropathic pain associated with diabetic peripheral neuropathy (DPN).

100. Phase II- An efficacy and safety study of Novel Compound compared with a concurrent placebo control in subjects with neuropathic pain associated with post-herpetic neuralgia (PHN).

101. Phase I - A 16-Week, Phase 1, Multicenter, Double-Blind, Randomized, Novel Compound and Novel Compound controlled, Parallel-Group Pharmacological Study, to Assess the Effect of Novel Compound compared to Equimolar Doses of Novel Compound and to Novel Compound on Arterial Blood Pressure as Measured by Ambulatory Blood Pressure Monitoring in Osteoarthritis Patients with Controlled Essential Hypertension

102. A Randomized Double-Blind Parallel Study of Novel Compound 50 mg versus Novel Compound 40 mg for Healing and Symptomatic Relief of Moderate to Severe Erosive Gastroesophageal Reflux Disease (GERD)

103. A Randomized Double-Blind Parallel Study of Novel Compound 50 mg versus Novel Compound 40 mg for Healing and Symptomatic Relief of Mild to Moderate Erosive Gastroesophageal Reflux Disease (GERD)

104. Phase II - Phase II, Multicenter, Randomized, Placebo-Controlled, Study to Evaluate the Efficacy and Safety of Intramuscular Novel Compound 600 mg in Subjects with Uncomplicated Acute Influenza

105. A Multicenter, Randomized, Double-Blind, Assessor-Blind, Non-Inferiority Study Comparing the Efficacy and Safety of Once-Weekly Subcutaneous Biotinylated Novel Compound with oral Adjusted-Dose Warfarin in the Prevention of Stroke and Systemic Thromboembolic Events in Patients with Atrial Fibrillation

106. Phase IIIb – A Randomized, Double-blind, Placebo- and Active-Controlled, Parallel-arm, Multicenter Study in Subjects With End-Stage Joint Disease to Compare the Frequency of Constipation Symptoms in Subjects Treated With Novel Compound IR and Novel Compound IR Using a Bowel Function Patient Diary

2009

107. Phase IIb – A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Dose-Loading Study to Evaluate the Efficacy, Safety, and Tolerability of Novel Compound as Adjunctive Therapy in Subjects With Inadequately Controlled, Moderate to Severe, Chronic Low Back Pain

108. Phase IIb - A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Study to Evaluate the Efficacy, Safety, and Tolerability of Novel Compound as Adjunctive Therapy in Subjects With Inadequately Controlled, Moderate to Severe, Knee or Hip Pain From Osteoarthritis

109. Phase III – Evaluation of Novel Compound on Carotid Intima-Media Thickness (c-IMT) in Subjects with Type IIb Dyslipidemia with Residual Risk in Addition to Novel Compound

110. Phase IV – A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study of the Safety and Efficacy of Novel Compound D (1200 mg Novel Compound and 120 mg Novel Compound in and extended release bi-layer table) for Symptomatic Therapy in Patients with Acute Upper Respiratory Tract Infections Who Seek Treatment

111. Phase IV – A Randomized, Multi-center Trial of Novel Compound doses of 75mg for 5 days or 10 days in Influenza Patients with Pandemic (H1N1) 2009.

2010

112. Phase III – A Long-Term, Randomized, Double-blind Study of the Safety, Tolerability and Efficacy of Novel Compound At Two dosage Levels When Administered to Patients With Moderate to Severe, Stable Chronic Obstructive Pulmonary Disease.

113. Phase IIIB – A Randomized, Double-Blind, Parallel-Group Study of Novel Compound Immediate Release (IR) vs. Novel Compound Immediate Release for the Treatment of Acute Low Back Pain.

114. Phase III – A Randomized-Withdrawal, Placebo-Controlled, Study Evaluating the Efficacy, Safety and Tolerability, of Novel Compound Extended-Release (ER) in Subjects with Chronic, Painful Diabetic Peripheral Neuropathy (DPN)

115. Phase III – A Phase 3, Randomized, Double-blind, Double-dummy, Parallel Group, Multi-Center, Multi-National Study for Evaluation of Efficacy and Safety of Novel Compound Versus Warfarin in Subjects with Atrial Fibrillation – Effective Anticoagulation with Factor ax Next Generation in Atrial Fibrillation

116. Phase IIIb – A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Cardiovascular Outcomes Following Treatment with Novel Compound in Addition to Standard of Care in Subjects with Type 2 Diabetes and Acute Coronary Syndrome

117. A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Novel Compound in Subjects with Uncomplicated Acute Influenza

118. Phase IV – A Multi-Center, Primary Care-Based, Open-Label Study to Assess the Success of Converting Opioid-Experienced Patients, with Chronic, Moderate to Severe Pain, to Novel Compound Using a Standardized Conversion Guide, and to Identify Behaviors Related to Prescription Opioid Abuse, Misuse, and Diversion

2011

119. Phase IIIb - A Multicenter, Randomized, Double-blind, Placebo-Controlled Study to Evaluate Cardiovascular Outcomes Following Treatment with Novel Compound in Addition to Standard of Care in Subjects with Type 2 Diabetes and Acute Coronary Syndrome.

120. Phase III – An Open-Label 52 week Study to Assess the Long-Term Safety of Novel Compound in Opioid-Induced Constipation (OIC) in Patients with Non-Cancer-Related Pain

121. Phase IV – Open Label, Study of Safety and Effectiveness of Novel Compound (Novel Compound) Tablets in the Treatment of Patients with Postherpetic Neuralgia in Clinical Practice.

