

CURRICULUM VITAE

Pamela M. Turner
Clinical Research Coordinator

Quality Medical Research, PLLC

Nashville Gastroenterology and Hepatology, PC

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EDUCATION

1968 Graduated John Overton High School

CERTIFICATION AND LICENSURE

National Laboratory Training Network Certification “588-302-12 Packaging and Shipping Division 6.2 Materials Online Course” October 2013

The Collaborative IRB Training Initiative (CITI) Certification “Good Clinical Practice and ICH (GCP)” October 2015

National Institutes of Health (NIH) certification “Protecting Human Research Participants” September 2013

Annual OSHA/Blood borne Pathogens Training November 2, 2015

Medidata Rave Certification October 30, 2014

TRAINING

Onsite training to include patient assessment, documentation, phlebotomy, specimen processing, specimen shipping and handling, drug supply monitoring, electronic data entry.

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EMPLOYMENT HISTORY

Jul 2013-Present Quality Medical Research

Specializing in Hepatology and gastroenterology

Compile data for electronic data capture of study progress and patient data. Maintain Regulatory Documents required for accurate documentation of progression of Research Study. Assist Study Director/CRC in office organization and patient care.

*September 2007- Present Nashville Gastroenterology and Hepatology, PC
Clinical Research Coordinator,*

Compile data for electronic data capture of study progress and patient data. Maintain Regulatory Documents required for accurate documentation of progression of Research Study. Assist Study Director/CRC in office organization and patient care.

1994-2007 Self employed: Managed and maintained office for family owned business.

1990-1994 Interactive Learning Center: Managed and maintained small office computer training facility. I conducted one on one training and facilitated self paced computer training classes.

1984-1990 AT&T:

Customer Service Representative, Worked with corporate accounts establishing long distance services and maintaining existing services. Assisted in setting up new data systems for coordination and maintaining new billing system for customers.

1968-1984 South Central Bell:

Customer Service Representative managed and maintained large customer base of business customers, large corporate customers and political accounts. Responsibilities included customer relations, setting up and organizing installation of customer networks and telephone systems, collections, and establishing directory listings.

INVESTIGATIONAL/STUDY PROTOCOLS

1. Protocol ML18179: “A Prospective, Multicenter, Open-Label, Efficacy Study of Pegasys plus Copegus in Treatment-Naïve Latino Patients with chronic Hepatitis C-Genotype 1, as Compared to Treatment-Naïve non-Latino Caucasian Patients with Chronic Hepatitis C-Genotype 1”. Principal Investigator: Robert W. Herring, Jr., MD
2. Protocol HGS1008-C1060: “A Phase 3, Randomized, Multi-Center Study to Evaluate the Efficacy and Safety of Albumin Interferon, Alfa-2b (alb-IFN) in Combination with Ribavirin Compared with Peginterferon Alfa-2a (PEGASYS or PEG-INF@2a) in Combination with Ribavirin in Interferon Alfa Naïve Subjects with Chronic Hepatitis C, Genotype 1”. Principal Investigator: Robert W. Herring, Jr., MD

