

Robert William Herring, Jr., M.D., F.A.C.P., F.A.C.G.

CURRICULUM VITAE

Robert William Herring, Jr., M.D., F.A.C.P., F.A.C.G.

(615) 832-5530 (work)

(615) 833-1617 (work)

Quality Medical Research
330 Wallace Road, Suite 103
Nashville, TN 37211

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

Southern Endoscopy Center
330 Wallace Road, Suite 103
Nashville, TN 37211

EDUCATION

John Overton High School, Nashville, Tennessee, 1972
GPA 4.00, Valedictorian

Bachelor of Science, Majors in Biology and Chemistry (Double),
Birmingham-Southern College, Birmingham, Alabama, 1976
GPA 3.81, magna cum laude. Phi Beta Kappa Scholastic Honorary Fraternity

Doctor of Medicine, University of Tennessee, Memphis, Tennessee,
1980, GPA 3.62, cum laude. Alpha Omega Alpha Scholastic Honorary Fraternity

Residency in Internal Medicine, Bowman Gray School of Medicine,
Wake Forest University, Winston-Salem, North Carolina, 1980-1983

Fellowship in Gastroenterology and Hepatology, Johns Hopkins
University, Baltimore, Maryland, 1983-1985

CURRICULUM VITAE

PROFESSIONAL ORGANIZATIONS

Specialty

American College of Physicians
American Society of Internal Medicine
Tennessee Society of Internal Medicine
Nashville Society of Internal Medicine
American Medical Association
Tennessee Medical Association
Nashville Academy of Medicine

Subspecialty

Fellow, American College of Gastroenterology
American Society for Gastrointestinal Endoscopy
Tennessee Society for Gastroenterology and Endoscopy
National Foundation for Ileitis and Colitis
American Liver Foundation
American Association for the Study of Liver Diseases
European Association for the Study of the Liver

CERTIFICATION AND LICENSURE

American Board of Internal Medicine, 1983
American Board of Gastroenterology, 1985
Medical License, Tennessee MD0000016892, issued February 25, 1986
American Heart Association ACLS Provider

INSURANCE INFORMATION

State Volunteer Mutual Insurance Company. Policy 89-0975

CURRICULUM VITAE

HONORS

Hepatologist of the Year Award 2016
American Liver Foundation, Nashville Division

Recognized as Doctor of Excellence and a
Top Gastroenterologist of Tennessee
International Association of Healthcare Professionals, 2013

Physician Member
National Medical Advisory Committee
American Liver Foundation, 2013 - present

Americas Top Gastroenterologists
Consumers Research Council of America, 2012

Chairman of the Board
Board of Trustees
Nashville Division
American Liver Foundation, 2005 - present

Chairman
Medical Advisory Committee
Nashville Division
American Liver Foundation, 2003 - present

CURRICULUM VITAE

NON MEDICAL EXTRACURRICULAR ACTIVITIES

Sustaining Member
Beta Chapter, Alabama
Phi Beta Kappa Society

Frist Center President's Circle
Frist Museum of Art
Nashville, Tn

Quality Medical Research
Frist Center Corporate Partner
Frist Museum of Art
Nashville, Tn

Lifetime Member
Murfreesboro Chapter
NAACP

Varsity Debate Champion
Tennessee and Southeastern United States District
National Forensic League
1972

President and Treasurer
Alpha Tau Omega Fraternity
Birmingham-Southern College
1975 - 1976

President
Interfraternity Council
Birmingham-Southern College
1976

Vice-President
Class of 1980
School of Medicine
University of Tennessee-Memphis
Memphis, Tennessee
1976 - 1980

CURRICULUM VITAE

PROFESSIONAL ASSIGNMENTS

Finance Committee for
Representative Jim Cooper
U. S. Congress
1993 – 1995

Chairman and Founder
Institutional Review Board
Southern Hills Medical Center
1992 – 1994

Governor
Tennessee Chapter
American College of Gastroenterology
1998 – 2004

Chairman
Pharmacy and Therapeutics Committee
Southern Hills Medical Center
1990 - 1994

