CURRICULUM VITAE

Christina Stanley, CCRC

Executive Research Director

Quality Medical Research
Nashville Gastroenterology and Hepatology, PC
330 Wallace Road, Suite 103
Nashville, TN 37211

Office: 615-835-4750
Fax: 615-835-4752

EDUCATION

1992 National EMT Training, United States Army- Medical Assistant,
1992 Business, University of West Florida,
1991 General Studies, Palm Beach Atlantic College,

PROFESSIONAL EXPERIENCE

Executive Research Director **2013-Current**
Quality Medical Research
330 Wallace Road, Suite 103
Nashville, TN 37211

Clinical Research Director **2011-2013**
Nashville Medical Research Institute
4230 Harding Rd. Suite 529E
Nashville, TN. 37205

Clinical Research Director **2010-2011**
West Tennessee Research Institute
371 North Parkway, Suite 400
Jackson, TN. 38305

Clinical Research Assistant/Certified Clinical Research Coordinator **2009-2010**
Renstar Medical Research
104 S.E. 1st Avenue, Suite B
Ocala, FL. 34471

Clinical Supervisor-Research Department **1999-2009**
Certified Clinical Research Coordinator
Anchor Health Center's
800 Goodlette Road N. Suite 200
Naples, FL. 34102

Clinical Supervisor/Medical Assistant **1996-1999**
Clinical Research Coordinator
Collier Neurologic Specialist
720 Goodlette Road N.
Naples, FL. 34102

Medical Assistant **1995-1996**
Pediatric Neurology
Dr Ira
Naples, Fl 34102

US Army **1992-1995**
Ft. Leonard wood, Missouri
Ft. Sam Houston, Texas
Ft. Bliss, Texas

CERTIFICATION AND LICENSURE

Association of Clinical Research Professionals (CCRC)
Medical Assistant
National Emergency Medical Technician
CITI Training
IATA Training
Saf-T-Pak Training
National Institute of Health (NIH) Certificate # 1339496
ICH/GCP Certified, TransCelerate
Society for Clinical Research Sites (SCRS)
American Heart Association ACLS Provider, Issued June 23, 2015 TC ID#: TN000464
Medidata Certified Professional, Issued October 23, 2012 ID#MDSO3216257

MEMBERSHIPS

American College of Gastroenterological (AGA)
American Association for the Study of Liver Diseases (AASLD)
European Association for the Study of the Liver (EASL)
Association of Clinical Research Professional (ACRP), Greater Nashville Chapter
American Liver Foundation (ALF), Nashville Chapter, Board of Directors
American Liver Foundation (ALF), Nashville Chapter, Secretary of Board of Directors

INVESTIGATIONAL/STUDY PROTOCOLS:

1. A Randomized, Double-Blind, Comparative Study of XXX and YYY for the prevention of Venous Thromboembolism Following Total Hip Arthroplasty.

2. A Randomized, Double-Blind, Comparative Study of XXX and YYY for the prevention of Venous Thromboembolism Following Total Hip Arthroplasty.

3. A Randomized, Multi-Center, Double-Blind, Double Dummy, Parallel, Placebo-Controlled Trial to Compare the Safety and Efficacy of XXX and YYY in the Treatment of Minor Arthritis Pain.

4. Rosiglitazone (Avandia) Evaluation: Advancing Current Treatment of Type 2 Diabetes Mellitus (React 2 Diabetes).

5. Efficacy and Safety Study of the Oral Direct Thrombin Inhibitor XXX Compared with Dose-Adjusted YYY in the Prevention of Stroke and Systemic Embolic Events in Patients with Atrial Fibrillation. (Sportif O)

6. A Randomized, Double-Blind, Placebo-Controlled Trial of the Effect of Weekly XXX on the Incidence of Coronary Artery Disease in Subjects with Evidence to C. Pneumonia.

7. A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Flexible Dose, Multi-Center Study to Evaluate the Efficacy, Safety, and Toleration of Oral XXX Administered for 12 weeks to Women Who are Post-Menopausal or Post-Hysterectomy, Who have Physiologic Levels of Estrogen and Testosterone and Who have been Diagnosed with Female Sexual Arousal Disorder.

8. A Prospective, Randomized, Double-Blind, Multi-Center Study Comparing the Effects of Aggressive Lipid Lowering with Moderate Lipid Lowering on the Reduction of Myocardial Ischemia in the Elderly as Measuring by Halter Monitoring by Comparing the Maximal Doses of Two Statins: Study Assessing Goals in the Elderly (SAGE)

9. Efficacy and Safety of XXX in Combination with Aspirin, in Patients with a Recent Acute Coronary Syndrome with Elevated Biochemical Markers of Myocardial Damage. A Multi-Center, Double-Blind, Controlled, Dose-Guiding Study.

10. A Phase 3, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating the Efficacy and Safety of XXX in the Prevention of Ischemic Events in Subjects with Moderate to Severe Peripheral Arterial Disease.

11. A Multi- Center, Randomized, Double-Blind, Parallel Group, Single Dose, Placebo-Controlled Study of the Efficacy and Safety of a Combination of WWW and XXX to YYY and ZZZ in Subjects with Acute Migraine Attacks.