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

3. Roche Protocol NV19865C: “A Phase II, Randomized, Double-Blinded, Multicenter, Dose Finding Study Evaluating the Efficacy and Safety of the HCV Polymerase Inhibitor Prodrug (RO4588161) When Given in Combination with Pegasys® and Copegus® versus the Currently Approved Combination of Pegasys® and Copegus® in Treatment-Naive Patients with Chronic Hepatitis C Genotype 1”. Principal Investigator: Robert W. Herring, Jr., MD
4. Schering-Plough Research Institute Protocol P03471-108: “Comparison of PEG-Intron 1.5 ug/kg/wk Plus Rebetol vs PEG-Intron 1 ug/kg/wk Plus Rebetol vs Pegasys 180 ug/wk Plus Copegus in Previously Untreated Adult Subjects with Chronic Hepatitis C Infected with Genotype 1”. Principal Investigator: Robert W. Herring, Jr., MD
5. Phase II Study of Long Term Peg-Intron for Patients Who have Failed to Respond to Rebetron/Interferon with Advanced Fibrosis and Cirrhosis Secondary to Hepatitis C Infection
6. Kendle Protocol ML21301D: “Multicenter, Randomized, Open-Label, Controlled Study of the Effect of Treatment with Once Weekly Pegasys® Plus Daily Copegus® with or without Concomitant Pioglitazone (Actos®) on Early Viral Kinetics in treatment-Naïve Patients with Chronic Hepatitis C (Genotype-1 HCV Infection) and Insulin Resistance”
7. Protocol: CI-PSI-5268-06-305: “A Multi-center, Randomized, Double-Blind, Active-Control, 96 Week, Phase III Trial of the Efficacy and Safety of Clevudine Compared with Adefovir at Weeks 48 and 96 in Nucleoside Treatment-Naive Patients with HBeAg Positive Chronic Hepatitis due to Hepatitis B Virus.” Principal Investigator: Robert W. Herring, Jr., MD
8. Protocol: CI-PSI-5268-06-306: “A Multi-center, Randomized, Double-Blind, Active-Control, 96 Week, Phase III Trial of the Efficacy and Safety of Clevudine Compared with Adefovir at Weeks 48 and 96 in Nucleoside Treatment-Naive Patients with HBeAg Negative Chronic Hepatitis due to Hepatitis B Virus.” Principal Investigator: Robert W. Herring, Jr., MD
9. Protocol: AGI003-003: “A Randomized, Double-blind, Placebo-controlled Study of AGI-003 (Averapamil) in the Treatment of Irritable Bowel Syndrome with Diarrhea (IBS-D) Principal Investigator: Robert W. Herring, Jr., MD
10. Eisai Protocol: E3810-G000-301/302/303: “A Randomized Double-Blind Parallel Study of Rabeprazole Extended Release 50 mg versus Esomeprazole 40 mg of Healing and Symptomatic Relief of Moderate to Severe Erosive Gastroesophageal Reflux Disease”. Principal Investigator: Robert W. Herring, Jr., MD

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

11. Eisai Protocol: E3810-G000-305: “A Randomized Double-Blind Parallel Study of Rabeprazole Extended-Release 50 mg versus Ranitidine 150 mg for Maintenance of Healed Erosive Gastroesophageal Reflux Disease (GERD)”. Principal Investigator: Robert W. Herring, Jr., MD
12. Eisai Protocol: E3810-G000-307: “A Multicenter Randomized Double-Blind Study to Compare the Efficacy, Safety and Tolerability of Rabeprazole ER 50 mg with Placebo in Subjects with Symptomatic Gastroesophageal Reflux Disease (sGerd) Principal Investigator: Robert W. Herring, Jr., MD
13. Roche Protocol MV21542: “A Randomized, Open-Label, Multicenter Study Examining the Effects of 24 Versus 48 Weeks of Combination Therapy with PEGASYS® (Peginterferon alfa-2a 40KD) plus COPEGUS® (Ribavirin) on Sustained Virological Response in Patients with Chronic Hepatitis C, Genotype 2 or 3 who do not Achieve a Rapid Viral Response”. Principal Investigator: Robert W. Herring, Jr., MD
14. Roche Protocol NV20536: “A Randomized, Double-blinded, Multicenter, Dose and Duration Finding Study to Evaluate the Sustained Virologic Response of the HCV Polymerase Inhibitor Prodrug (RO5024048) in Combination with Pegasys® and Copegus® versus the Currently Approved Combination of Pegasys® and Copegus® in Treatment-Naive Patients with Chronic Hepatitis C Genotype 1 or 4 Virus Infection”
15. Roche Protocol NV21928 (retreatment): “An open-label, multicenter protocol providing pegylated interferon alfa-2a (PEGASYS®) as monotherapy or in combination with ribavirin (COPEGUS®) for patients with chronic hepatitis C who have participated in previous Roche or Roche partner protocols”
16. Roche Protocol NV22776): “A Randomized, Open label, Multicenter, Dose and Duration Finding Study to Evaluate the Sustained Virologic Response of the HCV Protease Inhibitor Danoprevir (RO5190591) Boosted with Low Dose Ritonavir (danoprevir/r) in Combination with Pegasys® and Copegus® versus Pegasys® and Copegus® alone in Treatment-Naive Patients with Chronic Hepatitis C Genotype 1 or 4 Virus Infection”
17. Roche Protocol NV22688(long term monitoring): “A long-term monitoring study to evaluate the persistence of direct acting antiviral (DAA) treatment-resistant mutations or the durability of sustained virological response (SVR) in patients treated with DAA-containing regimens for chronic hepatitis C infection (CHC)”
18. SPRI Protocol P06086: Boceprevir and peg interferon/Ribavirin for the Treatment of Chronic Hepatitis C in Treatment-Naïve Subjects: A Comparison of Erythropoietin Use Versus Ribavirin Dose Reduction for the Management of Anemia (Protocol No. P06086)