Medical Director
Quality Medical Research
1986 - Present

Chairman, Tennessee Medical Association
Judicial Council
2000 - 2001

President
Tennessee Society for Gastrointestinal Endoscopy
2003 - 2004

Chairman
Committee on Governmental Services and Third Party Payors
Tennessee Medical Center
1996 - 1999

CURRICULUM VITAE

PROFESSIONAL ASSIGNMENTS (Continued)

Co-Director
Endoscopy Laboratory
Southern Hills Medical Center
1988 – 2000

Vice-Chairman, Council of Medical Specialty Societies
Tennessee Medical Association
2005 – 2007

Chairman
Medicare and Medicaid
Committee on Governmental Services and Third Party Payors
Tennessee Medical Association
1992 - 1996

Chairman
Young Physicians Section
Tennessee Medical Association
1993 - 1994

Chairman
Tennessee Medicare Physician Carrier Advisory Committee of CIGNA
and Health Care Finance Administration
1992 - 1995

Chairman, Medicare Committee
Tennessee Society of Gastrointestinal Endoscopy-American College of
Gastrointestinal Endoscopy Medicare Committee
1992 - 1994

Member, Quality Assurance Committee
StoneCrest Medical Center
2003 - 2013

Chairman, Tennessee Medical Association
House of Delegates
Reference Committee
1999 - 2000

CURRICULUM VITAE

PROFESSIONAL ASSIGNMENTS (Continued)

Member, Medical Advisory Committee
Southern Hills Medical Center
1989 - 1996, 2000 – 2004

President
Nashville Gastrointestinal Specialists, Inc.
1997 - 2000, 2007 – 2009

Member, Board of Directors
Tennessee Health Care Campaign
2004 – 2010

Member, National Affairs Committee
American College of Gastroenterology
2005 - 2008

Member, Constitution and By-Laws Committee
American Society for Gastrointestinal Endoscopy
1993 - 1996

Medical Director/Administrator
Southern Endoscopy Center
1988 – Present

Secretary
Tennessee Chapter, American College of Physicians
1993 - 1995

Member, Governing Council
American College of Physicians
1993 - Present

Member, Ad Hoc Committee on Managed Care
American College of Gastroenterology
1996 – 1997

CURRICULUM VITAE

PROFESSIONAL ASSIGNMENTS (Continued)

Member, Managed Care Subcommittee
Practice Management Committee
American College of Gastroenterology
1997 - 2001

Member, Executive Council
Tennessee Society of Internal Medicine
1997 – 2000

Tennessee Representative
Peptic Ulcer Disease Project
Health Care Finance Administration
Birmingham, Alabama
October 1996

Member, Communications and Public Service Committee
Nashville Academy of Medicine
1987 - 1996

Delegate, Nashville Academy of Medicine
Tennessee Medical Association Annual Meeting
2007, 2008, 2009, 2010, 2011, 2012

Member, Medicaid Remedy Committee
Tennessee Medical Association
1992

Member, Delegation Tenure Subcommittee, Tennessee Medical Association Delegation
to the American Medical Association
1992

Member, Governmental Affairs Committee
Nashville Academy of Medicine
1994 - 1999

Associate Clinical Coordinator
Peptic Ulcer Disease Project
MidSouth Foundation for Medical Care, Inc.
1997

CURRICULUM VITAE

PROFESSIONAL ASSIGNMENTS (Continued)

Member, Pharmacy and Therapeutic Committee
Tennessee Managed Care Network
1997 - 2001

Member, Credentialing Committee
CIGNA HealthCare
1997 - 1999

Member, Blue Cross-Blue Shield of Tennessee Provider Advisory Committee
Blue Cross-Blue Shield of Tennessee
1998 - 2001

Member, Tennessee Small Group Health Insurance Committee
Tennessee State Legislature and Tennessee Commerce and Insurance Department
1998 - 2002

Member, CIGNA HealthCare
Physician Review Committee
1999 - 2000

Member, Department of Health
Bureau of TennCare
TennCare Administrative Task Force
1999

Member, Blue Cross Blue Shield of Tennessee
Regional Clinical Practice Committee
1999 - 2001