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

12. Optimization of Dose (Study A) and Combination of Study and Efficacy (Study B) of XXX (Oral Direct Thrombin Inhibitor) Compared to YYY for the Prevention of Venous Thromboembolism Following Total Knee Arthroplasty

13. A Randomized, Double-Blind, Placebo-Controlled, Parallel Groups, Outpatient Study to Examine the Safety, Tolerability, and Efficacy of XXX PO for the Acute Treatment of Migraine in Adolescents

14. A Multi-Center 8-Week, Double-Blind Assessment Comparing the Efficacy and Assessing the Safety of XXX at starting Doses of 10mg, 20mg, 40mg, and 80mg.

15. An Open-Label Study to Demonstrate Equivalence of Twice Daily Dosing of XXX Compared to Once Daily Dosing of Vitamin E In Regard to Compliance and to Determine Caregiver and Physician Satisfaction with XXX in the treatment of Patients with Alzheimer's Disease Using the XXX Satisfaction Questionnaire

16. Systolic and Pulse Pressure Homodynamic Improvement Restoring Elastic

17. An Open-Label Study to Evaluate the Long-term Safety of Subcutaneous MOA-728 for Treatment of Opioid-Induced Constipation in Subjects with Nonmalignant Pain.

18. A Double-Blind, Randomized, Parallel-Group, Vehicle-Controlled, Multi-Center Study to Evaluate the Safety and Bioequivalence of Calcipotriene Cream 0,005% (TOLMR INC.) and Dovonex (Calcipotriene Cream) Cream, 0.0005% and Compare Both Active treatments to a Vehicle Control in the treatment of Plaque Psoriasis.

19. A Phase 3 open-label extension of the MTE08 trial-A Phase III open-label titration trial to evaluate the effectiveness and safety of different doses of a dermal application of Testosterone MD-Lotion (cutaneous solution) in hypogonadal men) to evaluate skin-safety

20. An Open-Label Study To Evaluate the Safety of NP 101, a Sumatriptan Iontophoretic Transdermal Patch, in the Treatment of Acute Migraine over 12 Months.

21. An Open-Label Study To Evaluate the Safety of NP101, a sumatriptan Iontophoretic Transdermal Patch, in the Treatment of Acute Migraine over 12 Months.

22. A Phase 3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Tolerability of Dimebon (PF-01913539) for up to 26 Weeks in Patients with Mild to Moderate Alzheimer's Disease.

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

23. A Phase 3, Double-Blind, Randomized, Efficacy and Safety Study Comparing the TAK-491 Plus Chlorthalidone Fixed-Dose Combination, vs Benicar HCT (Olmesartan Medoxomil-Hydrochlorothiazide) in Subjects With Moderate to Severe Essential Hypertension.

24. A Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of Avanafil (TA-1790) in the Treatment of Erectile Dysfunction in Diabetic Men.

25. An Open-Label, Long-Term Evaluation of the Safety and Efficacy of Avanafil in Men with Erectile Dysfunction.

26. A randomized, double-blind, placebo-and active-controlled study of carisbamate in the treatment of neuropathic pain in diabetic peripheral neuropathy followed by a blinded extension phase.

27. A Phase 2a multi-center, randomized, double-blind, placebo controlled study to investigate the efficacy and safety of T-817MAa in patients with mild to moderate Alzheimer's disease.

28. A randomized, double-blind, placebo-controlled, parallel-group, multicenter 24-week study followed by an extension assessing the efficacy and safety of AVE0010 on top of metformin in patients with Type 2 diabetes not adequately controlled with Metformin.

29. A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Trial of Linaclotide Administered Orally for 12 Weeks Followed by a 4 Week Randomized Withdrawal Period in Patients with Type Irritable Bowel Syndrome with Constipation.

30. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Carisbamate as Adjunctive Therapy in Subjects With Partial Onset Seizures, Followed by an Open-Label Extension Study.

31. A Phase 2b Multicenter, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Efficacy, and Safety of Apremilast (CC-10004) in subjects with Moderate-to-Severe Plaque-Type Psoriasis (Core Study).

32. A Phase 2b, Multicenter, Treatment-Arm Blind, Safety and Efficacy 28-Week Extension Study of Apremilast (CC-10004) in Subjects who Completed the Treatment Phase of the Core Study CC-10004-PSOR-005.

33. An Open-Label Study To Evaluate the Safety of NP101, a Sumatriptan Iontophoretic Transdermal Patch, in the Treatment of Acute Migraine over 12 Months.

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

34. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Safety and Efficacy of Dutogliptin in Patients with Type 2 Diabetes Mellitus on Background Treatment with Glimepiride with or without Metformin.

35. An Open-Label Extension to the B1451027 Protocol to Evaluate the Long-Term Safety and Tolerability of Dimebon (PF-01913539) in Patients with Alzheimer's Disease.

36. A 12-week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Trial to Evaluate the Efficacy and Safety of Fesoterodine Flexible Dose Regimen in Vulnerable Elderly Patients with Overactive Bladder.

37. A 26 Week Randomized, Multinational, Open Labeled, 2 Armed, Parallel Group, Treat-To-Target Once Daily Treatment Trial with Insulin Detemir Versus Insulin Glargine, Both in Combination with Metformin in Subjects with Type 2 Diabetes.