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

19. Mochida Pharmaceutical MCH-02-001: “A Phase II Double-Blind, Placebo-Controlled Study of two doses of EPA-E IN patients with Nash”
20. Idera Pharmaceuticals, Inc. Protocol 2125-001: “A Phase 1, Multi-center, Placebo-controlled, Dose-escalation Study of the Safety of IMO-2125 in Hepatitis C-infected Patients Unresponsive to Standard Treatment with Pegylated Interferon and Ribavirin”
21. Cope HCV Protocol 4316001:”A Phase II, Multicenter, Randomized, Open-Label, Active-Control, Dose-Ranging Study of Interferon-Alfa-2b Given Via Continuous Subcutaneous Infusion in Subjects with Hepatitis C Virus Genotype 1 Infection”
22. Roche, Protocol MV21542 (PROPHESYS 3): Prospective observational study on predictors of early on-treatment response and sustained virological response in a cohort of treatment naïve HCV-infected patients treated with Pegylated interferon”. Principal Investigator: Robert W. Herring, Jr., M.D.
23. Roche, Protocol PP25213 - INFORM-SVR: “A Randomized, Multi-Center Study of Interferon-Free Treatment with a Combination of a Polymerase Inhibitor (RO5024048) and a Ritonavir boosted HCV Protease Inhibitor (RO5190591/r, DNV/r) with or without Copegus[®] in Interferon Naïve HCV Genotype 1 Infected Patients”.
24. Roche, Protocol WV21913 (Matterhorn): “A Randomized, Open-label, Multicenter Study to Evaluate the Sustained Virologic Response of the HCV Protease Inhibitor Danoprevir Boosted with Low Dose Ritonavir (DNV/r) and Copegus[®], in Combination with the HCV Polymerase Inhibitor Prodrug RO5024048 and/or Pegasys[®] in Chronic Hepatitis C Genotype 1 Patients Who Failed with a Previous Course of Peg interferon alfa plus Ribavirin Combination Therapy”
25. Gilead, Protocol GS-US-248-0120: “A Phase 2 Randomized, Open-Label Study of GS-5885 Administered Concomitantly with GS-9451, Tego buvir and Ribavirin (RBV) to Treatment-Naïve Subjects with Chronic Genotype 1 HCV Infection”
26. Anadys, Protocol ANA598-505: “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”.
27. “Efficacy and Safety of Mericitabine (MCB) in Combination with PegIFN α -2A/RBV in G1/4 Treatment Naïve RCV Patients: Final Analysis From the PROPEL Study.” Wedemeyer, H., Jensen, D., Herring, Jr., R., Ferenci, P., Mang-Ming, M., Zeuzem, S., Rodriguez-Torres, M., Bzowej, N., Pockros, P., Vierling, J., Ipe, D., Thommes, J.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