Member, Council of the Tennessee Chapter of the American College of Physicians / American Society of Internal Medicine
2000 - 2004

Member
Committee on Practice Management and Managed Care
Tennessee Medical Association
2001 - 2003

CURRICULUM VITAE

PROFESSIONAL ASSIGNMENTS (Continued)

Member, Credentials Committee
American College of Gastroenterology
2000-2002

Member, Access Med Plus Creditors Committee
TMA General Counsel
2002

Tennessee Representative
Medicare Carrier Advisory Committee
American Society of Gastrointestinal Endoscopy
and American College of Gastroenterology
Baltimore, Maryland
1996 - 2002

Member, Nutrition and Diet Committee
Nashville Memorial Hospital
1986 - 1988

Member, Continuing Education Committee
Baptist Hospital
1987 - 1989

Member, Quality Assurance Committee
Southern Hills Medical Center
1989 - 1995

INTERESTS AND HOBBIES

Music Collecting
Reading
Fast Cars

CURRICULUM VITAE

PUBLICATIONS

1. Eric Lawitz, Kris Kowdley, Michael Curry, Nancy Reau, Mindle Nguyen, Paul Kwo, Ira M. Jacobson, Tram Tran, Ronald Nahass, Frederico Hinestroza, Robert Herring, et al. “High Efficacy of Sofosbuvir/Velpatasvir Plus GS-9857 for 12 Weeks in Treatment Experienced Genotype 1-6 HCV-Infected Patients, Including Those Previously Treated with Direct-Acting Antivirals” Supplement to The American Journal of Gastroenterology, October, 2016. Abstracts submitted for the 81st Annual Scientific Meeting of the American College of Gastroenterology. October 2016.
2. Eric Lawitz, Gary Matusow, Edwin DeJesus, Eric Yoshida, Franco Felizarta, Reem Ghalib, Eliot Godofsky, Robert Herring, et al. “Simeprevir plus sofosbuvir in patients with Chronic Hepatitis C Virus Genotype 1 Infection and Cirrhosis: A Phase 3 Study (OPTIMIST -2)” Hepatology, Vol.64, No 2, 2016.
3. Eric Lawitz, Nancy Reau, Federico Hinestroza, Mordechai Rabinovitz, Eugene Schiff, Aasim Sheikh, Ziad Younes, Robert Herring, Jr., et al. “Sofosbuvir, velpatasvir, and GS-9857 in patients with genotype 2-6 hepatitis C virus infection: an open-label, phase 2 trial.” Abstract Annual Meeting. European Association for the Study of the Liver, April, 2016.
4. O’Leary J, Brown R, Reddy K, Tenkel J, Korenblat K, Younes Z, Herring R, et al. “Clinical Benefits of Successful Treatment in HCV Infected Patients with Decompensated Cirrhosis treated with sofosbuvir/Velpatasvir.” Abstract. Annual Meeting. European Association for the Study of the Liver, April, 2016.
5. Muir AJ, Poordad F, Lalezari J, Everson G, Dore GJ, Herring R, et al. “Daclatasvir in combination with asunaprevir and beclabuvir for hepatitis C virus genotype 1 infection with compensated cirrhosis.” Journal of the American Medical Association. 313 (17): 1736-1746, May 2015.
6. Eric Lawitz, Gary Matusow, Edwin DeJesus, Eric Yoshida, Franco Felizarta, Reem Ghalib, Eliot Godofsky, Robert Herring, et al. “ A Phase 3, open-label, single-arm study to evaluate the efficacy and safety of 12 weeks of simeprevir (SMV) plus sofosbuvir (SOF) in treatment-naïve or -experienced patients with chronic HCV genotype 1 infection and cirrhosis: OPTIMIST-2 .” Poster Presentation. Annual Meeting. European Association for the Study of the Liver, 2015.
7. Christophe Hézode, Robert Herring Jr, et al. “Effect of Baseline Factors on Response to the Fixed-Dose Combination of Daclatasvir, Asunaprevir, and Beclabuvir, With or Without Ribavirin, in Patients with HCV Genotype 1 Infection and Cirrhosis.” Poster Presentation. Annual Meeting. European Association for the Study of the Liver, 2015.

