

**Phase II-IV studies
Tacoma, WA
1989-1995**

1. An 18 month, multicenter, double blind, placebo controlled safety, tolerability, and efficacy study of a hormone replacement therapy on osteoporosis in postmenopausal women.
2. A 6 month, multicenter, double blind, placebo controlled study of a hormone replacement therapy on the symptoms of menopause.
3. A multicenter, dose escalation trial of XXX on blood pressure and lipids in patients with mild to moderate hypertension and hyperlipidemia.
4. An ascending dose, multicenter trial of the efficacy of XXX on the symptoms of Benign Prostatic Hyperplasia.
5. A multicenter study comparing 2 doses of XXX versus placebo in preventing symptoms of meal induced GERD.
6. A multi-center study of the safety and efficacy of XXX on hypertension and glucose tolerance in patients with mild to moderate hypertension.
7. The safety and efficacy of XXX in patients with mild to moderate hypertension.
8. A randomized, double blind trial of the safety and efficacy of two different single doses of XXX in GERD.
9. A randomized trial of the safety and efficacy of an effervescent vs. standard formulation of XXX in GERD.
10. A multicenter, randomized, double blind comparison of the efficacy and tolerability of XXX vs. a standard reference product in patients with mild to moderate hypertension.
11. A randomized, placebo controlled multicenter trial of the efficacy and tolerability of XXX in patients with mild to moderate hypertension.
12. A 12 month multicenter, randomized, dose titration study of the safety and efficacy of XXX in patients with mild to moderate hypertension
13. The safety and efficacy of XXX for patients with severe GERD

**Phase I/IIa Studies
Northwest Kinetics, Tacoma WA
1995-2000**

◆ = Subinvestigator per 1572,

14. A multicenter, sequential dose escalation Phase Ib/IIa safety, tolerability, and efficacy trial of XXX as a radiosensitizer in patients with metastatic lung or breast cancer to the brain.
15. ♦ A Phase II multicenter, randomized, placebo controlled, double blind, dose response, safety and efficacy study of XXX in 24 patients with Diabetes II.
16. {First Time in Humans} Safety, Tolerability, and pharmacokinetic profile of ascending single doses of intravenous XXX in 21 normal, healthy volunteers.
17. An open label, parallel group comparison of single dose and steady state pharmacokinetics of XXX in subjects with various degrees of renal impairment compared with normal healthy controls.
18. Effects of XXX on the pharmacokinetics and pharmacodynamics of Glyburide 2.5 mg BID in patients with Diabetes II.
19. Efficacy and tolerability of a device in achieving local anesthesia prior to lumbar puncture in 13 normal healthy adults.
20. A crossover study comparing pharmacodynamics of whole tablet and powdered XXX and whole tablet and powdered YYY in glucose control in 30 patients with Diabetes II.
21. Pharmacokinetics, safety and tolerability of lyophilized XXX administered subcutaneously in normal healthy male volunteers.
22. {First time in elderly} An open label, ascending, single dose pharmacokinetic study of XXX in 14 healthy elderly subjects.
23. {First multiple dose} Safety, tolerability, and pharmacokinetics of ascending multiple intravenous doses of XXX in 15 normal healthy male volunteers.
24. {First time in pediatrics} Efficacy and tolerability of a medical device in achieving topical anesthesia in healthy 9 to 12 year old children.
25. A double blind crossover comparison of the pharmacokinetics, safety, and tolerability of XXX with placebo vs. XXX with Cimetidine in 18 normal healthy volunteers.
26. A double blind crossover comparison of the safety, tolerability, and pharmacokinetics of single doses of 30, 45, 60, and 100 mg. capsules of XXX in healthy volunteers.
27. A multicenter double blind, parallel group, placebo controlled, safety, tolerability, and pharmacokinetic study of XXX in patients with renal impairment.
28. The safety, tolerability, pharmacokinetic and bioavailability of lyophilized XXX by subcutaneous injection in normal healthy females.
29. A randomized, open label, crossover study to determine the pharmacokinetics of XXX when taken with a fatty meal vs. fasting in 24 healthy postmenopausal women.
30. Single dose kinetics, safety, and tolerability of 5 mg. of XXX in 13-17 year old adolescents and adults with a history of migraine headaches.

31. A randomized, double blind study of the safety, tolerability, pharmacokinetics, and CSF levels following single dose intravenous administration of XXX in 5 healthy males.
32. A crossover study comparing the glucose and insulin profiles following XXX, placebo, glyburide, and metformin administration in 24 patients with Diabetes II.
33. The safety, tolerability, and pharmacokinetics of inhaled recombinant XXX in normal volunteers.
34. A 4 way crossover study of the tolerability of various excipients for injectable use in healthy volunteers.
35. {First time in humans} The safety, tolerability, and pharmacokinetics of single doses of 200 mg, 400 mg, 600 mg, and 800 mg. of XXX in normal healthy male and female volunteers.
36. {First time in humans} The safety, tolerability, pharmacodynamics, and pharmacokinetics of single ascending doses and multiple ascending doses of XXX in 64 normal healthy volunteers.
37. A multiple dose, crossover study of the tolerability and efficacy of XXX administered as a tablet vs. as a powder mixed with food, in 20 patients with Diabetes II.
38. {First time in a patient population} A randomized, placebo-controlled, double blind multicenter study to assess the safety, tolerability, and antiretroviral activity of XXX in asymptomatic HIV-infected patients.
39. {First time in this patient population} A Phase Ib, double blind, placebo-controlled sequential, ascending dose study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of a single intravenous dose of XXX in 24 patients with stable exertional angina.
40. Evaluation of the pharmacokinetics, safety, and tolerability of single and multiple doses of a new pediatric formulation of XXX in 20 7 to 11 year old children who are healthy or have mild asthma.
41. Pharmacokinetic and pharmacodynamic interactions of single and multiple doses of XXX and Glyburide in 18 patients with Diabetes II.
42. The safety and tolerability of liquid XXX compared with Neupogen (G-CSF) via subcutaneous injection in 24 healthy volunteers.
43. {First time in this patient population} An open-label, two phase, four period, multiple dose, dose escalation study to assess the pharmacokinetics of XXX in 18 patients with congestive heart failure.
44. A randomized, placebo controlled, three period, blinded crossover study to evaluate the pharmacokinetic and pharmacodynamic interaction of XXX and Troglitazone in 12 patients with Diabetes II.
45. A multiple dose study of the effect of YYY on the tolerability and pharmacodynamics of XXX in 26 patients with Diabetes II.
46. A randomized, five way crossover bioavailability comparison of immediate release tablets versus four controlled release tablets of XXX in 10 normal healthy volunteers.
47. A randomized, single blind, single dose, two period crossover study of the safety of XXX and Lespro Insulin administered as two separate subcutaneous injections in conjunction with NPH, Lente, or Ultralente Insulin in 12 patients with Diabetes type I.

