



Curriculum Vitae

Gregory Morgan Flippo, M.D.
Alabama Clinical Therapeutics, LLC
3528 Vann Road, Suite 101
Birmingham, Alabama 35235

Telephone: (205) 833-2228

Fax: (205) 833-6225

Additional Offices:

Deerfoot Internal Medicine
6725 Deerfoot Parkway
Pinson, Alabama 35126

Brownstone Total Family Healthcare
48 Medical Park East Drive, Suite 154
Birmingham, AL 35235

Gastro Health
100 Pilot Medical Drive, Suite 250
Birmingham, AL 35235

Hilton Garden Inn- Birmingham/Trussville
3230 Edwards Lake Parkway
Birmingham, AL 35235

Education:

1982 Doctor of Medicine
University of Alabama School of Medicine
Birmingham, Alabama

1978 Bachelor of Science, with Honors
University of Alabama at Birmingham
Birmingham, Alabama

Work Experience:

2000– Present Investigator, Alabama Clinical Therapeutics, LLC
Birmingham, Alabama and Pinson, Alabama

1990 – Present Private Practice / Deerfoot Internal Medicine
Pinson, Alabama

1986 – 1990 Private Practice
Carbon Hill, Alabama

1986 Chief Resident in Internal Medicine, Carraway Methodist Medical Center,
Birmingham, Alabama

1982 – 1985 Residency in Internal Medicine, Carraway Methodist Medical Center, Birmingham,
Alabama

Gregory Morgan Flippo, M.D.
Curriculum Vitae
Page 2

Credentials: Medical License Alabama #11160

Certifications: Board Certified Internal Medicine, September 1986

Professional Affiliations: St. Vincent's East
Active Staff

Honors: EBSCO Industries Professional Scholarship Award- 4 yrs

Presentations:

Flippo, G.M. and K.R. Marion. 1977. The fence lizard (Sceloporus undulatus) in Alabama: a study in r-selection. ASB Bull. 24(2) :51. Presented at ASB meetings, Raleigh, N.C., 1977.

Flippo, G.M. and K.R. Marion. 1977 A field study of reproduction in the fence lizard, Sceloporus undulatus, in central America. The journal of the Alabama Academy of Science 48(3):60. Presented at Alabama Academy of Science meetings, Tuscaloosa, Alabama 1977.

Marion, K.R. and G.M. Flippo. 1977. The life history strategy of the fence lizard, Sceloporus undulatus, in central Alabama. The journal of the Alabama Academy of Science 48(3) :60-61. Presented at Alabama Academy of Science meetings, Tuscaloosa, Alabama 1977.

Research Experience:

1. XXX Cardiovascular Treatment Assessment Versus XXX.
2. An Open Label, Randomized, Multi-Center Clinical Trial to Assess the Long-Term Safety of XXX Extended Release (ER) 150mg Twice Daily, and XXX ER 300mg Once Daily in Subjects with Erosive Gastroesophageal Reflux Disease.
3. A Study to Evaluate the Safety and Efficacy of XXX (30mg BID and 120 mg BID) Versus Placebo in Subjects with Irritable Bowel Syndrome
4. A Randomized, Multicenter, Double-Blind, Parallel-Group Clinical Study to Compare the Effects of XXX Versus Placebo as Initial Oral Therapy in Subjects with Type II Diabetes Mellitus Who Fail to Achieve Adequate Control with Diet and Exercise Alone.
5. An Open-Label, Multicenter, Multinational, Uncontrolled Study of the Efficacy and Safety of 7 Days of Oral XXX (XXX 800 mg Once Daily) in the Treatment of Community- Acquired Pneumonia Due to Streptococcus Pneumonia in Adolescents and Adults.
6. The Efficacy and Safety of 5 Days Oral XXX (XXX 800mg Once Daily) Versus 10 Days Oral XXX (XXX mg Twice Daily) in the Treatment of Acute Exacerbation of Chronic Bronchitis.
7. The Effect of Increasing the Surface Area of Application of a Fixed Dose of XXX on the Pharmacokinetics of Testosterone.
8. A Randomized Multicenter, Double-Blind, Double-Dummy Trial Comparing XXX 500 mg daily for 3 days with XXX 1 Gram Daily for 10 Days for the Treatment of Acute Bacterial Exacerbation of Chronic Bronchitis.
9. A Twelve Week, Randomized, Double-Blind, Placebo-Controlled Study of XXX in Female Subjects with Alternating Diarrhea/ Constipation Irritable Bowel Syndrome.