38. A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study of the Safety and Efficacy of a Single Treatment of BOTOX (Botulinum Toxin Type A) Purified Neurotoxin Complex Followed by a Treatment with BOTOX as Applicable in Patients with Idiopathic Overactive Bladder with Urinary Incontinence.

39. A Randomized, Double-Blind, Placebo-Controlled, Multicentre, Parallel Group Study of the Safety, Tolerability and Efficacy of V3381 for Up to 13 Weeks in Patients With Diabetic Peripheral Neuropathic Pain (DPNP).

40. A Multicenter, Long-term Follow up Study of the Safety and Efficacy of BOTOX (Botulinum Toxin Type A) Purified Neurotoxin Complex in Patients with Idiopathic Overactive Bladder with Urinary Incontinence.

41. A Randomized, Placebo-controlled, Double-Blind, Parallel Design, Phase 3 Study to Assess the Safety and Efficacy of WC3040 Tablets in Male Subjects with Erectile Dysfunction.

42. A Randomized Controlled Trial of Duloxetine added to NSAIDs in Patients with Knee Pain due to Osteoarthritis who have had Suboptimal Response to NSAID Treatment.

43. A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Adding Methotrexate to Etanercept to Etanercept in Subjects With Moderate to Severe Plaque Psoriasis.

44. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Discontinuation Study to Evaluate the Durability of Effect of Milnacipran for the Treatment of Fibromyalgia in Patients With Long Term Milnacipran Treatment.

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

45. A Phase 2, Randomized, Double-Blind, Double-Dummy, Placebo-and Active-Controlled, Multicenter Study to Determine the Efficacy and Safety of TAK-875 in Subjects with Type 2 Diabetes Mellitus.

46. A Double-blind, Placebo-Controlled, Flexible-Dose Study of F2695 SR in Patients with Major Depressive Disorder.

47. A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel-Group Study to Compare XXXXX and XXXXX to YYYYY and Both Active Treatments to a Vehicle Control in the Treatment of Psoriasis Vulgaris.

48. A phase 2, Randomized, Double-Blind, Placebo-Controlled Trial of the Safety and Efficacy of ANA598 Administered with Pegylated Interferon and Ribavirin in Genotype 1 Patients with Chronic Hepatitis C Infection.

49. A Randomized, Double-Blind Study to Evaluate the Safety and Antiviral Activity of IDX184 in Combination with Pegylated Interferon and Ribavirin for 12 Weeks in Treatment-Naïve Subjects with Genotype 1 Chronic Hepatitis C Infection.

50. A Phase 2b, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating Response Guided Therapy using Combinations of Oral Antivirals (GS-5885, tegobuvir, and/or GS-9451) with Pegintergeron Alfa 2a and Ribavirin in Treatment Experienced Subjects with Chronic Genotype 1 Hepatitis C Virus Infection

51. A Long Term Follow-up Registry for Subjects Who Achieve a Sustained Virologic Response to Treatment in Gilead-Sponsored Trials in Subjects with Chronic Hepatitis C Infection.

52. A Long Term Follow-up Registry for Subjects Who Did Not Achieve a Sustained Virologic Response to Treatment in Gilead-Sponsored Trials in Subjects with Chronic Hepatitis C Infection.

53. A randomized, open-label trial of the safety and efficacy of DEB025/Alisporivir in combination with pegylated interferon-a2a and ribavirin (peg-INFa2a/RBV) and boceprevir in combination with peg-INFa2a/RBV in African American treatment-naïve patients with chronic hepatitis C genotype 1.

54. A Phase 2, Open-Label Study of Daclatasvir (BMS-790052) and TMC435 in Combination With or Without Ribavirin (RBV) For Treatment-Naïve Subjects or Null Responders to Prior Peginterferon Alfa (PegINF)/RBV Therapy with Genotype 1 Chronic Hepatitis C.

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

55. A Randomized, Open-Label, Multicenter Study to Evaluate the Safety and Antiviral Activity of the Combination of ABT-450 with Ritonavir in Treatment-Experienced Subjects with Genotype 1 Chronic Hepatitis C Virus (HCV) Infection (PEARL-II).

56. A Phase 3, Multicenter, Randomized, Open-Label Study to Investigate the Efficacy and Safety of Sofosbuvir/GS-5885 Fixed-Dose Combination ∓ Ribavirin for 12 and 24 Weeks in Treatment-Naïve Subjects with Chronic Genotype 1 HCV Infection.

57. A Phase 2b Study of BMS-790052 in Combination with Peg-Interferon Alfa-2a and Ribavirin in Treatment Naïve Subjects with Chronic Hepatitis C Genotype 1 and 4 Infection.

58. A Phase 2B Study of BMS-790052 in Combination with Peginterferon Alfa-2a and Ribavirin in Chronic Hepatitis C Genotype 1 Infected Subjects Who are Null or Partial Responders to Prior Treatment with Peginterferon Alfa plus Ribavirin Therapy.

59. An open-Label Re-treatment study with Peg-Interferon Alfa-2a, Ribavirin and BMS-790052 with or Without BMS-650032 for Subjects with Chronic Hepatitis C.