48. The safety, tolerability, efficacy, and pharmacokinetics of a 3 different single doses of nebulized recombinant XXX in 24 adult patients with mild vs. moderate asthma.
49. An open, parallel, multiple dose study comparing the pharmacokinetics of XXX in 46 2D6 genotyped healthy normal age, gender, and weight matched Blacks vs. Caucasians.
50. {First time in a patient population} A randomized, placebo controlled, dose escalation trial of 3 intravenous doses of XXX in 12 patients with moderate to severe plaque type psoriasis.
51. A randomized pharmacokinetic trial to test the bioequivalence, safety and tolerability of two oral preparations of XXX in patients with cancer.
52. {First multiple dose study for this product} A multiple group, ascending dose (200 mg, 400 mg, 600 mg, 800 mg) study to evaluate the safety, tolerability, and pharmacokinetic profile of a five day multiple dose regimen of XXX in healthy male and female volunteers.
53. A multi-center, multiple-dose, escalating dose study to evaluate the safety, pharmacokinetics, and biological activity of intravenous XXX in subjects with moderate to severe plaque type psoriasis.
54. Pharmacokinetic, safety, and tolerability assessments of the potential interaction between XXX tablets and sustained-release theophylline in 16 children ages 5-11 years old.
55. Safety, tolerability and pharmacokinetics of multiple doses of XXX in 47 patients with Diabetes II.
56. A crossover study of the safety, tolerability, and pharmacokinetics of a single dose of an extended release form of XXX compared with standard formulation of XXX in 16 healthy subjects.
57. A multi-center, double blind, randomized, single dose, placebo controlled study to investigate the efficacy and safety of 20.6 mg and 10.3 mg of XXX in preventing meal-induced heartburn symptoms after a provocative meal in 52 adults with a history of meal-induced heartburn.
58. A randomized, double blind, placebo controlled, single dose, two period crossover study to determine the effect of XXX on the pharmacokinetics of Ethinyl Estradiol and Norgestrel in 18 healthy 18-35 year old females subjects receiving the oral contraceptive agent Lo/Ovral.
59. A safety, tolerability, and pharmacodynamic assessment of a single dose of XXX in 10 patients with Diabetes II treated with diet only.
60. A multi-center Phase II randomized, placebo controlled, crossover study of recombinant XXX , via infusion pump, as a means of glycemic control in 12 patients with Diabetes I.
61. {Pivotal trial} Comparative pharmacokinetics, safety, and tolerability of liquid and reconstituted lyophilized preparations of XXX in 80 normal, healthy Rhesus Negative volunteers.
62. {Japanese bridging study} A comparison of the safety, tolerability, and single dose and multiple dose pharmacokinetics of XXX in 14 healthy male Japanese with 14 age and weight matched Caucasian volunteers.
63. A six week trial of the safety, tolerability, and pharmacokinetics of XXX in children and adolescents with Obsessive-Compulsive Disorder.

64. A randomized, double blind, placebo controlled, titrated dose study of the safety, tolerability and antihypertensive efficacy of a multiple dose regimen of XXX in African American patients with mild to moderate hypertension.
65. A randomized, double blind, placebo controlled cross over study of 5 doses of XXX in the reversal of bronchoconstriction in 21 adults with mild to moderate asthma.
66. A double blind, placebo controlled safety, tolerability, pharmacokinetic and pharmacodynamic study of escalating multiple oral doses of XXX in 30 healthy volunteers.
67. {Japanese bridging study} A comparison of the safety, tolerability, and pharmacokinetic profile of a single dose of XXX in healthy postmenopausal Japanese and Caucasian women.
68. A single dose, randomized, open label, two way crossover bioequivalence study comparing a generic formulation of XXX with a proprietary formulation of XXX in 12 male and female patients with mild to severe psoriasis.
69. A randomized, placebo controlled, ascending single dose study of the safety, tolerability, and pharmacokinetics of XXX in 28 healthy normal volunteers.
70. An open label, multiple dose, dose escalation study of the safety, tolerability, and efficacy of intravenous XXX in 8 patients with moderate to severe psoriasis.
71. A randomized, placebo controlled, sequential group ascending dose, multiple dose study of the safety, tolerability, and pharmacokinetics of XXX in 35 healthy volunteers.
72. A double blind, placebo controlled study of the safety, tolerability and pharmacokinetics of sequential group, ascending dose, five day, BID multiple dose regimen of XXX in 24 healthy male and female subjects.
73. A double blind, placebo controlled, sequential group ascending dose study of the safety, tolerability, pharmacokinetics, and efficacy of XXX in 30 patients with Diabetes II.
74. A double blind, placebo controlled, multi-center crossover study of the safety, tolerability, and efficacy of XXX in the treatment of patients with Diabetes II inadequately controlled with diet and sulfonylurea therapy.
75. A randomized, open label, crossover study comparing the pharmacokinetics of two formulations of XXX administered subcutaneously to 24 normal healthy males.
76. Palatability testing of 4 different flavors of an oral syrup of XXX in 16 children.
77. A single dose safety, tolerability, and pharmacodynamic study of XXX in 10 Diabetes II patients treated with diet only.
78. Pharmacokinetics of standard formulation vs. 3 prolonged release capsules of XXX with different in-vitro dissolution rates; an open label randomized, single dose crossover trial in 15 healthy volunteers.
79. A double blind, placebo controlled, multicenter, crossover study of the safety, tolerability, and efficacy of XXX in the treatment of patients with Diabetes II inadequately controlled with diet.

80. A double blind, placebo controlled, multicenter, crossover study of the safety, tolerability, and efficacy of XXX in the treatment of patients with Diabetes II inadequately controlled with insulin.
81. A long term assessment of the safety, tolerability, and efficacy of weekly doses of XXX administered via inhaled nebulizer in adults with mild to moderate asthma.
82. A 4 way crossover study assessing the pharmacokinetic profile of XXX when administered under fasting conditions compared with fed, with an antacid, and with grapefruit juice in 16 healthy adults.
83. {First US study} A single dose, 6 level dose escalation study of the pharmacokinetics, safety, and tolerability of intranasal XXX in 10 healthy volunteers.
84. A randomized, double blind, placebo controlled sequential group study of the safety, tolerability, pharmacodynamics and pharmacokinetics of XXX when administered over progressively shorter intravenous infusion periods, in 35 healthy individuals using 7 different infusion rates.
85. A 2D6 genotype analysis of 15 volunteers correlating with pharmacokinetic data.
86. A randomized, crossover study of relative bioavailability of a pediatric pellet formulation of XXX compared with the standard adult tablet in 26 healthy adults.
87. A single dose study to compare the pharmacokinetics of XXX when administered by subcutaneous, intramuscular, or intravenous routes, utilizing standard and investigational assays, in 22 healthy male volunteers.
88. A safety, tolerability, and pharmacokinetic profile following single dose and after 30 days of q AM dosing of XXX in healthy male volunteers.
89. A single blind, placebo controlled study of the safety, tolerability, pharmacokinetics, and glucose lowering effects of ascending single doses of XXX in 14 subjects with Diabetes II.
90. A single dose, 3 way crossover comparison of the bioavailability and bioequivalence of a proprietary rectal suppository of XXX compared with two generic suppositories of XXX in 18 healthy normal male and female volunteers.
91. A double blind, randomized, placebo controlled, parallel group, multiple daily dose safety and pharmacokinetic and pharmacodynamic study of XXX in 24 healthy male and female volunteers.
92. A study of the safety, tolerability, and pharmacokinetic profile of XXX in 10 children age 5 and 6 who were healthy or had mild asthma.
93. {First time in humans} A double blind, randomized, placebo controlled, ascending single oral dose study of the safety, tolerability, pharmacokinetics, and pharmacodynamics of XXX in 35 healthy elderly volunteers.
94. An open label, single dose, dose ranging study to evaluate the safety, tolerability, and pharmacokinetics of XXX in 24 healthy volunteers pre-treated with Hydrochlorothiazide.
95. The safety, tolerability, pharmacokinetics and efficacy of multiple ascending doses of XXX in patients with stable moderate asthma.