Research Experience (continued):

10. A Twelve Week, Randomized, Double-Blind, Placebo Controlled, Parallel Group, Dose Ranging, Phase II Study to Assess the Clinical Efficacy of XXX in Male Subjects With Irritable Bowel Syndrome.
11. A Randomized, Double-Blind, Multicenter Study to Evaluate the Tolerability and Effectiveness of XXX 25 qm q.d. vs. XXX 500 mq bid. In Patients with Osteoarthritis
12. A Double-Blind, Double-Dummy, Multicenter, Parallel Group Study to Compare the Efficacy and Safety of XXX Given Either as a Single Oral Dose of 640mg or as 320mg Once Daily for Three Days Versus Oral XXX 250mg Twice a Day for Three Days in the Treatment of Uncomplicated Urinary Tract Infections (UTI) in Female Patients
13. A MultiCenter, Multinational, 12 Week, Double Blind, Randomized, 3 Arm Active Comparator, Parallel Group Study in Patients with Osteoarthritis (OA) of the Knee, Hip, or Hand.
14. A Multicenter, Multinational, 12 week, Double Blind, Randomized, 3 Arm, Active Comparator, Parallel Group Study in Patients with Osteoarthritis of the Knee, Hip, or Hand to Compare the Efficacy and Tolerability of XXX Versus XXX Comparator.
15. A Multicenter, Randomized, Double-Blind, Comparative Study of Oral XXX (800 mg once daily) Versus Oral XXX (500 mg twice daily) for Outpatient Treatment of Acute Exacerbation of Chronic Bronchitis in Adults.
16. A Randomized, Double-Blind, Double- Dummy, Multicenter, Parallel Group Study to Assess the Efficacy and Safety Of Oral SB-265805 320mg Once Daily for 7 days Versus Oral XXX 50mg Once Daily for 7 Days for the Treatment of Acute Exacerbations of Chronic Bronchitis.
17. A Randomized, Double-Blind, Double- Dummy, Multicenter, Parallel Group Study to Assess the Efficacy and Safety Of Oral XXX 320mg Once Daily Versus Oral XXX 200mg Once Daily for 7 or 14 Days in the Treatment of Bacterial Community Acquired Pneumonia (CAP) in Adults.
18. A Randomized, Double-Blind, Multi-Center, Comparative Study of Oral XXX Versus Oral XXX in the Treatment of Community Acquired Pneumonia.
19. A Randomized, Double-Blind, Multicenter Comparison of XXX to XXX in the Treatment of Patient with Acute Uncomplicated Maxillary Sinusitis.
20. Comparison of the Safety and Efficacy of XXX IR (250mq bid) or ER (1000mq QD) to XXX for the Treatment of Community Acquired Pneumonia.
21. A Multicenter, Randomized, Double-Blind Placebo-Controlled, Parallel 8 Week Study of XXX Administered Once Daily or Twice Daily in the Treatment of Mild to Moderate hypertension.
22. A Double-Blind, Multicenter, Randomized Active-Controlled Two-Arm Parallel Group Comparative Study of the Efficacy and Safety of Oral XXX (800 mg Once Daily) Versus Oral XXX (500mg Twice Daily) in the Treatment of Community-Acquired Pneumonia in Adults.
23. Comparative Safety and Efficacy of XXX XXX and XXX in the Treatment of Community Acquired Pneumonia.
24. Comparative Safety and Efficacy of XXX XXX and XXX in the Treatment of Patients with Acute Maxillary Sinusitis.
25. A Multicenter, Double-Blind, Randomized, Parallel Group Study to Compare the Efficacy, Tolerability and Safety of XXX and XXX to Placebo in Subjects with Non-Insulin Dependent Diabetes Mellitus inadequately Controlled on Diet Alone.

Research Experience (continued):