CURRICULUM VITAE

PUBLICATIONS (Continued)

8. Lawitz E, Matusow G, DeJesus E, Yoshida E, Felizarta F, Ghalib R, Godofsky E, Herring R, et al. "A Phase 3, Open-Label, Single-Arm Study to evaluate the efficacy and safety of 12 weeks of Simeprevir plus Sofosbuvir in Treatment-Naïve or Experienced patients with Chronic Hepatitis C virus Genotype 1 infection and Cirrhosis: The Optimist-2 Study." Abstract. Annual Meeting. European Association for the Study of the Liver, April, 2015.
9. Hezode C, Herring Jr., et al. "Effect of Baseline factors on response to the fixed-dose combination of Daclatasvir (DCF), Asunaprevir (ASV) and Beclabuvir (BCV), with or without Ribavirin (RBV), in patients with HCV Genotype 1 infection and Cirrhosis." Abstract. Annual Meeting. European Association for the Study of the Liver, April, 2015.
10. A. Muir, F. Poordad, A. Sheikh, M. Elkashab, R. Brennan, V. Ankoma-Sey, W.O. Riordan, R. Herring, Jr. et al. "SVR Results for the Combination of ACH-3102 and Sovaprevir, with Ribavirin, in Patients with Genotype 1 Chronic Hepatitis C Infection". Oral Presentation of Abstract. Annual Conference of APASL, the Asian Pacific Association for the Study of the Liver, Brisbane, Australia, March 2014.
11. A. Muir, R. Bren, R. Herring, Jr., et al. "A Single Direct-acting Anti-viral Agent AC-3102, with Ribavirin is Able to Achieve a Robust Anti-viral Response in Subjects with Genotype 1b Chronic Hepatitis C Infection". Abstract. Annual Conference of APASL the Asian Pacific Association for the Study of the Liver, Brisbane Australia, March, 2014.
12. Andrew J. Muir, Robert Herring, Jr., et al. "A Single Direct-Acting Anti-Viral Agent, ACH-3102, in Combination with Ribavirin is Able to Achieve SVR8 in Subjects with Genotype 1b Chronic Hepatitis C Infection." Abstract. Annual Meeting. European Association for the Study of the Liver, 2013.
13. M. Sulkowski, M. Rodriguez-Torres, E Lawitz, M. Shiffman, S Pol, R Herring, et al. "High Sustained Viral Response in Treatment-Naïve HCV Genotype 1a and 1b Patients Treated for 12 Weeks with an Interferon-Free All-Oral Quad Regimen: Interim Results." Poster Presentation. Annual Meeting. European Association for the Study of the Liver, April, 2012.
14. I Jacobson, E. Lawitz, J. Lalezari, I. Crespo, M. Davis, T. Hassanein, M. DeMicco, S. Arora, N. Gitlin, R. Herring, et al. "GS-7977 400 mg QD Safety and Tolerability in the Over 500 Patients Treated for 12 Weeks." Poster Presentation. Annual Meeting. European Association for the Study of the Liver, April, 2012.
15. Wyles DL, Rodriguez-Torres M, Lawitz E, Shiffman ML, Pol S, Herring RW, et al. "All-oral combination of ledipasvir, vedoprevir, tegobuvir, and ribavirin in treatment-naïve patients with genotype 1 HCV infection." *Hepatology*. 60 (1): 56-64, July, 2014.

CURRICULUM VITAE

PUBLICATIONS (Continued)