28. Gilead, Protocol P2938-0721 (Quantum) : “An International, Multi-Center, Blinded, Randomized Study to Investigate Safety, Tolerability, Pharmacokinetics and Pharmacodynamics following Administration of Regimens Containing PSI-352938, PSI-7977, and Ribavirin in Patients with Chronic HCV Infection.”
29. Gilead, Protocol P7977-1231 (Fission): “A Phase 3, Multicenter, Randomized, Active-Controlled Study to Investigate the Safety and Efficacy of PSI-7977 and Ribavirin for 12 Weeks Compared to Pegylated Interferon and Ribavirin for 24 Weeks in Treatment-Naïve Patients with Chronic Genotype 2 or 3 HCV Infection”
30. Gilead, Protocol GS-US-256-0148: “A Phase 2b Randomized, Double Blind, Placebo Controlled Trial Evaluating Response Guided Therapy of GS 5885 Alone or in Combination with GS-9451, and Ribavirin (RBV) to Treatment-Naïve Subjects with Chronic Genotype 1 HCV Infection”
31. Gilead, Protocol GS-US-256-0124: “A Phase 2b Randomized, Double Blind, Placebo Controlled Evaluating Response Guided Therapy using Combinations of Oral Antivirals Study of (GS-5885, GS-9451, Tegobuvir and/or GS-9451) with Peg interferon and Ribavirin (RBV) in Treatment-Experienced Subjects with Chronic Genotype 1 HCV Infection”.
32. Gilead, Protocol GS-US-248-0122 (Registry): “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”.
33. Gilead, Protocol GS-US-248-0123 (Registry): “A Long Term Follow-up Registry Study of Subjects Who Did Not Achieve a Sustained Virological Response in Gilead Sponsored Trials in Subjects with Chronic Hepatitis C Infection”
34. Gilead, Protocol GS-US-334-0107 (Positron): “A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of GS-7977 + Ribavirin for 12 Weeks in Subjects with Chronic Genotype 2 or 3 HCV Infection who are Interferon Intolerant, Interferon Ineligible or Unwilling to Take Interferon”
35. Gilead, Protocol GS-US-334-0108 (Fusion): “A Phase 3, Multicenter, Randomized, Double-Blind Study To Investigate The Efficacy And Safety Of GS-7977 + Ribavirin For 12 Or 16 Weeks In Treatment Experienced Subjects With Chronic Genotype 2 Or 3 HCV Infection”.
36. Gilead, Protocol GS-US-334-0109 (Open Label): “An Open-Label Study of GS-7977 + Ribavirin with or without Peg interferon Alfa-2a in Subjects with Chronic HCV Infection who participated in prior Gilead HCV Studies”.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

37. Gilead, Protocol GS-US-334-0110 (Neutrino): “A Phase 3, Multicenter, Open-Label Study to Investigate the Efficacy and Safety of GS-7977 with Peginterferon Alfa 2a and Ribavirin for 12 Weeks in treatment-Naïve Subjects with Chronic Genotype 1, 4, 5, or 6 HCV Infection”.
38. Vertex, Protocol VX11-222-108 : “A Multicenter, Randomized, Open-label, Phase 2b Study to Evaluate the Efficacy and Safety of Two Regimens of All-oral Triple Therapy (VX-222 in Combination With Telaprevir [Incivek™]and Ribavirin[Copegus®])in Treatment-Naïve Subjects With Genotype 1a Chronic Hepatitis C”.
39. Achillion, Protocol ACH102-005: “A phase 1b, open-label, pilot study to evaluate the safety, tolerability and antiviral activity of oral ACH-0143102 administered in combination with ribavirin after 12 weeks of dosing in treatment naïve subjects with chronic hepatitis C virus infection genotype 1b”.
40. Achillion, Protocol ACH102-007: “A Phase 2a Trial to Evaluate the Safety, Tolerability and Efficacy of 12 Weeks of Sofasprevir, ACH-0143102 and Ribavirin in Treatment-Naïve Subjects with Chronic Hepatitis C Genotype-1 Viral Infection”.
41. Gilead, Protocol GS-US-337-0102 (ION 1): “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”.
42. Gilead, Protocol GS-US-337-0109 (ION 2) : “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-Experienced Subjects with Chronic Genotype 1 HCV Infection”.
43. Gilead, Protocol GS-US-337-0108 (ION 3) : “A Phase 3, Multicenter, Randomized, Open-Label Study to Investigate the Efficacy and Safety of Sofosbuvir/Ledipasvir Fixed-Dose Combination ± Ribavirin for 8 Weeks and Sofosbuvir/Ledipasvir Fixed-Dose Combination for 12 Weeks in Treatment-Naïve Subjects with Chronic Genotype 1 HCV Infection”.
44. Gilead, Protocol GS-US-342-0102: “A Phase 2, Multicenter, Randomized, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir + GS-5816 for 12 Weeks in Treatment-Naïve Subjects with Chronic HCV Infection”.
45. Gilead, Protocol GS-US-342-0109: “A Phase 2, Multicenter, Randomized, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir + GS-5816 for 12 Weeks in Treatment-Experienced Subjects with Chronic HCV Infection”.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