96. The safety, tolerability, and relative bioavailability of the test tablet and test capsule formulations of XXX compared with the proprietary formulation of XXX in patients with chronic Hepatitis C infection.
97. A study of the safety, tolerability, and pharmacodynamics of intravenous XXX when administered to healthy volunteers with varying blood types.
98. An open label, single dose, two way crossover study to evaluate the safety, tolerability, and pharmacokinetics of XXX in 18 healthy volunteers when administered under fed versus fasting conditions.
99. A double blind, escalating, single dose study of the safety, tolerability, and pharmacokinetics of XXX in 35 healthy male volunteers.
100. A double blind, randomized, placebo controlled, dose escalating study of the safety, tolerability, pharmacokinetics, and pharmacodynamics of XXX in healthy elderly volunteers.
101. An open label, single dose study of the safety, tolerability, and pharmacokinetics of XXX and its metabolites in 13-17 year old obese adolescents.
102. A randomized, open label, parallel group, multi dose, multicenter study comparing the pharmacokinetics and pharmacodynamics of XXX when administered under fed vs. fasted conditions in 9 volunteers with Diabetes

Phase I-III Studies
Radiant Research, Honolulu
2000-2006

◆ = Subinvestigator per 1572

* = Phase I/Clinical Pharmacology Study

103. *◆ {Japanese bridging study} Safety and Pharmacokinetic assessment of 150, 300, and 600 mg XXX Single and Multiple Doses in Healthy Japanese and Non-Japanese Subjects.
104. *◆ {Japanese bridging study} An Eight-Day, Double-Masked, Randomized, Parallel, Safety and IOP-Lowering Response Study of XXX Ophthalmic Solutions compared to Vehicle Following topical Ocular Administration in Normal Healthy Male Japanese Subjects.
105. ◆ An 18 month, double-blind, Placebo-Controlled, Phase III Trial with a 12 Month Interim Analysis of the Effect of XXX on Fracture Incidence in Women with Postmenopausal Osteoporosis.
106. {Japanese bridging study} A multi-center, randomized, double blind, placebo controlled, parallel group, forced titration study of the safety and effectiveness of XXX vs. placebo in Japanese-American and Caucasian-American patients with hypercholesterolemia.
107. {Asian study} Collection of lymphocytes for an “Index” genetic repository database in participants with pure three generation ethnic pedigrees.

108. {Asian study} Collection of lymphocytes in three generations within the same family for an “Index” genetic repository database.
109. The Safety and Efficacy of XXX Versus Rosiglitazone: A One-year, Randomized, Double Blind, Parallel Group, Active Comparator Study.
110. A double-blind, randomized, parallel group, dose response, multi-center study to compare the safety and efficacy of XXX extended release capsules to placebo dosed at bedtime and to XXX dosed in the morning in patients with essential hypertension.
111. A double-blind, randomized, multi-center study comparing the safety, tolerability, and efficacy of XXX vs. Enalapril in patients with hypertension.
112. A Phase 2, randomized, triple blind, placebo controlled, multicenter, forced dose escalation study to examine dose tolerability of subcutaneously administered XXX in subjects with Diabetes II.
113. *{Japanese bridging study} A pharmacokinetic assessment of multiple oral doses of XXX in healthy and untreated mildly hypertensive Japanese volunteers.
114. Combination therapy of metformin with once daily evening dose of XXX vs. YYY: comparison of safety and efficacy in subjects with Type 2 Diabetes previously inadequately controlled with monotherapy or oral combination therapy.
115. A randomized, multicenter, double-blind, parallel-group study to compare the effects of XXX vs. placebo as initial oral therapy in subjects with Diabetes Mellitus II.
116. A Double-blind Randomized study to evaluate the effects of fixed combination of XXX/YYY in subjects with Type II Diabetes
117. *{Japanese bridging Study} An open-label, non-randomized, parallel-group study to assess the influence of smoking and ethnicity on XXX pharmacokinetics following a single oral dose in healthy male and female volunteers from four ethnic groups.
118. *{Japanese bridging study} A Randomized, Placebo-Controlled, Double-Blind, Single-Dose Study of Intravenous XXX Comparing the Pharmacokinetic Properties in Caucasian and Japanese Healthy Volunteers.
119. * {Japanese bridging Study} Assessment of effects of a High Caloric Diet vs. XXX once daily for seven days on hepatic Transaminases in a healthy Japanese male volunteer.
120. *♦ A multi-center, randomized, double-blind, placebo-controlled, dosing regimens and dose ranging study of the safety and tolerability of repeated intravenous administration of XXX in patients with atherosclerosis.
121. *♦ {Japanese bridging study} A phase I, randomized, double-blind, placebo-controlled, 4-way crossover study of the safety, toleration and pharmacokinetics of single oral doses of XXX in healthy male Japanese and Caucasian subjects.
122. ♦ A 6-week, open-label, dose-comparison study to evaluate the safety and efficacy of XXX vs. {3 FDA approved alternate medications} in subjects with hypercholesterolemia.

123. ♦ An Open-label, Multinational, Multicentre, Extension Trial to Assess the Longterm Safety and Efficacy of XXX in Subjects in the XXX Clinical Trial Program.
124. ♦ A multi-national, multicenter, randomized, double-blind, parallel group, placebo-controlled clinical trial of the effects of XXX on the incidence of new vertebral fractures in osteoporotic postmenopausal women.
125. ♦ {Asian Study} Study of the efficacy and tolerability of once daily XXX and twice daily YYY vs. placebo in the treatment of Asian American subjects with osteoarthritis of the knee.
126. {Japanese bridging Study} Benefit of skin brightening efficacy using benchmark skin benefit agent.
127. A multi-center, double-blind, randomized, placebo and active-controlled parallel study to evaluate the glucose and lipid-altering efficacy and safety of XXX in patients with Type 2 Diabetes.
128. A multi-center, double-blind, randomized, placebo- and active-controlled, parallel study to evaluate the lipid altering efficacy and safety of XXX in patients with metabolic syndrome and dyslipidemia.
129. ♦ Study of vasomotor symptoms in postmenopausal women receiving combination XXX and oral estrogen.
130. ♦ A multicenter, double-blind, randomized, placebo and Raloxifene controlled study to assess safety and efficacy of XXX in the prevention of postmenopausal osteoporosis.
131. *♦ {Japanese bridging Study} A comparison of two different diets and their effect upon liver function in healthy Japanese volunteers.
132. * {Japanese bridging study} XXX: a randomized, single-blind, placebo-controlled, 4-treatment, 4-period crossover design study comparing the pharmacokinetics, pharmacodynamics, and safety of XXX in healthy, adult male, First-generation Japanese and Caucasian subjects.
133. *{Japanese bridging study} Randomized, single ascending dose, placebo-controlled, parallel design study to assess safety, tolerability, pharmacokinetics and pharmacodynamics of intravenously administered XXX: Direct comparison study between Japanese and Caucasian healthy male volunteers.
134. A Randomized, Double-Blind, Placebo Controlled Trial of XXX in Type 2 Diabetics Inadequately Controlled on a Sulfonylurea.
135. *{Japanese bridging study} An Open-label study to compare the cytochrome P450-mediated metabolizing ability among first, second, and third generation Japanese residing outside of Asia and Caucasians.
136. A Double-blind, randomized, Placebo- and Active-controlled, Multicenter, Parallel-Groups Study Evaluating the Safety and Efficacy of XXX and YYY and Placebo in subjects with asthma.
137. *♦ {Japanese bridging study} A Double-Blind, Randomized, Placebo-Controlled, Rising-Single-Oral Dose Study to Assess the Safety, Tolerability, and Pharmacokinetics of XXX in Healthy Male Japanese Subjects.

138. A Randomized, Double-Blind, Multicenter Study to Evaluate the Tolerability and effectiveness of XXX vs. YYY in Patients with Osteoarthritis.
139. A Phase 2, Randomized, Triple-Blind, Placebo-Controlled, Short-Term, Dose-Response Study to Examine the Effect on Glucose Control and Safety and Tolerability of XXX Given Two Times a Day in Subjects with Type 2 Diabetes Mellitus.
140. A Phase 2 multi-center, double-blind, placebo-controlled, randomized, parallel group, dose ranging study of the efficacy, safety, tolerability, and pharmacokinetics of XXX and open-label YYY when concurrently administered orally once daily for 12 weeks to subjects with elevated low-density lipoprotein cholesterol and without overt cardiovascular disease.
141. A Dose Range-Finding, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Assess the Safety, Tolerability, and Efficacy of XXX in Obese Subjects.
142. Phase 2 multi-center, double-blind, placebo-controlled, randomized, parallel group, dose ranging study of the efficacy, safety, tolerability, and pharmacokinetics of XXX and open-label YYY when concurrently administered orally twice daily for 12 weeks to subjects with elevated low-density lipoprotein cholesterol and without overt cardiovascular disease.
143. ♦ A Multiple Dose, Safety, Tolerability and Pharmacokinetic Dose Escalation Study of XXX in Patients with Chronic Moderate-To-Severe Osteoarthritis Pain.
144. * {Japanese bridging study} Assessment of the Safety, Tolerability and Pharmacokinetics of Subcutaneous XXX After Administration of Single Escalating Doses to Caucasian and Japanese Healthy Volunteers.
145. *♦ {Japanese bridging study} A Double-Blind, Randomized, 2-Panel Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of Multiple Doses of XXX in Healthy Japanese and Non-Japanese Subjects.
146. A Randomized, Multicenter, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of XXX in Patients with Chronic Pain Caused by Mild to Moderate Osteoarthritis of the Knee.
147. *♦ A Randomized, Double-Blind Factorial Design Study Comparing the XXX patch to a Lidocaine Patch, Tetracaine Patch and Placebo Patch
148. *An Open-Label, Randomized, Replicate, Four-Period Crossover Study in Healthy Post-Menopausal Women to Assess the Bioequivalence of a Single Unit Dose Tablet of 150 mg XXX to 3 x 50 mg Tablets of XXX.
149. An Open-Label Study to Examine the Long-Term Effect on Glucose Control (HbA_{1c}) and Safety and Tolerability of XXX Given Two Times a Day to Subjects With Type 2 Diabetes Mellitus.
150. *An Open-Label, Randomized, Replicate, Four-Period Crossover Study in Healthy Post-Menopausal Women to Assess the Bioequivalence of a Single Unit Dose Tablet of 100 mg XXX to 2 x 50 mg Tablets of XXX.