26. A Multicenter, Randomized, Double-Blind Comparative Study of Oral XXX (800mg Once Daily) Versus Oral XXX XXX (500mg Twice Daily) for Outpatient Treatment of Acute Exacerbation of Chronic Bronchitis in Adults.
27. A Prospective, Multicenter, Double-Blind, Randomized Comparative Study To Evaluate The Safety, Tolerability, And Efficacy of XXX Versus XXX In The Treatment of Complicated Urinary Tract Infections In Adults.
28. A Randomized, Double-Blind, Multicenter, Phase II/III Comparison Of XXX To XXX In The Treatment Of Complicated Urinary Tract Infection and Pyelonephritis
29. A Multicenter, Randomized, Double-Blind, Placebo controlled, Parallel 8 Week Study of XXX Administered Once Daily or Twice Daily in the Treatment of Mild to Moderate Hypertension.
30. A Multicenter 24-Week, open-Label Dose Escalation Trial of XXX in Combination with Insulin or Sulfonylurea in Type II Diabetes Mellitus Patients.
31. A Randomized, Double-Blind, Multicenter, Parallel Group Study to Assess the Efficacy and Safety of Oral XXX Twice Daily for 10 Days in the Treatment of Acute Bacterial Sinusitis (ABS) Infections.
32. Safety and Efficacy of Fixed Combination XXX Products as First Line Therapy in Patients with Type II Diabetes Mellitus Who Have Inadequate Glycemic Control With Diet and Exercise.
33. A Double-Blind, Multicenter, Parallel Group Study To Compare The Efficacy And Safety Of Oral XXX Once Daily Versus Oral XXX Once Daily For 10 Days In The Treatment Of Pyelonephritis Or Complicated Urinary Tract Infections
34. Study to Evaluate the Effect of XXX 5mg t.i.d., 10mg t.i.d., 20mg t.i.d., Versus Placebo in Females with Non-erosive Gastroesophageal Reflux Disease.
35. A Multicenter, Randomized, Double-Blind, Safety and Efficacy Study of XXX with XXX plus XXX Compared to XXX with XXX for the Eradication of XXX XXX in Subjects with Active Duodenal Ulcer or History of Duodenal Ulcer Disease.
36. A Multicenter, Randomized, Double-Blind, Placebo controlled, Parallel 8 Week Ambulatory Blood Pressure monitoring Study of Three Dose Regimens of XXXX Administered Once-Daily or Twice Daily In the Treatment of Mild to Moderate Hypertension.
37. A Randomized, Double-Blind, Multicenter, Comparative Phase III Study of XXX Versus XXX in the Treatment of Community Acquired Pneumonia.
38. A Multicenter, Double-Blind, Randomized, Parallel Group Study to Compare the Efficacy, Tolerability and Safety of XXX Monotherapy and a Combination of XXX and XXX to Placebo in Subjects with Non-Insulin Dependent Diabetes Mellitus Inadequately Controlled on Diet Alone.
39. An Open-Label, Randomized, Rater-Blinded Study to Compare Rate of Remission in Patients with Major Depressive Disorder Treated with XXX Extended Release Versus Using Treatment Algorithms
40. A Comparison of the Analgesic Efficacy and Safety of XXX Versus Placebo for the Treatment of the Pain of Diabetic Neuropathy
41. A Phase III Evaluation of XXX (Testosterone Gel) in Hypogonadal Males
42. A Double-Blind, Multi-Center, Randomized, Placebo-Controlled, Parallel Group Study of the Effects of XXX on Safety and Efficacy Patients with Mild to Moderate Hypertension
43. A Multi-Center, Parallel Group Extension to Determine the Safety and Efficacy of Long-Term XXX Exposure in Patients with Mild to Moderate Hypertension

Research Experience (continued):

44. An In-Use Study of the Dose-Indicator for the XXX Inhaler System
45. A Randomized, Double-Blind, Double-Dummy, Placebo-And-Active Controlled, Parallel Group Efficacy and Safety Comparison of 12-Week Treatment of Two Doses of XXX, Placebo and XXX in Patients with Chronic Obstructive Pulmonary Disease (COPD)
46. An Open Label, Randomized Study to Evaluate Safety of XXX in Comparison with XXX in Smokers with Certain Underlying Disease Restrictions Specified in the Label
47. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 2 Trial to Evaluate the Safety and Efficacy of XXX as Monotherapy in Subjects with Type 2 Diabetes Mellitus Who Have Adequate Glycemic Control
48. A Randomized, Double-Blind, Placebo-Controlled, Pilot Study to Evaluate the Efficacy and Safety of XXX In Depressed and Anxious Patients with Multiple, Unexplained Somatic Symptoms in Primary Care
49. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Efficacy Study Comparing 4 Weeks Treatment with XXX and XXX to Placebo in Patients with Heartburn and Sleep Disturbances Associated with Gastroesophageal Reflux Disease (GERD)
50. A Randomized, Double-Blind, Parallel Group Study to Compare the Safety and Efficacy of XXX and XXX in the Treatment of Uncomplicated Female Urinary Tract Infections
51. A Double-Blind, Randomized, Multi-Center, Active-Comparator, Five Treatment Study of the Effects of XXX Compared to XXX on Cardiovascular Hemodynamics and Exercise Capacity in Patients With Mild to Moderate Hypertension
52. A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Phase 2 Trial to Evaluate the Safety and Efficacy of XXX as Monotherapy in Subjects with Type 2 Diabetes Mellitus Who Have Adequate Glycemic Control
53. A Multi-Center, Open Extension Study to Assess the Safety and Efficacy of Long-Term XXX Exposure in Patients with Mild to Moderate Hypertension
54. A Twelve Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Safety and Efficacy of XXX and XXX in Female Subjects with Severe Diarrhea-predominant IBS Who Have Failed Conventional Therapy
55. A Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of XXX and XXX Combined and Alone, XXX and XXX in Hypertensive Patients and Pharmacogenetic Sub-Study for XXX and A 54-Week, Open Label Extension to a Randomized, Double-Blind, Multi-Center, Placebo-Controlled Parallel Group Study to Evaluate the Efficacy and Safety of XXX and XXX Combined and Alone, XXX and XXX in Hypertensive Patients
56. A Multi-Center, Double-Blind, Randomized Placebo-Controlled Study of the Safety and Efficacy of a Combination of XXX and XXX Compared to Placebo and XXX in the Treatment of Patients with Type 2 Diabetes Mellitus
57. A Multi-Center, Double-Blind, Randomized, Placebo-Controlled Parallel Safety and Efficacy Study of XXX in the Treatment of Patients with Type 2 Diabetes Mellitus
58. A Multi-Center, Double-Blind, Active- and Placebo-Controlled Efficacy and Safety Study of XXX and XXX in Patients with Low Back Pain
59. A Randomized, Double-Blind, Multicenter, Active-Control Study Evaluating The Efficacy and Safety of XXX in Subjects With Moderate to Severe Osteoarthritis Pain