46. Abbott, Protocol M14-002 (AbbVie): “A Randomized, Double-Blind, Controlled Study to Evaluate the Efficacy and Safety of the Combination of ABT-450/Ritonavir/ABT-267 (ABT-450/r/ABT-267) and ABT-333 With and Without Ribavirin (RBV) in Treatment-Naïve Adults with Genotype 1a Chronic Hepatitis C Virus (HCV) Infection (PEARL-IV)”.
47. Gilead, Protocol GS-US-334-0153: “A Phase 3B Randomized, Open-Label, Multi-Center Trial Assessing Sofosbuvir + Ribavirin for 16 or 24 Weeks and Sofosbuvir + Pegylated Interferon + Ribavirin for 12 Weeks in Subjects with Genotype 2 or 3 Chronic HCV Infection”. IND No: 106,739
48. Merck, MK-5172, Protocol 003-02: “A Randomized, Active-Controlled, Dose-Ranging Estimation Study to Evaluate the Safety, Tolerability, and Efficacy of Different Regimens of MK-5172 When Administered Concomitantly with Peg interferon alfa-2b and Ribavirin in Treatment-Naïve Patients with Chronic Genotype 1 Hepatitis C Virus Infection”.
49. Bristol-Meyers Squibb, Protocol AI443-102: “A Phase 3 Evaluation of a daclatasvir/asunaprevir/BMS-791325 Fixed Dose Combination in Non-cirrhotic Subjects with Genotype 1 Chronic Hepatitis C”.
50. Bristol-Meyers Squibb, Protocol AI443-113: “A Phase 3 Evaluation of a daclatasvir/asunaprevir/BMS-791325 Fixed Dose Combination in Subjects with Genotype 1 Chronic Hepatitis C and Compensated Cirrhosis”.
51. Gilead, Protocol GS-US-337-1118: “An Open-Label, Multicenter Study To Evaluate The Efficacy And Safety Of Sofosbuvir/Ledipasvir Fixed-Dose Combination + Ribavirin For 12 Weeks In Chronic Genotype 1 HCV Infected Subjects Who Participated In A Prior Gilead-Sponsored HCV Treatment Study”.
52. Ferring International Pharma science 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”.
53. 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”.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

54. Hologic Incorporate,; Protocol P10433-HCVQPS-CSP-01: “Collection of Plasma and Serum Samples From Individuals Initiating Therapy With Sofosbuvir for Chronic Hepatitis C Virus Infection for the Clinical Evaluation of the Aptima HCV Quant Dx Assay”.
55. 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”.
56. 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”.
57. 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”.
58. 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”.
59. 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”.
60. 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”.
61. Janssen Research and Development LLC, Protocol TMC435HPC3017: “A Phase 3, Multicenter, Randomized, Open-Label Study to Investigate the Efficacy and Safety of a 12- or 8-Week Treatment Regimen of Simeprevir in Combination with Sofosbuvir in Treatment-Naïve and -Experienced Subjects with Chronic Genotype 1 Hepatitis C Virus Infection Without Cirrhosis”.
62. Janssen Research and Development LLC, Protocol TMC435HPC3018: “A Phase 3, Multicenter, Open-Label, Single-Arm Study to Investigate the Efficacy and Safety of a 12-Week Regimen of Simeprevir in Combination with Sofosbuvir in Treatment-Naïve or - Experienced Subjects with Chronic Genotype 1 Hepatitis C Virus Infection and Cirrhosis”.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