122. Phase III – A randomized, double-blind, placebo-controlled, event-driven trial of quarterly subcutaneous Novel Compound in the prevention of recurrent cardiovascular events among stable post-myocardial infarction patients with elevated hsCRP

2012

123. Phase IV – Novel Compound, a Safety and Efficacy Study of Inhaled Novel Compound / Novel Compound Combination versus Inhaled Novel Compound in the Treatment of Adolescent and Adult Subjects with Asthma.

124. Phase III - A Randomized, Double-bind, Double-dummy, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Clinical Equivalence of Novel Compound 24 mcg Capsules with Novel Compound 24 mcg Capsules in the Treatment of Chronic Idiopathic Constipation

125. Phase IV - A 1-Year Prospective, Multi-center, Observational Registry Study of Treatment Patterns and Outcomes for Patients with Chronic Obstructive Pulmonary Disease.

126. Phase III - A Randomized, Double-Blinded, Active-Controlled Study of XXX in Patients with Clostridium Difficile Associated Diarrhea

127. Phase IV - Global Registry on Long-Term Oral Anti-thrombotic Treatment in Patients with Atrial Fibrillation

128. Phase III - A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Novel Compound Controlled-release Tablets to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-Induced Constipation (Compared to Novel Compound Controlled-release Tablets) in Opioid-experienced Subjects with Uncontrolled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy.

129. Phase II - A Phase 2, Randomized, Double-Dummy, Double-Blind, Placebo-Controlled Study to Assess the Efficacy, Safety, and Tolerability of Novel Compound for the treatment of symptoms of agitation in patients with Alzheimer's Disease.

130. Phase IIIb - A Multi-Center, Prospective, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Novel Compound on Cardiovascular Health and Mortality in Hypertriglyceridemic Patients with Cardiovascular Disease or at High Risk for Cardiovascular Disease: REDUCE-IT (Reduction of Cardiovascular Events with EPA-Intervention Trial)

131. Phase IV - A Prospective, open label study evaluating the efficacy of two management strategies (pantoprazole 40 mg q.a.m. and taking Novel Compound with food (within 30 minutes after a meal)) on gastrointestinal symptoms (GIS) in patients newly on treatment with Novel Compound 150 mg b.i.d. or 75 mg b.i.d. for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation (NVAF)

132. Phase IV - A Prospective, Open Label Study to Evaluate the Pharmacokinetics of Dabigatran in Non-Valvular Atrial Fibrillation (NVAF) patients with severely impaired renal function on Dabigatran Etexilate 75 mg BID Therapy

2014

133. Phase III - Randomized, Double-Blind, Placebo-controlled, Parallel-Group Study To Assess Cardiovascular Outcomes Following Treatment with XXX in Subjects with Type 2 Diabetes Mellitus and Established Vascular Disease.

134. Phase II - A Prospective, Randomized, Double-Blind, Placebo-Controlled, Phase 2 Efficacy and Safety Study of Oral XXX for Treatment of Agitation and Aggression in Patients With Moderate to Severe Alzheimer's Disease.

135. Phase III - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 26-Week, Phase 3 Study of Two Doses of XXX or Placebo in Subjects with Mild to Moderate Alzheimer's Disease Currently or Previously Receiving an Acetylcholinesterase Inhibitor Medication.

136. Phase III - Medically Ill Patient Assessment of XXX Versus Placebo IN Reducing Post-Discharge Venous Thrombo-Embolism Risk (Mariner).

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

2015

138. Phase III - Randomized, Double-Blind, Placebo Controlled, Multi-Center Registration Trial to Evaluate the Efficacy and Safety of XXX in Patients with Mild Alzheimer's Disease Receiving Acetylcholinesterase Inhibitors and/or Memantine.

139. Phase III - A 26-Week Extension Study of the Safety and Clinical Effects of XXX in Subjects with Alzheimer's Disease Currently or Previously Receiving an Acetylcholinesterase Inhibitor Medication.

140. Phase III - A Phase 3, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of XXX (XXX) for the treatment of agitation in patients with dementia of the Alzheimer's type.

141. Phase III - A Phase 3, Multicenter, Long-term, Extension Study of the Safety and Efficacy of XXX (XXX) for the Treatment of Agitation in Patients with Dementia of the Alzheimer's Type.

142. Patient and Provider Assessment of Lipid Management Registry.

2016

143. Phase III – Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral XXX for the Correction of Anemia in Subjects with Non-Dialysis-Dependent Chronic Kidney Disease (NDD-CKD)

144. Phase III – Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral XXX for the Maintenance Treatment of Anemia in Subjects with Non-Dialysis-Dependent Chronic Kidney Disease (CDD-CKD)

145. Phase III – A Randomized, Double-Blind, Placebo-Controlled and Delayed-Start Study of XXX in Mild Alzheimer's Disease Dementia (The DAYBREAK Study)

146. Phase IV – Post-authorisation Safety (PAS) Observational Cohort Study to Quantify the Incidence and Comparative Safety of Selected Cardiovascular and Cerebrovascular Events in COPD Patients Using Inhaled UMEC/VI Combination or Inhaled UMEC versus Tiotropium (Study 201038)

147. Phase III – Open Label Extension Study for Continued Safety and Efficacy Evaluation of XXX in Patients with Mild Alzheimer's Disease

148. Phase II - A 36-Week Safety Extension Study of Oral XXX for Treatment of Agitation and Aggression in Patients With Moderate to Severe Alzheimer's Disease

149. Registry of Amyloid Positive Patients for Alzheimer's Disease Drug Research Trials (RAmP)

150. Phase III – A Placebo-Controlled, Double-Blind, Parallel-Group, 24-Month Study to Evaluate the Efficacy and Safety of XXX in Subjects with Early Alzheimer's Disease