60. A Multicenter, Open-Label Study of the Human Anti-TNF Monoclonal Antibody Adalimumab to evaluate the Long Term Safety and Tolerability of Repeated Administration of Adalimumab in Subjects With Ulcerative Colitis.

61. A Phase IIb Randomized, Placebo-Controlled Study to Evaluate the Clinical Efficacy and Safety of Induction and Maintenance Therapy with BMS-936557 in Subjects with Active Ulcerative Colitis (UC).

62. A Phase 2 Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Study to Investigate the Safety and Efficacy of Multistem (PF-05285401) In Subjects With Moderate To Severe Ulcerative Colitis.

63. A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Subjects with Moderately to Severely Active Crohn's Disease Who Have Failed or Are Intolerant to TNF Antagonist Therapy (UNITI 1).

64. A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Subjects with Moderately to Severely Active Crohn's Disease (UNITI 2).

65. A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Maintenance Therapy in Subjects with Moderately to Severely Active Crohn's Disease (UNITI 3).

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

66. A Long-Term Follow-up Study of Subjects Who Participated in a Clinical Trial in Which Asunaprevir (BMS-650032) and/or Daclatasvir (BMS-790052) Was Administered for the Treatment of Chronic Hepatitis C.

67. Comparative Assessment of Effectiveness of Antiviral Therapies in Hepatitis C (COMPASS)

68. Collection of Blood Specimens from HCV Antibody Positive Subjects.

69. A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of SAR236553/REGN727 Versus Ezetimibe in High Cardiovascular Risk Patients With Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.

70. HALO Patient Registry: Ablation of Barrett's Esophagus.

71. 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 Celecoxib with Naproxen and Ibuprofen.

72. A Study to Assess Repeat Treatment Efficacy and Safety of Rifaximin 550mg TID in Subjects with Irritable Bowel Syndrome with Diarrhea (IBS-D).

73. A Phase 3 study to evaluate the Efficacy and Safety of Induction and Maintenance Regimens of Brodalumab Compared with Placebo and Ustekinumab in Subjects with Moderate to Severe Plaque Psoriasis: AMAGINE-3.

74. A Randomized, Double-Blind, Placebo-controlled, Dose-Ranging, Multicenter study to assess the efficacy and Safety of Rifaximin Soluble Solid Dispersion (SSD) Tablets For the Prevention of Complications in Subjects with Early Decompensated Liver Cirrhosis.

75. A Double-blind, Randomized, Placebo-controlled, Phase 3 Trial in Patients with Chronic Idiopathic Constipation to Demonstrate the Efficacy and Safety of Elobixibat 5mg and 10mg for 26 Weeks.

76. A Multicenter, Open-Label, Safety and Tolerability Extension Trial of 5mg and 10mg Elobixibat Daily in the Treatment of Chronic Idiopathic Constipation.

77. A Phase 2, Multicenter, Open-Label, Randomized, Parallel-Group Study to Evaluate the Safety, Tolerability, Antiviral Activity, and Pharmacokinetics of Oral Ribavirin (RBV) Administered Once Daily Versus Oral Ribasphere Administered Twice Daily in Combination with Sofosbuvir 400mg in Subjects With Genotype 2, Chronic Hepatitis C.

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

78. Ferring International Pharmascience Center US, Inc.,; Protocol 000080: "A double-blind, Randomized , Placebo-controlled, Phase 3 Trial in Patients with Chronic Idiopathic Constipation to Demonstrate the Efficacy and Safety of Elobixibate 5 mg and 10 mg for 12 Weeks Followed by a 4-week Withdrawal Period".

79. Kadmon Corporation; Protocol Number RBV-201: "A Phase 2, Multicenter, Open-Label, Randomized, Parallel-Group Study to Evaluate the Safety, Tolerability, Antiviral Activity, and Pharmacokinetics of Oral Ribavirin (RBV) Administered Once Daily Versus Oral Ribasphere® Administered Twice Daily in Combination with Sofosbuvir 400 mg in Subjects With Genotype 2, Chronic Hepatitis C".

80. Boehringer Ingelheim; Protocol #: 1311.6: "A Phase II, Multicenter, Randomized, Double-blind, Multiple Dose, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy, Pharmacokinetics, and Safety of BI 655066, an IL-23 p19 Antagonist Monoclonal Antibody, in Patients With Moderately to Severely Active Crohn's Disease, Who Are naïve to, or Were Previously Treated With Anti-TNF Therapy".

81. Pfizer; Protocol #: A3191172 (PRECISION): "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 Celecoxib With Naproxen And Ibuprofen"

82. Evoke Pharma; Protocol #: METO-IN-003: "A multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Clinical Study to Evaluate the Efficacy and Safety of Metoclopramide Nasal Spray in Women with Symptoms Associated with Diabetic Gastroparesis".

83. Evoke Pharma; Protocol #: METO-IN-004: "A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Clinical Study to Evaluate the Efficacy and Safety of Metoclopramide Nasal Spray in Men with Symptoms Associated with Diabetic Gastroparesis".