151. *{Japanese bridging Study} A Randomized, Double-Blind, Placebo-Controlled, 2-Panel, Rising Single Oral Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX in Healthy Japanese Male Subjects.
152. *{Japanese bridging Study} A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single Ascending Oral Doses of XXX Tablets in Healthy Male and Female Japanese and Caucasian Subjects.
153. *Characterization of Fasting and Postprandial Concentrations of Pancreatic/Gastrointestinal Hormones and Related Biochemical Measures in Different Subject Populations.
154. *{Japanese bridging Study} A Randomized, Single-Blind, Placebo-Controlled Study to Evaluate the Safety and Pharmacokinetics of XXX in Healthy Older Japanese and Caucasian Women.
155. ♦ A Phase II, Multicenter Study to Evaluate the Effect of XXX on primary Humoral Response, Recall Response, and Maintenance of Acquired Immunity to Specific Antigens.
156. A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Assess the Safety, Tolerability, and Efficacy of XXX in Obese Patients.
157. *A Study to Evaluate the Effect of Repeat Oral Doses of XXX on Cardiac Conduction as assessed by 12-lead Electrocardiogram as Compared to Placebo and Single Oral Doses of Moxifloxacin.
158. *♦ {Asian Study} A Phase I Study to Examine the Effect of Race on the Single Dose Pharmacokinetics of XXX in Healthy Subjects.
159. *{Japanese bridging Study} A Study to Investigate the Potential Pharmacokinetic Interaction Between XXX and Rifampin in Healthy Caucasian and Japanese Subjects.
160. ♦ A Randomized, Single-Blind, Placebo-Controlled, Dose-Rising Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Preliminary Pharmacodynamics of Single and Repeat Oral Doses of XXX in Healthy Postmenopausal Women.
161. A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Examine the Safety and Pharmacokinetics of XXX in Subjects with Type 2 Diabetes Mellitus.
162. A 26-Week, Randomized, Placebo- and Active-Comparator-Controlled, Parallel-group, Double-Blind, 2-Part Study to Assess the Safety and Efficacy of XXX vs. YYY in Patients with Osteoarthritis.
163. *{Japanese bridging Study} An open-label, randomized, crossover study of XXX given subcutaneously to healthy male Japanese and Caucasian subjects.
164. A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Assess the Safety, Tolerability, and Efficacy of XXX in Obese Patients.
165. A Study Evaluating the Temperature Profile of XXX when Applied to Adult Volunteers.
166. *{Japanese bridging Study} A placebo controlled, double blind (within dose group), randomized, parallel group and single center study to investigate the safety, tolerability, and pharmacokinetics of ascending single oral dose of XXX tablet formulation in Caucasian and Japanese healthy female (post menopausal or post hysterectomy) and male subjects.

167. *{Japan to US Bridging Study} A Phase I, Pilot Study to Evaluate the Effects of XXX Delivered Transdermally.
168. *◆ {Japanese bridging Study} Evaluation of the Dose Proportionality of 100 mcg, 200 mcg, 400 mcg, and 800 mcg Single Doses of XXX Administered Buccally to Healthy Japanese Volunteers.
169. * {Japanese bridging Study} Single-center, randomized, placebo-controlled, single-blind, dose-escalating single-injection study to assess the safety and pharmacokinetics of XXX (0.01, 0.03, 0.05, or 0.1 mmol/kg) in Japanese healthy male or female subjects.
170. A Multicenter, Double-Blind, Randomized Study to Evaluate the Safety and Efficacy of the Addition of XXX Compared with Sulfonylurea Therapy in Patients with Type 2 Diabetes With Inadequate Glycemic Control on Metformin Monotherapy.
171. A randomized, double-blind study comparing an XXX patch with heat to an XXX patch without heat prior to vascular access.
172. A randomized, double-blind study comparing XXX patch with heat to YYY patch without heat for induction of local anesthesia prior to vascular access.
173. * An Open-Label Pharmacokinetic and Safety Study to Evaluate the Effect of Repeated Administration of XXX on CYP1A2 Activity in Healthy Subjects using Caffeine as the Probe Substrate.
174. * An open-label, multiple-dose study in normal healthy volunteers to evaluate the pharmacokinetics, safety and tolerability of XXX and ramipril (Altace®) administered alone and in combination.
175. * {Japanese bridging Study} A Randomized, Controlled trial of the Safety, Tolerability and Immunogenicity of XXX Vaccine in Healthy Japanese Adults.
176. * An Open-Label, Randomized, Crossover Study to Assess the Dose Proportionality and Pharmacokinetics of 4 Doses (100, 200, 400, and 800 mcg) of XXX in Healthy Subjects.
177. * {Japanese bridging Study} The Accumulation and Pharmacokinetics of XXX during and following a Multiple Buccal Administration Regimen of XXX to Healthy Japanese Volunteers.
178. An Open Label Study Evaluating the Temperature Profile of the XXX Patch and a Dummy Patch When Applied Concurrently Above the Knees on Adult Subjects.
179. * {First in Humans} A Phase I, Randomized, Placebo-Controlled, Double-Blind, Dose-Escalation Study of Safety, Pharmacokinetics and Activity of Single Intravenous Doses of XXX in Adults with Moderate-to-Severe Pain from Osteoarthritis of the Knee.
180. A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Examine the Safety and Pharmacokinetics of XXX Administered Weekly in Subjects with Type 2 Diabetes Mellitus.
181. *Multiple-Dose Safety Study in Premenopausal Women.
182. *{Japanese bridging Study} Comparative Systemic Bioavailability of XXX following Administration of (Treatment A); (Treatment B); and (Treatment C).