Research Experience (continued):

60. A multicenter, Double-Blind, Randomized, Phase 3 Study to Compare the Safety and Efficacy of XXX and XXX in Complicated Lower Urinary Tract Infection or Pyelonephritis
61. A Multicenter, Double-Blind, Active-and Placebo-Controlled Efficacy and Safety Study of XXX and Low-Dose XXX in Patients with Low-Back Pain
62. A Double-Blind, Multicenter, Randomized, Placebo-Controlled Single Dose Study to Evaluate the Safety and Efficacy of XXX in the Acute Treatment of Migraine Headaches
63. A Multicenter, Open-Label, Randomized Trial to Compare the Efficacy and Safety of XXX in Combination with XXX and XXX to XXX and XXX Alone in Insulin Naive Subjects with Type 2 Diabetes
64. XXX in Type 2 Diabetes Subjects: A Fifty-Two Week Double-Blind, Parallel, Active-Controlled (XXX and XXX) Study (Followed by a Fifty-Two Week Open-Labeled Extension) to Investigate Safety and Efficacy
65. A 12-Week, Randomized, Double Blind, Placebo-Controlled Study with PRN BID and Fixed Dosing Regimens of XXX in Female Subjects with Severe Diarrhea-Predominant Irritable Bowel Syndrome Who Have Failed Conventional Therapy
66. A multicentre, randomized, double-blind, placebo-controlled study of the efficacy and safety of XXX HCl in patients suffering from functional dyspepsia
67. A multicentre, open-label study to evaluate the long-term safety and efficacy of XXX HCl in patients suffering from functional dyspepsia
68. A Phase 3b, Randomized, Open-Label, Active Controlled Study to Compare the Effects of XXX and XXX in Hypertensive, Type 2 Diabetic Subjects with Diabetic Nephropathy
69. Trail to Reduce Cardiovascular Events with XXX Therapy
70. An open-label, randomized, multicenter, clinical study to compare the effects of XXX, XXX and XXX on the penicillin or macrolide resistance of Streptococcus pneumoniae in patients with acute exacerbation of chronic bronchitis
71. A Randomized, Double Blind, Placebo Controlled, Multicenter, Phase III Study of XXX 20 mg In the Primary Prevention of Cardiovascular Events Among Subjects with Low Levels of LDL-Cholesterol and Elevated Levels of C-Reactive Protein
72. A Randomized, Double-Blind, Dose-Ranging, Dose Comparison-Controlled Trial to Determine The Safety and Efficacy of XXX in Subjects With Type 2 Diabetes
73. A Randomized, Single-And Multiple-Dose, Parallel Group Study Of The Pharmacokinetics Of Testosterone Following Administration Of 2.5, 5.0 And 7.5 G Of XXX To Hypogonadal Adult Males
74. Bioavailability And Safety Of 2 Dose Volumes Of XXX
75. A Phase II Study to Evaluate the Effects of XXX on Safety and Efficacy in Subjects with Resistant Systolic Hypertension Receiving Combination Therapy with Three or More Antihypertensive Drugs, Including a Diuretic
76. An international, multicenter, stratified, randomized, double-blind, double- dummy, parallel-group, 52-week gastrointestinal clinical safety study to demonstrate that XXX (400 mg od) reduces the risk to develop complicated ulcers as compared to NSAIDs (naproxen 500 mg bid and ibuprofen 800 mg tid), in osteoarthritis patients

Research Experience (continued):