84. Janssen Research & Development, LLC; Protocol #: CNTO136ARA3005; Phase 3; "A Multicenter, Randomized, Double-blind, Parallel Group Study of CNTO 136 (sirukumab) Administered Subcutaneously as Monotherapy Compared With Adalimumab Monotherapy, in Subjects With Active Rheumatoid Arthritis"

85. Salix Pharmaceuticals; Protocol #: RNLC2131; "A Randomized, Double-blind, Placebo-controlled, Dose-ranging, Multicenter Study to Assess the Efficacy and Safety of Rifaximin Soluble Solid Dispersion (SSD) Tablets for the Prevention of Complications in Subjects With Early Decompensated Liver Cirrhosis"

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

86. Synergy Pharmaceuticals Inc.; Protocol #: SP304203-03; "A National, Randomized, 12-Week, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of Plecanatide (3.0 and 6.0 mg) in Patients with Chronic Idiopathic Constipation" (The National CIC3 Study)

87. Targacept Inc.; Protocol # TC-6499-12-CLP-005; "A Randomized, Double-Blind, Placebo-Controlled, Crossover Study To Assess The Effects of TC-6499 On Gastric Emptying Time In Diabetic Subjects With Gastroparesis (Pro00009709)"

88. Gilead; Protocol # GS-US-342-1139 (ASTRAL 2); "A Phase 3, Multicenter, Randomized, Open-Label Study to Compare the Efficacy and Safety of Sofosbuvir/GS-5816 Fixed Dose Combination for 12 Weeks with Sofosbuvir and Ribavirin for 12 Weeks in Subjects with Chronic Genotype 2 HCV Infection"

89. Gilead: Protocol # GS-US-342-1137 (ASTRAL 4) "A Phase 3, Multicenter, Open-Label Study to Investigate the Efficacy and Safety of Sofosbuvir/GS-5816 Fixed-Dose Combination in Subjects with Chronic HCV Infection and Child-Pugh Class B Cirrhosis"

90. Gilead: Protocol # GS-US-367-1168 "A Phase 2, Global, Multicenter, Open-Label Study to Investigate the Safety and Efficacy of GS-9857 Plus Sofosbuvir/GS-5816 Fixed Dose Combination in Subjects with Chronic Genotype 1 HCV Infection"

91. Gilead: Protocol # GS-US-367-1169 "A Phase 2, Global, Multicenter, Open-Label Study to Investigate the Safety and Efficacy of GS-9857 Plus Sofosbuvir/GS-5816 Fixed Dose Combination in Subjects with Chronic Non-Genotype 1 HCV Infection"

92. Gilead: Protocol # GS-US-342-1446 "An Open Label Study of Sofosbuvir/GS-5816 Fixed-Dose Combination in Subjects with Chronic HCV Infection"

93. Gilead: Protocol # GS-US-342-1553 "An Open-Label Study to Evaluate The Efficacy And Safety Of Sofosbuvir/GS-5816 Fixed Dose Combination with Ribavirin For 24 weeks In Chronic HCV Infected Subjects Who Participated In Prior Gilead-Sponsored HCV Treatment Studies"

94. Tobira Therapeutics: Protocol # 652-2-203 (CENTAUR) "Efficacy and Safety Study of Cenicriviroc for the Treatment of Nonalcoholic Steatohepatitis (NASH) in Adult Subjects with Liver Fibrosis"

95. Intercept Pharmaceuticals, Inc.: Protocol # 747-302" A Phase 3b, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study Evaluating the Effect of Obeticholic Acid on Clinical Outcomes in Subjects with Primary Biliary Cirrhosis"

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

96. Theravance Biopharma R & D, Inc.: Protocol # 0099 "A Multicenter, Double-Blind, Randomized, Placebo- Controlled, Parallel-Group Phase 2 Study to Assess the Efficacy, Safety, and Tolerability of Velusetrag for the Treatment of Diabetic or Idiopathic Gastroparesis"

97. F. Hoffmann-La Roche Ltd: Protocol # GA28949 "Phase III, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy (Induction of Remission) and Safety of Etrolizumab compared with Adalimumab and Placebo in Patients with Moderate to Severe Ulcerative Colitis who are Naïve to TNF Inhibitors"

98. F. Hoffmann-La Roche Ltd: Protocol # GA28951 "An Open-Label Extension and Safety Monitoring Study of Moderate to Severe Ulcerative Colitis patients previously Enrolled in Etrolizumab Phase III Studies"

99. Salix Pharmaceuticals, Inc: Protocol # RECD3125 "A Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Multiregional, Study to Assess the Efficacy and Safety of Rifaximin Delayed Release Tablets for the Induction and Maintenance of Remission in Subjects With Active Moderate Crohn's Disease"

100. Synergy Pharmaceuticals Inc.: Protocol # SP-333101-04 "A Phase 1b, Exploratory, Double-Blind, Placebo-Controlled, Four-Week Study of Rectally Administered SP-333 for the Treatment of Patients with Mildly to Moderately Active Left-Sided Ulcerative Colitis"

101. Braintree Laboratories Inc.: Protocol # BLI400-301 "A Safety and Efficacy Evaluation of BLI400 Laxative in Constipated Adults"

102. Hologic Incorporated; Protocol #: P10434-HBVQPS-CSP-01: "Collection of Plasma and Samples From Individuals Initiating Therapy with Entecavir or Tenofovir for the Clinical Evaluation of the Aptima HBV Quant Dx Assay"

103. Celgene Corporation: Protocol # GED-0301-CD-001 "A Randomized, double-blind, multicenter study to explore the effect of GED-0301 on endoscopic and clinical outcomes in subjects with active Crone's Disease".