183. Survey of Blood and Urine Samples for Markers Indicative of Breast Cancer.
184. *An open label study of the pharmacokinetics, safety and tolerability of XXX in extremely obese subjects.
185. *A Phase I, Single-Blind, Controlled, Randomized, Study of the Safety, Tolerability, and Immunogenicity of XXX Vaccine when administered at a 0, 2, 6 or a 0, 1, 2, 6-Month Dose Schedule in Healthy Adults.
186. *◆ An open-label, single center study to determine the absorption, distribution, metabolism, and excretion (ADME) of XXX after a single oral administration of 400 mg [100 µCi ¹⁴C] XXX in healthy male volunteers.
187. *{Japanese bridging Study} Pharmacokinetic Evaluation of XXX in Healthy Japanese Subjects.
188. A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability, and Efficacy of XXX in the Treatment of Postmenopausal Women With Osteoporosis.
189. *{Microdose Study} A Pharmacokinetic Study of A Single 450 Nanogram Dose of Carbon-14 Labeled Zidovudine In A Healthy Volunteer.
190. * An open-label single dose study assessing the effect of age on the pharmacokinetics of XXX.
191. *{Japanese bridging Study} Safety, Tolerability, Pharmacokinetic and Pharmacodynamic Evaluation of Multipel Oral Doses of XXX in Healthy Japanese and Caucasian Adults.
192. A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Assess the Safety, Tolerability, and Efficacy of XXX in Obese Patients.
193. A 2-Year Study to Assess the Efficacy, Safety, and Tolerability of XXX in Obese Patients.
194. An 18-Month Study to Assess the Efficacy, Safety, and Tolerability of XXX in Obese Patients.
195. * A Study to Evaluate the Relative Bioavailability, Food and Age/Gender Effect on the Pharmacokinetics of XXX in Healthy Subjects.
196. A Single-Center, Open-Label Study Evaluating the Heating Characteristics of 10 cm², 20 cm² and 40 cm² XXX Heating Patches When Applied to Adult Volunteers.
197. * A Randomized, Double-Blind, Placebo-Controlled, Multiple-Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamic Efficacy of XXX in Healthy Postmenopausal Women.
198. ◆ * {ADME study} Excretion balance, pharmacokinetics, and metabolic profiles of XXX following a single oral dose of ¹⁴C labeled XXX in male patients with Type 2 Diabetes.
199. * A Randomized, Open-label, 4-Period, Crossover Study to Characterize the Pharmacokinetics of 4 Dose Strengths of XXX in Healthy Subjects.

200. * An Open Label, Fixed Sequence Study to Assess the Effect of Repeat Oral Dosing of Ketoconazole on the Pharmacokinetics of Repeat Oral Dosing of XXX.
201. * {ADME study} A Phase I, open-label, single-dose study to evaluate the Absorption, Distribution, Metabolism, and Excretion of ²H, ¹⁴C XXX blend in healthy adult male volunteers.
202. A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group, Phase 2 Trial to Evaluate the Safety and Efficacy of XXX as Monotherapy in Subjects with Type 2 Diabetes Mellitus who are Treatment Naïve and have Inadequate Glycemic Control on Diet and Exercise.
203. A Randomized, Parallel Arm, Placebo-Controlled, Double-Blind, Multiple-Dose Study of the Safety and Efficacy of XXX in Adults with Moderate-to-Severe Pain due to Osteoarthritis of the Knee.
204. * Phase I Bioequivalence Study for XXX Phase II and Phase III Tablets.
205. A Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and Efficacy of XXX and YYY Combination Therapy to XXX and YYY Monotherapy in Subjects with Mixed Dyslipidemia.
206. * {Japanese bridging Study} An Open-Label, Randomized, 2-Period, Single-Dose Crossover Study in Healthy Subjects to Investigate the Influence of Formulation on the Pharmacokinetics of XXX in Healthy Subjects.
207. * {FTIH} A single-center, randomized, double-blind, placebo-controlled, single-dose, dose-escalation study to evaluate the safety, tolerability, pharmacokinetics, and effects on bone biomarkers of XXX administered to healthy, postmenopausal volunteers.

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◆ = Subinvestigator per 1572

* = Phase I/Clinical Pharmacology Study

208. * A single-blinded randomized, placebo-controlled, staggered-parallel, escalating-dose study to investigate the safety tolerability, pharmacokinetics and pharmacodynamics of subcutaneous injections of XXX in Subjects with Type 2 Diabetes Mellitus.
209. A 36 week randomized, double-blind, parallel group, multi-center, active-controlled study comparing an XXX based regimen to a YYY based regimen in patients ≥ 65 years old with systolic essential hypertension.
210. * Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX after Multiple Subcutaneous Doses in Patients with Type 2 Diabetes Mellitus.
211. * {Japanese and Chinese bridging study} A Study to Evaluate the Single-Dose Pharmacokinetics of XXX in Asians Compared to Caucasians.

212. * {Japanese bridging Study} A Double-Blind, Randomized, Placebo-Controlled, Alternating-Panel, Multiple-Period, Single Oral Rising Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX in Healthy Young Japanese Male Subjects.
213. * A 4-Period, Single Ascending Dose, Randomized, Placebo-Controlled, Double-Blind Study to Evaluate the Safety, Tolerability and Pharmacokinetics in Healthy Postmenopausal Women of Oral XXX, Followed by Randomized, Placebo-Controlled Once Daily Repeated Oral Doses for 10 Days.
214. A Study to Evaluate XXX in the Treatment of Postmenopausal Osteoporosis.
215. A Randomized Double-Blind Study to Evaluate XXX in the Prevention of Postmenopausal Osteoporosis.
216. A Randomized, Double-blind, Placebo-Controlled Study to Assess the Safety, Tolerability, and Efficacy of XXX in the Treatment of Postmenopausal Women With Osteoporosis.
217. Effects of XXX on Bone Mineral Density and Endometrial Histology in Postmenopausal Women.
218. A Double-Blind, Randomized, Placebo- and Active-controlled Efficacy and Safety Study of XXX/Conjugated Estrogens Combinations for Prevention of Endometrial Hyperplasia and Prevention of Osteoporosis in Postmenopausal Women.
219. Open-Label, Multiple-Dose Study of the Safety and Efficacy of XXX in Adults with Pain due to osteoarthritis of the Knee
220. * {Japanese bridging study} A Phase I Open-Label Randomized Study to Investigate the Potential Pharmacokinetic Interaction between XXX and Rifampin in Healthy Caucasian and Japanese Subjects.
221. A Randomized Study to Evaluate Safety and Efficacy of Transitioning Therapy from XXX to YYY in Postmenopausal Women with Low Bone Mineral Density
222. * {Microdose study} XXX bioavailability in skin determined by accelerator mass spectrometry.
223. *A Multi-center, Double Blind, Active-controlled, Parallel Design Study to assess the Efficacy, Safety and Pharmacokinetics of XXX upon Multiple Dose Oral Administration of a (AAA formulation), a (BBB formulation) or a (DDD formulation) Administered Weekly for 13 Weeks to Postmenopausal Women.
224. *A multiple-center, Open-label, multiple-dose, three period, single-sequence crossover study to investigate the potential pharmacodynamic and potential pharmacokinetic interaction between glyburide and XXX in type 2 diabetic (T2D) patients not adequately controlled with glyburide as a standard prescribed therapy.
225. *A Randomized, Single-blind, Placebo-controlled, 4-Week Treatment Study of the Safety and Biological Activity of Escalating Multiple Oral Doses of XXX in Subjects with Chronic Kidney Disease Not Requiring Dialysis.
226. A Phase IIb/III Randomized, Placebo-controlled Clinical Trial to Study the Safety and Efficacy of XXX in Obese Patients and in Overweight Patients with Obesity-related Co-morbidities.