77. Effects of Blood Pressure Reduction on High Sensitivity C-Reactive Protein (hsCRP): A Multicenter, Randomized, Open-label, 2-Arm Parallel Group Study to Evaluate the Efficacy of Moderate Vs. Aggressive Antihypertensive Therapy with XXX and XXX to Reduce Blood Pressure and Plasma hsCRP levels in Patients with Stage 2 Hypertension
78. A Multicenter, Open-Label, Randomized Trial to Compare the Efficacy and Safety of XXX in Combination with Metformin and Pioglitazone to Metformin and Pioglitazone Alone in Insulin Naïve Subjects with Type 2 Diabetes.
79. A Multicenter, Double-Blind, Randomized, Phase 3 Study to Compare the Safety and Efficacy of Intravenous XXX and XXX in Complicated Lower Urinary Tract Infection or Pyelonephritis
80. A 4 Week, Randomized, Double Blind, Placebo And Positive Controlled, Parallel Group, Multicenter Study Of In Subjects With Symptomatic Osteoarthritis Of The Knee
81. A Multicenter, Double-Blind, Randomized, Placebo-Controlled Parallel Safety and Efficacy Study of XXX in the Treatment of Patients with Type 2 Diabetes Mellitus
82. A 12-Week, Open-Label, Multi-Center Study to Evaluate the Efficacy and Tolerability of XXX in Patients who have Previously Demonstrated either a Lack of Tolerability or Lack of Therapeutic Response with XXX
83. An uncontrolled long-term safety trial of XXX in patients with osteoarthritis of the knee
84. A 12 Week, Randomized, Double-Blind, Multi-Center, Vehicle-Controlled, Parallel Group Study to Assess the Efficacy and Safety of XXX for the Relief of Signs and Symptoms in Patients with Osteoarthritis of the knee
85. A Randomized, Multi-Center, Double-Blind, Parallel-Group Study Assessing the Analgesic Efficacy and Safety of Different Dosages of XXX compared to Active Comparator Bid and Placebo in Subjects with Chronic Knee-Joint Osteoarthritis
86. XXX for the Relief of Signs and Symptoms in Patients with Osteoarthritis of the Knee
87. Double-Blind, A Phase 3, Randomized, Multicenter, Double-Blind Study Comparing the Analgesic Efficacy of XXX to Placebo in Subjects with Osteoarthritis Parallel-Group Study Assessing the Analgesic
88. Efficacy and Safety of Different Dosages of XXX compared to Active Comparator Bid and Placebo in Subjects with Chronic Knee-Joint Osteoarthritis
89. A Double-Blind, Randomized, Placebo- Controlled, Multi-Dose, Phase III, Parallel Group Study of XXX for the management of Moderate to Moderately Severe Chronic Pain of Osteoarthritis of the Hip and Knee in Adults
90. A Six Week, Multi-Center, Randomized, Parallel-Group Treatment Regimen Study to Evaluate the Efficacy of Initial High Dose XXX or Combination XXX and XXX to XXX in Managing Patients with Hypertension
91. A Two-Arm, Open-Label Randomized, Multi-Center Pharmacokinetic and Long-term Safety Study of XXX In Hypogonadal Men
92. A Randomized, Double-Blind, Single-Dose, Placebo-Controlled Evaluation of the Safety and Efficacy of XXX in the Acute Treatment of the Headache of Migraine

Research Experience (continued):

93. Double-Blind, Randomized, Placebo-Controlled, Parallel Study to Evaluate the Efficacy and Safety of XXX, as an Adjunct to Oral Hypoglycemic Therapy, in the Treatment of Hypogonadal and Low Testosterone Men with Type 2 Diabetes.
94. A Phase III, Randomized, Double-Blind, Placebo-Controlled and Open-Label Active-Controlled Study to Evaluate the Safety and Efficacy of XXX Treatment In Men With Secondary Hypogonadism
95. A Double-Blind, Randomized, Placebo-Controlled, Multi-Dose, Phase III, Parallel Group Study of XXX for the Management of Moderate to Moderately Severe Chronic Pain of Osteoarthritis of the Hip and Knee in Adults
96. An 8-week, multi-center, randomized, double-blind, placebo-controlled, parallel group trial of XXX in patients with primary osteoarthritis of the hand
97. A Phase III open-label titration trial to evaluate the effectiveness and safety of different doses of a dermal application of XXX in hypogonadal men
98. A Phase IIa, Repeat Dose, Pharmacokinetic Study of Oral Testosterone Ester Formulations in Hypogonadal Men
99. A Randomized, Double Blind, Parallel-Group Study of Cardiovascular Safety In Osteoarthritis or Rheumatoid Arthritis Patients With or at High Risk for Cardiovascular Disease Comparing XXX With XXX and XXX.
100. Phase I/II, Open-Label, Multi-Dose XXX Study of Oral XXX Formulations
101. A Phase III open-label extension of the XXX trial (A Phase III open-label titration trial to evaluate the effectiveness and safety of different doses of a dermal application of XXX in hypogonadal men) to evaluate skin-safety
102. A Randomized, Double-Blind, Active-Controlled Crossover Study to Evaluate the Efficacy and Safety of XXX Tablets Compared With XXX for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Pain
103. A Phase 2, Double-Blind, Randomized, Placebo-Controlled, Multiple-Dose, Dose Escalation Study to Evaluate the Efficacy, Safety and Tolerability of XXX in Patients with Opioid-Induced Constipation (OIC)
104. A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate Efficacy, Safety, Tolerability, and Pharmacokinetics of a Single Intraoperative Localized Instillation of XXX in Patients Undergoing Primary Unilateral Total Hip Arthroplasty
105. A Phase 3, Multicenter, Randomized, Placebo-Controlled, Parallel-Group, Double-Blind Study to Evaluate the Efficacy, Tolerability, Safety, and Pharmacokinetics of XXX in Patients Undergoing Primary Unilateral Total Knee Arthroplasty
106. Multi-center, open-label, uncontrolled study to investigate the efficacy and safety of the transdermal contraceptive patch containing XXX in a 21-day regimen for 13 cycles in 1650 healthy female subjects