104. Merck: Protocol # MK5172-017 "A Long-Term Follow-up Study to Evaluate the Durability of Virology Response and/or Viral Resistance Patterns of Subjects With Chronic Hepatitis C Who Have Been Previously Treated with MK-5172 in a Prior Clinical Trial".

105. Bristol-Myers Squibb Research and Development: Protocol # MB130045 "A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multiple Dose Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamic Effects of BMS-986036 in Adults with Non-alcoholic Steatohepatitis".

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

106. AbbVie Inc.: Protocol #: M13-576. "A Follow-up Study to Assess Resistance and durability of Response to AbbVie Direct-Acting Antiviral Agent (DAA) Therapy (ABT-493 and/or ABT-530) in Subjects Who Participated in Phase 2 Clinical Studies for the Treatment of Chronic Hepatitis C Virus (HCV) Infection ".

107. Gilead: Protocol # GS-US-367-1171 (POLARIS 1): "A Phase 3, Global, Multicenter, Randomized, Open-LabelStudy to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS-9857 Fixed-Dose Combination for 8 Weeks and Sofosbuvir/Velpatasvir for 12 Weeks in Subjects with Chronic Genotype 3 HCV Infection and Cirrhosis".

108. Gilead: Protocol # GS-US-367-1172 (POLARIS 2): " A Phase 3, Global, Multicenter, Randomized, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS-9857 Fixed-Dose Combination for 8 Weeks Compared to Sofosbuvir/Velpatasvir for 12 Weeks in Direct-Acting Antiviral-Naïve Subjects with Chronic HCV Infection". .

109. Gilead: Protocol # GS-US-367-1173 (POLARIS 3): "A Phase 3, Global, Multicenter, Randomized, Open-Labe Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS-9857 Fixed-Dose Combination for 8 Weeks and Sofosbuvir/Velpatasvir for 12 Weeks in Subjects with Chronic Genotype 3 HCV Infection and Cirrhosis". .

110. Gilead: Protocol # GS-US-367-1170 (POLARIS 4) "A Phase 3, Global, Multicenter, Randomized, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS-9857 Fixed-Dose Combination for 12 Weeks and Sofosbuvir/Velpatasvir for 12 Weeks in Direct-Acting Antiviral-Experienced Subjects with Chronic HCV Infection who Have Not Received an NS5A Inhibitor".

111. AbbVie Inc.: Protocol # M13-590 "A Randomized, Open-label, Multicenter Study to Evaluate the Efficacy and Safety of ABT-493/ABT-530 in Adults with Chronic Hepatitis C Virus (HCV) Genotype 1 Infection (ENDURANCE-1)".

112. Arrowhead:..Protocol # Heparc 2004 "A Multicenter, Randomized, Double-blind, Placebo-controlled, Multi-dose Study to Determine the Depth of Hepatitis B Surface Antigen (HBsAg) Reduction Following Intravenous ARC-520 in Combination with Entecavir or Tenofovir in Patients with HBeAg Positive, Chronic Hepatitis B Virus (HBV) Infection".

113. Celgene Corporation: Protocol # GED-0301-UC-002 "A Phase 2, Open-Label, Multicenter study to explore the efficacy and safety of Mongersen (GED-0301) in subjects with active Ulcerative Colitis".

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

114. Ardelyx, Inc.: Protocol # TEN-01-301 "A 12-Week, Randomized, Double-Blind, Placebo-Controlled Study with a 4-Week randomized Withdrawal Period to Evaluate the Efficacy and Safety of Tenapanor for Treatment of Constipation-Predominant Irritable Bowel Syndrome (IBS-C)".

115. Janssen Research & Development: Protocol # CNTO1275UCO3001; (Phase 3) "A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis"

116. Synergy Pharmaceuticals Inc.: Protocol # SP-304203-04 "Randomized, 12-Week, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Plecanatide in Patients with Irritable Bowel Syndrome with Constipation (IBS_C)"

117. Synergy Pharmaceuticals Inc.: Protocol # SP-304203-01 "An Open-Label, Long-Term Safety and Tolerability Study of Plecanatide in Patients with Chronic Idiopathic Constipation (CIC)"

118. Ferring International: Protocol # 000174 "A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study Investigating the Efficacy and Safety of Mesalamine 4 g Extended Release Granules (Sachet) for the Induction of Clinical and Endoscopic Remission in Active, Mild to Moderate Ulcerative Colitis"

119. Ferring International: Protocol # 000175 "A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study Investigating the Efficacy and Safety of Mesalamine 2 g Extended Release Granules (Sachet) for the Induction of Clinical and Endoscopic Remission in Ulcerative Colitis"

120. Ardelyx, Inc.: Protocol # TEN-01-302 "A 26-Week, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Tenapanor for Treatment of Constipation-Predominant Irritable Bowel Syndrome (IBS-C)".