227. *{Asian Study} An Open-Label, Randomized, 2-Period, Crossover Study to Assess the Effects of XXX on the Pharmacokinetics of Rosiglitazone in Healthy Adult Subjects.
228. An Open Label Study Evaluating the Temperature Profile of the XXX Patch When Applied Above the Knee on Adult Subjects.
229. *An Open-Label, Multiple Ascending Dose Trial of the tolerability and Safety of XXX in Normal Volunteers.
230. A Randomized, Double-blind, Placebo-controlled, Parallel Group Study to Evaluate the Ability of XXX (A) mg, (B) mg, and (C) mg to Alleviate the Insomnia Symptoms Associated with Eastward Bound Jet Lag Across 5 Time Zones in Healthy Adult Volunteers.
231. *A Randomized, Open-Label, Single-Center, Single-dose, Two-Way Crossover Study in Healthy Subjects to Determine the Fed Bioequivalence of XXX Tablets to YYY Tablets.
232. *{Japanese bridging Study} A Phase I Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Pharmacokinetics and Safety of Multiple Oral Doses of XXX in Healthy, Adult Japanese Subjects and Age-, Gender- and Weight-Matched Caucasians.
233. *{Microdose Study} Study of the Pharmacokinetics of XXX after a single Oral Microdose in Healthy Subjects.
234. A Phase II, 28-day, Partially-blinded, Multicenter, Randomized, Parallel-group Study to Evaluate XXX mcg total daily doses of XXX compared to YYY on Bone turnover Markers, Pharmacokinetics, and Safety in Postmenopausal Women
235. *An Open-label Pharmacokinetic, Safety, and tolerability Study of Single Intravenous Doses of XXX in Subjects with Normal Renal Function or Severe Renal Impairment.
236. An Open Label Study to Compare the Temperature Profiles of Two XXX Patch formulations When Applied Above the Knee on Adult Subjects.
237. {Japanese bridging Study} Effects of Daily Multi-Supplementation on Selected *in vivo* Nutrient Concentrations and Risk Factors in Healthy Japanese-American Adults.
238. *{Japanese bridging Study} A Double-blind, Randomized, Placebo-Controlled, Multiple Intravenous Dose Study to Evaluate the Safety and Tolerability of XXX and YYY, and Pharmacokinetics of XXX in Healthy Male Japanese Subjects.
239. *♦ An Open-Label, Single-Dose, Randomized, Crossover Study of the food Effects on the Pharmacokinetics of Orally-Administered XXX in Healthy Male Volunteers.
240. *♦ Pharmacokinetic Comparison of the 6mg/24hr and 12 mg/24 r XXX transdermal system in Healthy Elderly and Non-elderly Volunteers.
241. *♦ A Single-Center Randomized, Double-Blind, Placebo-Controlled, Ascending Single and Multiple dose Escalation Study of the Safety, Tolerability, and Pharmacokinetics of XXX in Healthy Older Volunteers.

242. *{FTIH} A Phase I Randomized, Double-Blind, Placebo-Controlled, Single-Dose, Dose-Escalation Study of XXX in Healthy Adult Volunteers.
243. *{Asian Study} Evaluation of the Effects of CYP2A6 Genotype on the Safety, Tolerability, and Pharmacokinetics of Single, Oral Doses of XXX.
244. ♦ {PET study} Study of Fluorine-18 XXX Clinical Safety As A Positron Emission Tomography Imaging Agent.
245. *{Japanese bridging study} A Double-Blinded, Randomized, Placebo-Controlled, 2-Part Study of Assess the Safety, Tolerability, and Pharmacokinetics of Single and Multiple Oral Doses of XXX in Healthy Japanese Male, Female and Caucasian Male Subjects.
246. *{Japanese bridging study} A study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of single oral doses of XXX in healthy Japanese male subjects.
247. *♦ {QTc intensive} A Placebo- and Positive-Controlled Study of the Electrophysiological Effects of a single Supratherapeutic Dose of XXX on the 12-Lead Electrocardiogram QT Interval.
248. *{Japanese bridging study} An ethnic sensitivity study to compare XXX pharmacokinetics between Japanese and Caucasian healthy volunteers in combination with a randomized two-way crossover comparison to assess the relative bioavailability of XXX versus YYY in Japanese subjects.
249. *A Randomized, Open-Label, Single-Center, Single-dose, Two-Way Crossover Study in Healthy Subjects to Determine the Fasting Bioequivalence of XXX 80 mg Tablets to YYY 80 mg Tablets.
250. An Open-Label, Single Arm, Extension Study to Evaluate the Long Term Safety and Sustained Efficacy of XXX in the Treatment of Postmenopausal Osteoporosis.
251. *♦ An exploratory, open label, multicenter parallel group study to evaluate the effects of single and repeat dosing of XXX (400 mg or 100 mg) or YYY on the fractional renal excretion of calcium and phosphate in healthy postmenopausal females.
252. *{FTIH} A Phase 1A, randomized, double-blind, placebo-controlled, dose-escalation study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of a single intravenous dose of XXX in healthy postmenopausal women.
253. *An Open-Label Phase I Study to Determine the Pharmacokinetics and Safety of XXX in Subjects with Renal Insufficiency.
254. *♦ XXX: Definitive Food Effect Study.
255. * A Phase 1, Multiple-Dose Pharmacokinetic Drug Interaction Study of XXX and Rifabutin
256. *♦ Randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, PK and efficacy of XXX applied twice daily for 3 or 5 days to the anterior nares of healthy adult subjects nasally colonized with *Staphylococcus aureus*.
257. *{Japanese Bridging Study} A Double-Blinded, Randomized, Placebo-Controlled, 2-part Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX: Part 1 as a 3-

Period Crossover Single Dose Study and Part 2 as a One-Period Parallel-Group Multiple Dose Study in Healthy Male Japanese Subjects.

258. *♦ {FTIH and Japanese Bridging Study} Single-Dose, Dose-Escalation, Safety Study of XXX in healthy Subjects.
259. *{Japanese Bridging Study} A Randomized, Open-Label, Crossover Study to Assess the Bioequivalence of the XXX Tablet (Four 50 mcg Tablets Versus One 200 mcg Tablet) in Healthy Japanese Subjects Residing in the United States
260. * ♦ A Single-Center Open-Label Methodological Study for Assaying Pharmacologically-Induced Acetylcholinesterase and Butyrylcholinesterase Inhibition in Peripheral Blood of Patients with Alzheimer's Disease on a Stable Dosing Regimen of XXX.
261. A Phase I Cutaneous Photosensitivity Study in Healthy Volunteers.
262. *♦ {Biologic, First Time In Humans} A Phase 1, Single-Center, Safety, tolerance, and Pharmacokinetic Study of Escalating Bolus Loading Doses Plus Infusions of XXX in Healthy Male Subjects.
263. *{First Time In Humans, Biologic} A Phase 1 Randomized, Double-Blind, Placebo-Controlled, Single-Dose, Dose-Escalation Study of XXX in Healthy Adult volunteers.
264. *♦ Effect of Active Pharmaceutical ingredient Particle Size on the Relative Bioavailability of a 40 mg XXX Dose in Healthy Female Subjects.
265. *Double-Blind, Placebo-Controlled Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerance, Pharmacokinetics and Pharmacodynamics of XXX with a Single-Dose, Open-Label, Food Effect Segment in Healthy Adult Volunteers.
266. *{Japanese Bridging Study} A Phase IIa, Prospective, Randomized, Blinded, Intra-Subject Controlled, Single Dose, Dose Escalation Study of XXX for Mitigation of Acetaldehyde Related Toxicity in Human Subjects with Symptoms of Inborn Altered Ethanol Metabolism with Concomitant Ethanol Exposure.
267. *{Biologic} A Randomized, Single-blind, Placebo-controlled Study to Evaluate the Safety and Tolerability of XXX in Healthy Subjects.
268. *{Asian study} An Open-label, 2-Period, Fixed-Sequence Study to Assess the Pharmacokinetics of XXX and YYY in Healthy Chinese Subjects.
269. * ♦ {Elderly} A Randomized, Double-Blind, Placebo-Controlled, Single-Dose Study to Assess the Safety, Tolerability, and Pharmacokinetics of XXX in Healthy Elderly Male and Healthy Elderly Female Subjects.
270. *♦ {Biologic} A phase I, Single-dose, Randomized, Parallel-group, Open-label Study of the Safety, Tolerability, and Pharmacokinetics of XXX in Healthy Volunteers.
271. *♦ {Japanese Bridging Study} Multiple-Dose, Dose-Escalation, Safety Study of XXX in Healthy Subjects.

272. *A Randomized, Double-Blind, Double Dummy, Placebo-controlled, Multiple-dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamic Efficacy of XXX and YYY in Healthy Postmenopausal Women.
273. *{Biologic, First Time In Humans, Vaccine} A Phase 1, Open Label, Safety Study of XXX in Healthy Adults.
274. *{Renal Insufficiency} A Phase 1, Open-Label, Pharmacokinetic, Safety, and tolerability Study of a single Intravenous dose of XXX in Subjects With Normal Renal Function, Mild Renal Impairment, or Moderate Renal Impairment.
275. *{Japanese Bridging Study} A Double-Blind, Randomized, Placebo-Controlled, Alternating Panel, Single Rising Oral Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX in Healthy Japanese Male Subjects.
276. *♦ {Biologic} A Phase I, Safety, Tolerance, and Pharmacokinetic Study of a Bolus Loading Dose Followed by Infusion of XXX in Healthy Male Subjects.