63. Merck, Protocol MK5172-068: “A Phase III Randomized Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of MK-5172/MK-8742 in Subjects who have Failed Prior Treatment with Pegylated Interferon and Ribavirin (P/R) with Chronic HCV GT1, GT4, GT5, and GT6 Infection”.
64. 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)
65. AbbVie Inc.; Protocol #: M14-867; “An Open-Label, Multicenter Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Co-Administration of ABT-493 and ABT-530 in Subjects with Chronic Hepatitis C Virus (HCV) Genotype 1 Infection”
66. AbbVie Inc.; Protocol #: M14-868; “An Open-Label, Multicenter Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Co-Administration of ABT-493 and ABT-530 in Subjects with Chronic Hepatitis C Virus (HCV) Genotype 2 or Genotype 3 Infection”
67. Gilead; Protocol # GS-US-342-1138 (ASTRAL 1); A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of Sofosbuvir/GS-5816 Fixed Dose Combination for 12 Weeks in Subjects with Chronic HCV”
68. 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”
69. 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)”
70. 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”
71. 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”
72. 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 Gilead Combination in Subjects with Chronic Non-Genotype 1 HCV Infection”

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

73. Gilead: Protocol # GS-US-342-1446 “An Open Label Study of Sofosbuvir/GS-5816 Fixed-Dose Combination in Subjects with Chronic HCV Infection”
74. 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”
75. 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”
76. 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”
77. 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”
78. 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 Etralizumab compared with Adalimumab and Placebo in Patients with Moderate to Severe Ulcerative Colitis who are Naïve to TNF Inhibitors”
79. 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 Etralizumab Phase III Studies”
80. 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”
81. 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”
82. Braintree Laboratories Inc.: Protocol # BLI400-301 “A Safety and Efficacy Evaluation of BLI400 Laxative in Constipated Adults”

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

83. 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”
84. 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”.
85. 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”.
86. 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”. Primary Investigator
87. 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”.
88. Gilead: Protocol # GS-US-367-1171 (POLARIS 1): “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 and Sofosbuvir/Velpatasvir for 12 Weeks in Subjects with Chronic Genotype 3 HCV Infection and Cirrhosis”.
89. 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”.
90. 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”.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

91. 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”
92. 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)”.
93. 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”.
94. 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”.
95. 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)”.
96. 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”
97. 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)”
98. 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)”
99. 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”

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

100. 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”
101. 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)”.
102. Ardelyx, Inc.: Protocol # TEN-01-303 “An Open Long-Term Safety Study of Tenapanor for Treatment of Constipation-Predominant Irritable Bowel Syndrome (IBS-C)”.
103. 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”
104. 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”
105. 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)”
106. 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”
107. 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”
108. 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)”
109. 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)”

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

110. 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”
111. 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”
112. Braintree Laboratories Inc.: Protocol # BLI400-303 “An Open Label Study of Chronic Use of BLI400 Laxative in Constipated Adults”
113. Celgene Corporation: 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”
114. 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”
115. 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”
116. Gilead: Protocol # GS-US-418-3899 “A Long-Term Extension Study to Evaluate the Safety of Filgotinib in Subjects with Ulcerative Colitis”
117. 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”
118. Gilead: Protocol # GS-US-419-3896 “A Long-Term Extension Study to Evaluate the Safety of Filgotinib”
119. 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)”
120. 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)”

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

121. 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)”
122. 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)”
123. 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”
124. 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”
125. 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”
126. 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”
127. 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”
128. 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”
129. 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”
130. 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”

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

131. 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”
132. 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)”
133. 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”
134. 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”
135. Celgene: Protocol # RPC01-3204, “A Phase 3, Multicenter, Open-Label Extension Study of Oral Ozanimod for Moderately to Severely Active Crohn’s Disease Study”
136. Regeneron Pharmaceuticals: Protocol # R475-PN-1612, “A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Fasimumab in Patients with Moderate-to-Severe Chronic Low Back Pain and Osteoarthritis of the Hip or Knee”
137. 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”
138. 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”
139. 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”

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

140. 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”
141. 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
142. 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”
143. Laboratory for Advanced Medicine, Inc. (LAM): Protocol # 001-2018, “Collection of Blood from Healthy Patients, Patients with Benign Disease and Patients with Cancer”
144. 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”
145. 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”