121. Ardelyx, Inc.: Protocol # TEN-01-303 "An Open Long-Term Safety Study of Tenapanor for Treatment of Constipation-Predominant Irritable Bowel Syndrome (IBS-C)".

122. Pfizer: Protocol # A4091056 "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 Tanezumab In Subjects With Osteoarthritis Of The Hip Or Knee"

123. Pfizer: Protocol # A4091064 "A Phase 3, Multicenter, Long-Term Observational Study Of Subjects From Tanezumab Studies Who Undergo A Total Knee, Hip Or Shoulder Replacement"

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

124. Synergy Pharmaceuticals Inc.: Protocol # SP304203-06 "A Randomized, 12-Week, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Plecanatide in Patients with Irritable Bowel Syndrome with Constipation (IBS-C)"

125. Intercept Pharmaceuticals, Inc.: Protocol # 747-303 **"**A Phase 3, Double-Blind, Randomized, Long-Term, Placebo-Controlled, Multicenter Study Evaluating the Safety and Efficacy of Obeticholic Acid in Subjects with Nonalcoholic Steatohepatitis"

126. AbbVie Inc.: Protocol # M13-594 "Study Title/Description: A Randomized, Open-Label, Active-Controlled, Multicenter Study to Compare Efficacy and Safety of ABT-493/ABT-530 to Sofosbuvir Co-Administered with Daclatasvir in Adults with Chronic Hepatitis C Virus Genotype 3 Infection"

127. Novartis Research and Development: Protocol # CLMB763X2201 "A randomized, patient and investigator blinded, placebo-controlled, multicenter study to assess the safety, tolerability, pharmacokinetics and efficacy of LMB763 in patients with non-alcoholic steatohepatitis (NASH)"

128. Shire Human Genetic Therapies, Inc.: Protocol # SHP626-201 "A Phase 2 Double-Blind, Randomized, Placebo-controlled, Dose-finding Study to Evaluate the Safety, Tolerability and Efficacy of Volixibat Potassium, an Apical Sodium-Dependent Bile Acid Transporter Inhibitor (ASBTi) in Adults with Nonalcoholic Steatohepatitis (NASH)"

129. NuSirt Sciences, Inc.: Protocol # NS-0200-01 "A Randomized, Double-Blind, Placebo-Controlled Study To Evaluate the Effect Of Two Fixed-dose Leucine, Metformin and Sildenafil Combinations (NS-0200) Versus Placebo On Hepatic Fat Content Assessed By Proton-Density-Fat-Fraction In Patients With Non-Alcoholic Fatty Liver Disease"

130. Pfizer: Protocol # A4091059 "A Phase 3 Randomized, Double Blind, Placebo and Active-Controlled, Multicenter, Parallel-Group Study of the Analgesic Efficacy and Safety of Tanezumab in Adult Subjects with Chronic Low Back Pain"

131. Braintree Laboratories Inc.: Protocol # BLI400-303 "An Open Label Study of Chronic Use of BLI400 Laxative in Constipated Adults"

132. CelgeneCorporation: Protocol # CC-1004-UC-001 "A Phase 2, Randomized, Placebo-Controlled, Multicenter Study to Investigate the Efficacy and Safety of Apremilast (CC-10004) for Treatment of Subjects with Active Ulcerative Colitis"

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

133. MedImmune: Protocol # D5170C00002 "A Phase 2b Double-blind, Multi-dose, Placebo-controlled Study to Evaluate the Efficacy and Safety of MEDI2070 in Subjects with Moderate to Severe Crohn's Disease Who Have Failed or Are Intolerant to Anti-tumor Necrosis Factor-alpha Therapy"

134. Gilead: Protocol # GS-US-418-3898 Combined Phase 2b/3, Double-Blind, Randomized, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Ulcerative Colitis"

135. Gilead: Protocol # GS-US-418-3899 "A Long-Term Extension Study to Evaluate the Safety of Filgotinib in Subjects with Ulcerative Colitis"

136. Gilead: Protocol # GS-US-419-3895 "Combined Phase 3, Double-blind, Randomized, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Crohn's Disease"

137. Gilead: Protocol # GS-US-419-3896 "A Long-Term Extension Study to Evaluate the Safety of Filgotinib"

138. Gilead: Protocol# GS-US-384-3914, "A Proof of Concept, Open-Label Study Evaluating the Safety, Tolerability, and Efficacy of Regimens in Subjects with Nonalcoholic Steatohepatitis (NASH) (Pro00017529)"

139. Gilead: Protocol # GS-US-384-1943, "A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Selonsertib in Subjects with Nonalcoholic Steatohepatitis (NASH) and Bridging (F3) Fibrosis (Pro00020074)"

140. Gilead: Protocol # GS-US-384-1944, "A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Selonsertib in Subjects with Compensated Cirrhosis due to Nonalcoholic Steatohepatitis (NASH)"

141. Gilead: Protocol # GS-US-402-1852, "A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety, Tolerability, and Efficacy of GS-9674 in Subjects with Nonalcoholic Steatohepatitis (NASH)"

142. Gilead: Protocol # GS-US-426-3989, "A Phase 2, Randomized, Double-Blind Placebo-Controlled Study Evaluating the Safety, Tolerability, and Efficacy of GS-0976 in Subjects with Nonalcoholic Steatohepatitis"