Research Experience (continued):

107. A Safety and Efficacy Trial evaluating the use of XXX for the extended treatment of deep vein thrombosis and pulmonary embolism
108. A Safety and Efficacy Trial evaluating the use of XXX in the treatment of symptomatic Deep vein thrombosis and pulmonary embolism.
109. Multicenter, Randomized, parallel Group Efficacy and safety study for the prevention of deep vein thromboembolism in hospitalized medically ill patients comparing XXX XXX
110. An Open-Label 52-week Study to Assess the Long-Term Safety of XXX in Opioid-Induced Constipation (OIC) in patients with Non-Cancer-Related Pain.
111. A Phase III, hase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Safety and Efficacy of XXX in Patients with Type 2 Diabetes Mellitus on Background Treatment with Glimepiride with or without Metformin
112. A randomized, double-blind, placebo-controlled, 2-arm parallel-group, multicenter study with a 24-week main treatment period and an extension assessing the efficacy and safety of XXX on top of xxxx in patients with type 2 diabetes not adequately controlled with xxxx.
113. A randomised, double-blind, parallel group study to compare the efficacy and safety of the fixed dose combination of XXX 5 mg + XXX 45 mg to XXX 45 mg, administered orally once daily over 24 weeks in type 2 diabetic patients with insufficient glycaemic control despite 12 week maximum dose of XXX therapy (45 mg, with XXX 30 mg forced titrated after 6 weeks)
114. A Phase III randomized, double-blind, parallel group study to evaluate the efficacy and safety of once daily oral administration of XXX 25mg/XXX 5 mg and XXX 10mg/XXX 5 mg Fixed Dose Combination tablets compared with the individual components (XXX 25mg, XXX 10mg, and XXX 5mg) for 52 weeks in treatment naïve and metformin treated patients with type 2 diabetes mellitus with insufficient glycaemic control
115. A Phase III, multicentre, international, randomised, parallel group, double blind cardiovascular safety study of XXX (10 irig and 25 irig administered orally once daily) compared to usual care in type 2 diabetes mellitus patients with increased cardiovascular risk
116. A Randomized, Double-blind, Placebo-controlled, Parallel group, Dose ranging, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in the Treatment of Patients with Irritable Bowel Syndrom with Diarrhea.
117. An open label randomized multicenter study to assess patient preference for and evaluate clinical benefit of insulin glargine xxxxx pen versus conventional vial/syringe method of insulin glargine XXX injection therapy in patients with type 2 diabetes mellitus
118. A Large Simple Safety Study of XXX Inhalation Solution in Subjects with Chronic Obstructive Pulmonary Disease
119. A Multicenter, Randomized, Placebo-controlled, Double-blinded Study of the Efficacy and Safety of XXX in Subjects with Opioid-induced Bowel Dysfunction
120. A Multicenter, Randomized, Active-Control, Phase 3B Study to Evaluate the Cardiovascular Safety of XXX and XXX in Subjects with Gout and Cardiovascular Comorbidities

Research Experience (continued):