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277. A randomized, double-blind, parallel-group, placebo-controlled, active-referenced, fixed-dose study comparing the efficacy and safety of three doses of XXX in acute treatment of adults with generalized anxiety disorder.
278. A Phase III, multi-center, randomized, double-blind, placebo-controlled study of the safety and efficacy of once-daily XXX extended release tablets in the treatment of patients with post-therapeutic neuralgia.
279. An eight-week, multi-center, randomized, double-blind, placebo and Paroxetine-controlled study of the efficacy, safety and tolerability of XXX (25 or 50mg) given once daily in the treatment of Major Depressive Disorder (MDD) followed by a fifty-two week open-label treatment with XXX (25 or 50mg).
280. A three-week, double-blind, multi-center, placebo-controlled study evaluating the efficacy and safety of add-on oral XXX in subjects with acute mania treated with Lithium or Divalproex.
281. An eight-week randomized, double-blind, parallel-group, multi-center, active-controlled dose-escalation study to evaluate the efficacy and safety of XXX compared to Amlodipine (10mg) in patients with stage 2 Systolic Hypertension and Diabetes Mellitus.
282. A multi-center, randomized, blinded, controlled, parallel-group trial to demonstrate the efficacy of rEEG guided pharmacotherapy of subjects with depression treatment failure.

283. A Phase I, two-part, randomized, subject and investigator-blinded, placebo-controlled, cross-over trial to evaluate the safety, tolerability and pharmacokinetics of XXX in obese adult subjects with asymptomatic Cholelithiasis.
284. Maintenance of response after open-label treatment with XXX in adult outpatients with Attention Deficit Hyperactivity Disorder (ADHD): A placebo-controlled, randomized withdrawal study.
285. An open-label study of intramuscular XXX Depot in patients with Schizophrenia or Schizoaffective Disorder.
286. A standardized lipaspiration to evaluate adipose-derived stromal cell yield and viability.
287. {Japanese Bridging} A randomized, double-masked, vehicle-controlled, multiple-dose pharmacokinetic study of XXX following topical ocular administration in healthy Japanese subjects.
288. {Japanese Bridging} A single-center, open-label, parallel-group study to evaluate the pharmacokinetics, tolerability, and safety of a single dose of 40mg XXX in Japanese and Caucasian healthy male and female subjects.
289. DEFEND-1: A durable-response therapy evaluation for early or new-onset type 1 Diabetes.
290. A partially-blinded, randomized, placebo-controlled, active comparator, exploratory, four-week, multiple dose study to explore the safety, tolerability, pharmacokinetics and pharmacodynamics, including biomarker responses of XXX in healthy postmenopausal women.
291. A randomized, evaluator-blinded, Phase III study to compare the safety and efficacy of XXX with Linezolid in the treatment of adults with complicated skin and skin structure infection.
292. A randomized, double-blind, double-dummy, comparative, multi-center study to assess the safety and efficacy of topical XXX ointment, 1%, vs. oral Linezolid in the treatment of secondarily-infected traumatic lesions and Impetigo due to Methicillin-resistant *Staphylococcus Aureus*
293. A twelve-week, multi-center, randomized, double-blind, parallel-group, active-control study to evaluate the antihypertensive efficacy and safety of an XXX-based regimen vs. a Losartan-based regimen in patients with stage 2 Systolic Hypertension.
294. A randomized, double-blind, placebo and active-controlled, parallel-group, multi-center study to determine the efficacy and safety of XXX when used in combination with Metformin compared with Metformin plus Sitagliptin, Metformin plus Glimepiride, and Metformin plus Placebo in subjects with type 2 Diabetes Mellitus.
295. A randomized, double-blind, placebo-controlled, parallel-group, multi-center study to determine the efficacy and safety of XXX when used in combination with Pioglitazone with or without Metformin in subjects with type 2 Diabetes Mellitus.
296. A randomized, double-blind, placebo and active-controlled, parallel-group, multi-center study to determine the efficacy and safety of XXX administered in combination with Metformin and Glimepiride compared with Metformin plus Glimepiride and Placebo and with Metformin plus Glimepiride and Pioglitazone in subjects with type 2 Diabetes Mellitus.

297. A double-blind, randomized, placebo-controlled, multi-center trial to assess the safety, tolerability, and pharmacokinetics of the anti-Orthopoxvirus compound XXX when administered as a single daily oral dose for fourteen days in volunteers in the non-fasted state.
298. A single-center, open-label, two-period, two-treatment, randomized, cross-over study in healthy male and female subjects to compare the pharmacokinetics of 40mg capsules and tablets of XXX.
299. A Phase I, multi-center, randomized, double-blind, placebo-controlled study to evaluate the safety and effect on the virologic response of iron reduction with XXX 5 and 10mg/kg/d administered as pre-treatment for twenty-weeks before standard antiviral therapy in patients with chronic Hepatitis C with Genotype 1.
300. A randomized, double-blind, double-dummy, multi-center, Phase IIa study to assess the safety, tolerability and efficacy of XXX vs. Linezolid in the treatment of bacterial skin and skin structure infection.
301. A randomized, double-blind, multi-center study to evaluate the efficacy and safety of XXX in combination with Pegasys® and Copegus® for twenty-four weeks vs. the currently approved combination of Pegasys® and Copegus® in treatment-naive patients with chronic Hepatitis C Genotype 1 or 4 virus infection.

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302. A phase I, placebo-controlled, double-blind, single ascending and repeated dose study to determine the maximum-tolerated dose and assess the safety, tolerability, pharmacokinetics and pharmacodynamics of XXX in healthy volunteers.
303. A randomized, open label intra-patient dose escalation study with an untreated reference group to evaluate safety and tolerability, pharmacokinetics, and pharmacodynamics of multiple infusions of XXX in adults with moderate osteogenesis imperfect.
304. Comparison of the Pharmacokinetics and Safety of Liquid (30 µg) and Lyophilized Tetrodotoxin (15 µg and 30 µg) Following Single and Twice Daily Subcutaneous Dose Administration to Healthy Volunteers- Determinations in Blood and Urine.
305. A randomized, double-blind, placebo-controlled, single dose, parallel group study to assess the safety, tolerability, bioavailability, pharmacokinetics, and pharmacodynamics of subcutaneous and intravenous XXX in hypercholesterolemic patients on stable doses of atorvastatin or simvastatin.
306. A randomized, partially double blind, placebo controlled study to investigate the effect of the XXX treatment re-initiation on the initial negative chronotropic effect in healthy subjects.
307. Phase 1, Open-Label, Randomized, Safety and Pharmacokinetic Study of Two Final Formulations of XXX Following Subcutaneous Injections in the Submental Fat.

308. Phase 1b, Randomized, Double-Blind, Multiple-Dose Ranging Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Antiviral Activity of XXX in Subjects with Chronic Hepatitis C Virus Infection.
309. A randomized, double-blind, crossover study to assess the effects of XXX and valsartan in Asian patients with salt-sensitive hypertension.
310. Pharmacokinetics and Safety of XXX compared to YYY in Healthy Volunteers.