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

143. Gilead: Protocol # GS-US-320-4018, "A Phase 3, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Switching from Tenofovir Disoproxil Fumarate (TDF) 300 mg QD to Tenofovir Alafenamide (TAF) 25mg QD in Subjects with Chronic Hepatitis B who are Virologically Suppressed"

144. Vanda Pharmaceuticals Inc.: Protocol # VP-VLY-686-2301, "A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy of Tradipitant In Relieving Symptoms of Gastroparesis"

145. RedHill Biopharma Ltd.: Protocol # RHB-105-02, "A Randomized Double Blind Active Comparator Controlled Phase III Study to Assess the Safety and Efficacy of RHB-105 in the Treatment of Confirmed Helicobacter pylori (H. pylori) Infection"

146. Genfit: Protocol # GFT505-315-1, "A Multicenter, Randomized, Double-Blind, Placebo Controlled Phase III Study to Evaluate the Efficacy and Safety of Elafibranor in Patients with Nonalcoholic Steatohepatitis (NASH) and fibrosis"

147. Intercept: Protocol # 747-304, "A Phase 3, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Obeticholic Acid in Subjects with Compensated Cirrhosis due to Nonalcoholic Steatohepatitis"

148. Allergan Sales, LLC: Protocol # RLM-MD-01, "A 12-week, Randomized, Double-blind, Placebo controlled, Phase 3 Study to Evaluate the Safety and Efficacy of Relamorelin in Patients with Diabetic Gastroparesis"

149. Allergan Sales, LLC: Protocol # RLM-MD-03, "A 46-week, Double-blind, Placebo-controlled, Phase 3 Study with a 6-week Randomized-withdrawal Period to Evaluate the Safety and Efficacy of Relamorelin in Patients with Diabetic Gastroparesis"

150. Allergan Sales, LLC: Protocol # RLM-MD-04, "A 52-week, Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Safety and Efficacy of Relamorelin in Patients with Diabetic Gastroparesis"

151. Gilead: Protocol # GS-US-454-4378, "A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Selonsertib, GS-0976, GS-9674, and Combinations in Subjects with Bridging (F3) Fibrosis or Compensated Cirrhosis (F4) due to Nonalcoholic Steatohepatitis (NASH)"

152. Celgene: Protocol # RPC01-3201, "A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of Oral Ozanimod As Induction Therapy for Moderately To Severely Active Crohn's Disease Study"

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

153. Celgene: Protocol # RPC01-3203, "A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of Oral Ozanimod As Maintenance Therapy for Moderately To Severely Active Crohn's Disease Study"

154. Celgene: Protocol # RPC01-3204, "A Phase 3, Multicenter, Open-Label Extension Study of Oral Ozanimod for Moderately to Severely Active Crohn's Disease Study"

155. Regeneron Pharmaceuticals: Protocol # R475-PN-1612, "A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Fasinumab in Patients with Moderate-to-Severe Chronic Low Back Pain and Osteoarthritis of the Hip or Knee"

156. AbbVie Inc.: Protocol # M14-430, "A Multicenter, Randomized, Double-Blind, Placebo-Controlled Maintenance and Long-Term Extension Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Crohn's Disease Who Completed the Studies M14-431 or M14-433"

157. AbbVie Inc.: Protocol # M14-431, "A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Moderately to Severely Active Crohn's Disease Who Have Inadequately Responded to or are Intolerant to Biologic Therapy Incorporating Amendments 1, 2, and 3"

158. AbbVie Inc.: Protocol # M14-433, "Clinical Study Protocol M14-433A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Moderately to Severely Active Crohn's Disease Who Have Inadequately Responded to or are Intolerant to Conventional Therapies but Have Not Failed Biologic Therapy Incorporating Amendments 1, 2, and 3"

159. AbbVie Inc.: Protocol # M14-533 A Phase 3 multicenter, Long-Term Extension study to evaluate the long-term safety and efficacy of Upadacitinib (ABT-494) in subjects with ulcerative Colitis"

160. AbbVie Inc.: Protocol # M14-234 A multicenter, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of Upadacitinib (ABT-494) for induction and maintenance therapy in subjects with moderately to severely active ulcerative colitis

161. AbbVie Inc.: Protocol # M14-675, "A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study to Evaluate the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects With Moderately to Severely Active Ulcerative Colitis"

162. Laboratory for Advanced Medicine, Inc. (LAM): Protocol # 001-2018, "Collection of Blood from Healthy Patients, Patients with Benign Desease and Patients with Cancer"

INVESTIGATIONAL/STUDY PROTOCOLS (cont'd):

163. Vanda Pharmaceuticals, Inc.: Protocol # VP-VLY-686-3101, "A Randomized, Double-Blind, Placebo-Controlled, Efficacy Study Of The Neurokinin-1 Receptor Antagonist VLY-686 In Patients With Atopic Dermatitis"

164. Seres Therapeutics: Protocol # SERES-201, "A Phase 2B, Randomized, Double-Blind, Placebo-Controlled, Multiple Dose, Multicenter Study to Assess Efficacy and Safety of SER-287 in Adults with Active Mild-to-Moderate Ulcerative Colitis"