121. An Open-Label 52-week Study to Assess the Long-Term Safety of XXX in Opioid-Induced Constipation (OIC) in patients with Non-Cancer-Related Pain.
122. Phase III, Active Controlled, Safety and Efficacy Trial of Oral Testosterone XXX (TU) in Hypogonadal Men
123. A Multicenter, Randomized, Double-Blind, Phase 2 Study to Evaluate the Effect of XXX Versus Placebo in Joint Damage in Hyperuricemic Subjects with Early Gout.
124. GASTROINTESTINAL (GI) RANDOMIZED EVENT AND SAFETY OPEN-LABEL NSAID STUDY (GI-REASONS): A RANDOMIZED, OPEN-LABEL, BLINDED-ENDPOINT, PARALLEL-GROUP TRIAL OF GI SAFETY OF XXX COMPARED WITH NON-SELECTIVE NONSTEROIDAL ANTINFLAMATORY DRUGS (NSAIDS) IN OSTEOARTHRITIS PATIENTS
125. Phase III, A 90-Day, Randomized, Dose-Ranging Study, Including Potential Dose Titration, Evaluating the Efficacy and Safety of Intranasal XXX in the Treatment of Male Hypogonadism with Sequential Safety Extension Periods of 90 and 180 Days
126. START-CKD: Strategies Using Darbepoetin alfa to Avoid Transfusions in Chronic Kidney Disease
127. A Study to Assess Repeat Treatment Efficacy and Safety of XXX in Subjects with Irritable Bowel Syndrome with Diarrhea (IBS-D)
128. A Multicenter, Randomized, Double-blind, Placebo-Controlled, 8-Week Study to Evaluate the Safety and Efficacy of XXX and XXX Given as a Fixed-Dose Combination in Patients with Stage 1 or 2 Essential Hypertension
129. A Multicenter, Randomized, Active-Control, Phase 3B Study to Evaluate the Cardiovascular Safety of XXX and XXX in Subjects with Gout and Cardiovascular Comorbidities
130. Phase IV, Open-Label Study of Oral Testosterone Undecanoate in Hypogonadal Men
131. Phase III, Open-Label Study of the Safety and Efficacy of Oral Testosterone Undecanoate (TU) in Hypogonadal Men
132. A Phase 3 Randomized, Double-Blind, Multicenter, Placebo-Controlled Combination Study to Evaluate the Efficacy and Safety of XXX and XXX Compared to XXX Alone in Subjects with Gout Who Have Response to Standard of Care XXX
133. A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy, Safety and Tolerability of XXX in Patients with Type 2 Diabetes
134. An Open-Label Multi-Center Sub Study to Evaluate the Efficacy, Safety and Tolerability of XXX in Patients with Type 2 Diabetes with High Baseline HbA1c
135. A Phase 3, Randomized, Active Comparator, Double-Blind, Multi-Center Study to Compare the Efficacy, Safety and Tolerability of XXX to XXX as Add-on Therapy to Metformin in Patients with Type 2 Diabetes
136. A Randomized, Multicenter Study to Evaluate Cardiovascular Outcomes with XXX in Patients Treated with Standard of Care for Type 2 Diabetes

Research Experience (continued):

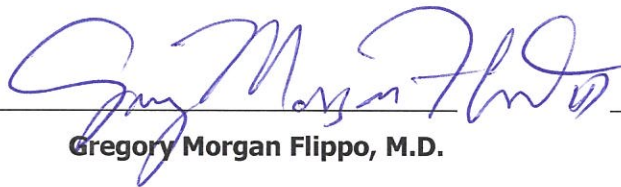
137. A double-blind, multiple-dose, 52-week study to evaluate the efficacy and safety of XXX administered subcutaneously once each week to adult males with hypogonadism
138. A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel group, Phase 3 Trial to Evaluate the Safety and Efficacy of Once Weekly XXX Therapy Added to Titrated Basal Insulin Glargine Compared to Placebo Added to Titrated Basal Insulin Glargine in Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on Basal Insulin Glargine
139. A 28-Week, Multicenter, Randomized, Double-Blind, Active-Controlled, Phase 3 Study with a 24-Week Extension Phase to Evaluate the Efficacy and Safety of Simultaneous Administration of XXX Once Weekly 2 mg and XXX Once Daily 10 mg Compared to XXX Once Week 2 mg Alone and XXX Once Daily 10 mg Alone in Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on Metformin
140. A Long-Term Outcomes Study to Assess Statin Residual Risk Reduction with XXX in High Cardiovascular Risk Patients with Hypertriglyceridemia (STRENGTH)
141. Phase 3, Active-Controlled, Safety and Efficacy Trial of Oral Testosterone Undecanoate XXX in Hypogonadal Men
142. A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Phase III Study in Men with Acquired Hypogonadotropic Hypogonadism to Compare Changes in Testosterone and Sperm Concentration Following Treatment with 12.5 mg or 25 mg XXX or XXX
143. A 6-Month Safety Study of XXX Testosterone Administered Subcutaneously Once Each Week to Adult Males with Hypogonadism
144. A 45-Day, Open-Label Titration Trial, Evaluating the Effectiveness and Safety of Intranasal XXX in the Treatment of Male Hypogonadism
145. A Phase 3, Multicenter, Long-Term Observational Study of Subjects from XXX Studies Who Undergo A Total Knee, Hip or Shoulder Replacement
146. A Phase 3, Multicenter, Long-Term Observational Study of Subjects from XXX Studies Who Undergo A Total Knee, Hip or Shoulder Replacement
147. A randomized, open-label, parallel group real world pragmatic trial to assess the clinical and health outcomes of XXX compared to commercially available basal insulins for initiation of therapy in insulin naïve patients with uncontrolled type 2 diabetes mellitus
148. An Open-Label, Multi-Center, Randomized, Phase 3b Study to Evaluate the Safety and Tolerability of Switching to One of Two Dosing Strategies of XXX in Patients with Type 2 Diabetes Receiving Stable Doses of Liraglutide
149. A PROSPECTIVE, RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED, MULTICENTER, PHASE 3 EFFICACY AND SAFETY STUDY OF XXX GIVEN AS A SINGLE INTRATYMPANIC INJECTION IN SUBJECTS WITH UNILATERAL MENIERE'S DISEASE
150. A PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY OF THE ANALGESIC EFFICACY AND SAFETY OF A DOSE TITRATION REGIMEN FOR THE SUBCUTANEOUS ADMINISTRATION OF XXX IN SUBJECTS WITH OSTEOARTHRITIS OF THE HIP OR KNEE
151. A PHASE 3 RANDOMIZED, DOUBLE-BLIND, ACTIVE-CONTROLLED, MULTICENTER STUDY OF THE LONG-TERM SAFETY AND EFFICACY OF SUBCUTANEOUS ADMINISTRATION OF XXX IN SUBJECTS WITH OSTEOARTHRITIS OF THE HIP OR KNEE