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Medical Director*/subinvestigator with substantial direct involvement
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311. An Open-Label Study to Characterize the Absorption, Distribution, Metabolism and Elimination of a Single Oral ¹⁴C Labeled Dose of XXX in Subjects with BRAF mutant Solid Tumors.
312. An Open-label mass balance study to investigate the Absorption, Distribution, Metabolism and Elimination of a Single Oral Dose of (enzyme) inhibitor XXX in Male Subjects with Solid Tumors.
313. Determination of the Absolute Bioavailability of XXX Following a Single Oral Dose Co-Administered with an Intravenous Radiolabelled Microtracer of XXX in Subjects with BRAF Mutant Solid Tumors.
314. Determination of the Absolute Bioavailability of GSK1120212 Following a Single Oral Dose Co-Administered with an Intravenous Radiolabelled Microdose of GSK1120212 in Subjects with Solid Tumors.
315. A Phase 1 Open Label Study to Evaluate the Potential Pharmacokinetic Interaction Between XXX and the CYP3A4 Substrate Amlodipine in Healthy Adult Male Volunteers
316. A Randomized, Crossover Study in Healthy Subjects, of the Effects of XXX Topical Solution, 5% on QT/QTc Intervals, with Moxifloxacin Positive Control.
317. A Phase 1, Randomized Clinical Trial to Evaluate the Safety, Tolerability, and Immunogenicity of the XXX + (adjuvant) Vaccine Compared to the XXX Alone in Healthy Adult Subjects.
318. A Study to Investigate the Absorption, Metabolism, Excretion, and Mass Balance of XXX.
319. A Phase 1 two-way cross-over study of the pharmacokinetics and pharmacodynamics of crystalline XXX tablets and amorphous XXX capsules administered in the fasting state, and of crystalline XXX tablets administered fed and fasting, in healthy subjects.
320. A Phase 1 Randomized, Double-Blind, Dose-Escalation Study to Assess the Safety, Tolerability and Immunogenicity of Inactivated (XXX) Whole Cell Vaccine Formulated with Alum (XXX+Alum) in Healthy Adults.

321. A Phase 1, Single-Center, Randomized, Double-Blind, Placebo-Controlled, Ascending Dose, Study to Evaluate the Safety, Tolerability, and Pharmacokinetic Profile of Single and Multiple Doses of XXX Administered Topically in Healthy Subjects.
322. Assessment of the Effect of XXX on the Pharmacokinetics and Pharmacodynamics of Estradiol/Norgestimate in Healthy Premenopausal Female Volunteers Who Are Receiving Combination Oral Contraceptive (Ethinyl Estradiol/Norgestimate) Therapy.
323. A Phase 1, Open-label Study to Investigate the Absorption, Metabolism, and Excretion of ¹⁴C-XXX in Subjects with Advanced Solid Tumors with an Optional Treatment Phase.
324. A Double-Blind Randomized Crossover Trial to Define the ECG Effects of XXX using the Highest Therapeutic and a Supratherapeutic Dose of XXX compared to Placebo and Moxifloxacin (a Positive Control) in Healthy Men and Women: A Thorough QT Study.
325. A Single Center, Sequential Design, Pharmacokinetic Study to Assess the Influence of P-glycoprotein Inhibition and Simultaneous CYP3A4 and P-glycoprotein Induction on XXX Pharmacokinetics Following Single Dose Oral Administration of 24 mg XXX to Healthy Volunteers.
326. A multi-center, randomized, double-blind, placebo and active controlled, parallel group, proof-of-concept study to evaluate the efficacy and safety of XXX compared to placebo after 4 weeks treatment in subjects with essential hypertension.
327. An Open Label, Single-Period, Phase 1 Study to Evaluate the Pharmacokinetics, Excretion, Mass Balance, and Metabolism of [¹⁴C]-XXX in Healthy Adult Male Subjects
328. An Open Label, Balanced, Randomized, Three-Cohort, Two-Treatment Per Cohort, Two-Period, Crossover Design Relative Bioequivalence Study of XXX Extended-Release Tablets 20 mg, 30 mg, and 40 mg, in Healthy Volunteers Following a Standard Meal
329. An Open Label, Balanced, Randomized, Three-Cohort, Two-Treatment Per Cohort, Two-Period, Crossover Design Relative Bioequivalence Study of XXX Extended-Release Tablets, 20mg, 30mg, and 40mg in Fasted Healthy Volunteers
330. Evaluation of the Pharmacokinetics and Relative Bioavailability of XXX in Healthy Men from Three XXX 8 mg Extended-Release Formulations with 13.2%, 17.6%, and 22.0% Coating, in Comparison with XXX 8 mg Extended-Release Formulation with 0.0% Coating.
331. Mass balance, pharmacokinetics, and Metabolism of [¹⁴C]-XXX in Patients With Advanced Solid Tumors or Lymphomas.
332. A Two-Way Crossover Study to Evaluate the Pharmacokinetics, Pharmacodynamics, and Tolerability of XXX in Healthy Adults.
333. A Four-Arm, Parallel Design, Randomized, Double-Blinded, Placebo and Active Controlled Study for the Evaluation of the Effect of Maximum Therapeutic and Supratherapeutic Single-Dose XXX on the QT/QTc Intervals in Healthy Volunteers.
334. An Open Label, Balanced, Randomized, Two Way Crossover Relative Bioavailability Study Of XXX Capsules, 40mg, In Normal, Healthy Adult Men Following A Standard Meal.

335. An Open Label, Single-Period, Phase 1 Study to Evaluate the Pharmacokinetics, Excretion, Mass Balance, and Metabolism of [14C]-XXX in Healthy Adult Male Subjects.
336. A Comparative Bioavailability Study of XXX Tablets in Healthy Subjects.
337. An Open-label, Single-dose Study to Evaluate the Absorption, Metabolism, and Excretion of Orally and Intravenously Administered [¹⁴C]-XXX in Healthy Adult Male Subjects.
338. Evaluation of the Potential Effects of XXX on QT/QTc Interval Prolongation.
339. A randomized, double-blind, placebo controlled, crossover study to assess safety and tolerability, pharmacokinetics, and explore pharmacodynamics of XXX in patients with mixed dyslipidaemia.
340. Single Dose Food Effect and 14C-Microdosing Absolute Bioavailability Study of XXX in Healthy Adult Volunteers.
341. An Open-label, Single-dose Study to Evaluate the Absorption, Metabolism, and Excretion of Orally Administered [14C]-XXX in Healthy Male Subjects
342. A 14C-microdose, absolute bioavailability study of single and multiple doses of XXX in healthy adult volunteers.
343. A Phase One Open-Label Single-Radiolabeled Dose Study to Investigate the Absorption, Metabolism, and Excretion of [14C]-XXX in Healthy Male Volunteers
344. A Pilot, Open Label, Balanced, Randomized, Two Way Crossover Relative Bioavailability Study Of XXX Capsules, 40mg, In Normal, Healthy Adult Men Following A Standard Meal
345. A Randomized, Three-treatment, Three-period, Six-sequence Crossover, Single-center, Bioequivalence Study to Evaluate the Impact of Varying Crystalline Polymorph Forms for the Commercial Oral Capsule Formulation of XXX in Healthy Volunteers
346. *A phase I, placebo-controlled, double-blind, single ascending and repeated dose study to determine the maximum-tolerated dose and assess the safety, tolerability, pharmacokinetics and pharmacodynamics of XXX in healthy volunteers.
347. *A randomized, open label intra-patient dose escalation study with an untreated reference group to evaluate safety and tolerability, pharmacokinetics, and pharmacodynamics of multiple infusions of XXX in adults with moderate osteogenesis imperfect.
348. *Comparison of the Pharmacokinetics and Safety of Liquid (30 µg) and Lyophilized XXX (15 µg and 30 µg) Following Single and Twice Daily Subcutaneous Dose Administration to Healthy Volunteers-Determinations in Blood and Urine.
349. *A randomized, double-blind, placebo-controlled, single dose, parallel group study to assess the safety, tolerability, bioavailability, pharmacokinetics, and pharmacodynamics of subcutaneous and intravenous XXX in hypercholesterolemic patients on stable doses of atorvastatin or simvastatin.
350. *A randomized, partially double blind, placebo controlled study to investigate the effect of the XXX treatment re-initiation on the initial negative chronotropic effect in healthy subjects.

- 351.** *Phase 1, Open-Label, Randomized, Safety and Pharmacokinetic Study of Two Final Formulations of XXX (XXX Injection) Following Subcutaneous Injections in the Submental Fat.
- 352.** *Phase 1b, Randomized, Double-Blind, Multiple-Dose Ranging Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Antiviral Activity of XXX in Subjects with Chronic Hepatitis C Virus Infection.
- 353.** *A randomized, double-blind, crossover study to assess the effects of XXX and valsartan in Asian patients with salt-sensitive hypertension