Research Experience (continued):

152. A Phase 2a, Multicenter, Randomized, Double-blind, Placebo-controlled and Active-controlled, Parallel-group Study Evaluating the Analgesic Efficacy and Safety of XXX in Subjects with Moderate to Severe Chronic Pain Due to Osteoarthritis
153. A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO ASSESS THE EFFECTS OF XXX ON THE OCCURRENCE OF MAJOR CARDIOVASCULAR EVENTS IN PATIENTS WITH, OR AT HIGH RISK FOR, CARDIOVASCULAR DISEASE WHO ARE STATIN INTOLERANT
154. XXX to REDUCE CARDIOVASCULAR OUTCOMES BY REDUCING TRIGLYCERIDES IN PATIENTS WITH DIABETES
155. Validation of Dosing Regimen of Oral Testosterone Undecanoate in Hypogonadal Men
156. Dosing Flexibility Study of Oral Testosterone Undecanoate in Hypogonadal Men
157. A PHASE 3, MULTICENTER, LONG-TERM OBSERVATIONAL STUDY OF SUBJECTS FROM TANEZUMAB STUDIES WHO UNDERGO A TOTAL KNEE, HIP OR SHOULDER REPLACEMENT
158. A Phase 3b, Study to Evaluate the Long-Term Safety and Efficacy of XXX in Combination with XXX for the Management of Heavy Menstrual Bleeding Associated with Uterine Fibroids in Postmenopausal Women
159. A 12-Month, Randomized, Active-controlled, Open-label Study of the Efficacy and Safety of Oral Testosterone Undecanoate in Hypogonadal Men
160. Ambulatory Blood Pressure Monitoring in Oral Testosterone (XXX) Treated Hypogonadal Men
161. Open-label Study of Safety and Tolerability of Chronic Intermittent Usage for 24 or 52 Weeks of XXX Device XXX in Patients with Migraine Headache XXX Trial (Safety and Tolerability of POD-DHE)
162. A Phase 3 Randomized, Double-blind, Placebo-controlled, Multi-center Study to Evaluate the Efficacy and Safety of XXX in Combination With the Standard-of-care Treatment in Adolescent, Adult, and Elderly Non-hospitalized Subjects with Influenza A Infection who Are at Risk of Developing Complications
163. Corticosteroid Lumbar Epidural Analgesia for Radiculopathy (C.L.E.A.R.)
164. A Multicenter, Randomized, Double-Blind, Comparator-Controlled, Placebo-Controlled Study to Assess the Efficacy and Safety of Oral XXX in the Treatment of Acute Migraine Pain, With or Without Aura, and the Prevention of Migraine-Associated Nausea and Vomiting (MANV)
165. 24-hour Ambulatory Blood Pressure Monitoring Study in Hypogonadal Men Treated with XXX Nasal Testosterone Gel (Phase 4 Study)
166. A PHASE IV OPEN-LABEL, RANDOMIZED, PARALLEL-GROUP, THREE TREATMENT ARM, MULTICENTER STUDY ON HYPOGONADAL MALES TO EVALUATE THE EFFECT ON 24-HOUR AMBULATORY BLOOD PRESSURE AFTER 16-WEEK CONTINUOUS TREATMENT WITH MARKETING TESTOSTERONE PRODUCTS

Research Experience (continued):

- 167. A Phase 3, Open-label, Multi-center, Single-arm Study to Assess Contraceptive Efficacy and Safety of the XXX + XXX Combined Oral Contraceptive (XXX) in Premenopausal Females up to 35 Years of Age
- 168. A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled and Parallel Group 48-Week Study to Evaluate the Efficacy and Safety of XXX in the Treatment of Obesity
- 169. A Phase 4, Open-Label, Single-Arm Study to Evaluate the Effects of XXX on 24-Hour Ambulatory Blood Pressure Monitoring in Hypogonadal Men Using Therapeutic Testosterone Replacement Therapy
- 170. A Randomized, A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of XXX Administered Subcutaneously to Patients with Severe Hypertriglyceridemia

 04/21/2023

Gregory Morgan Flippo, M.D. **Date**

Revised April 2023