16. Wedemeyer, H., Jensen, D., Herring, Jr., et al. "PROPEL: A Randomized Trial of Mericitabine Plus Peginterferon Alpha-2a Therapy in Treatment-Naïve HCV Genotype 1/4 Patients." Hepatology. 58 (2): 524-37, August, 2013.
17. Nezam Afdhal, M.D., K. Rajender Reddy, M.D., David R. Nelson, M.D., Eric Lawitz, M.D., Stuart C. Gordon, M.D., Eugene Schiff, M.D., Ronald Nahass, M.D., Reem Ghalib, M.D., Norman Gitlin, M.D., Robert Herring, M.D., et al. "Ledipasvir and Sofosbuvir for Previously Treated HCV Genotype 1 Infection." The New England Journal of Medicine. 17; 370 (16): 1483-93, April, 2014.
18. Kris V. Kowdley, M.D., Stuart C. Gordon, M.D., K. Rajender Reddy, M.D., Lorenzo Rossaro, M.D., David E. Bernstein, M.D., Eric Lawitz, M.D., Mitchell L. Shiffman, M.D., Eugene Schiff, M.D., Reem Ghalib, M.D., Michael Ryan, M.D., Vinod Rustgi, M.D., Mario Chojkier, M.D., Robert Herring, M.D., et al. "Ledipasvir and Sofosbuvir for 8 or 12 Weeks for Chronic HCV without Cirrhosis." The New England Journal of Medicine. 15; 370 (20): 1879-88, April, 2014.
19. Jacobson IM, Gordon SC, Kowdley KV, Yoshidia EM, Rodriques-Torres M, Sulkowski MS, Shiffman ML, Lawitz E, Everson G, Bennett M, Schiff E, Al-Assi MT, Subramanian GM, An D, Lin M, McNally J, Brainard D, Symonds WT, McHutchison JG, Patel K, Feld J, Lianko S, Nelson DR, George J, Leggett B, Pianko S, Thompson A, Elkashab M, Ramji A, Swain M, Willems B, Yoshida E, Gane E, Stedman C, Afdhal N, Aggarwal A, Bank L, Beavers K, Bennett M, Chung R, Davis M, Elion R, Etzkorn K, Everson G, Freilich B, Galambos M, Gordon S, Hassanein T, Herring R Jr, et al. "Sofosbuvir for hepatitis C genotype 2 or 3 in patients without treatment options." New England Journal of Medicine. 16; 368 (20): 1867-77, May, 2013.
20. Pruitt, R.E., M.D., Gremillion, Daniel, M.D., Herring, Robert W., Jr., et al. "Safety and Tolerance of Oral 5-ASA (Asacol) in the Treatment of Ulcerative Colitis and Crohn's Disease: Results of the US Multicenter Open-Label Study." Gastroenterology. 100: A 241, May, 1991.
21. DR Nelson, S Zeuzem, P Andreone, P Ferenci, R. Herring, et al. "Balapiravir Plus Peginterferon alfa-2a (40KD) and Ribavirin for the Treatment of Chronic Hepatitis C Genotype 1: Randomized, Double-Blind, Placebo-Controlled Phase 2 Study." Annals of Hepatology. 11 (1): 15-31, January-February, 2012.
22. Gaglio PJ, Rodrigues-Torres M, Herring R, et al. "Racial differences in response rates to consensus interferon in HCV infected patient's naïve to previous therapy." Journal of Clinical Gastroenterology. 38 (7): 599-604, August, 2004.

CURRICULUM VITAE

PUBLICATIONS (Continued)

23. Pruitt, Ron E., M.D., Gremillion, Daniel E., M.D., Herring, Robert W., Jr., et al. "Oral 5-ASA (Asacol) in the Treatment of Mild to Moderate Ulcerative Colitis (UC): The Nashville Experience." Journal of Tennessee Medical Association. 84: 237, 1991.
24. Herring, R.W., et al. "Effect of acute alcohol administration on erythrocyte aldehyde dehydrogenase activity in man." Alcoholism: Clinical and Experimental Research. 10 (6): 41S-45S, 1986.
25. Robert W. Herring Jr., et al. "A Single Direct-Acting Anti-viral agent, ACH-3102, with Ribavirin Is Able to Achieve a Robust Anti-viral Response in Subjects with Genotype 1B Chronic Hepatitis C infection." Late-Breaking Abstract. Annual Meeting. American Association for the Study of Liver Diseases, 2013.
26. Eric Yoshida, Mark Sulkowski, Edward Gane, Robert Herring, et al. "The Concordance Between SVR4, SVR12, and SVR24 in Patients With Chronic HCV Infection Who Received Treatment With Sofosbuvir (SOF) in Phase 3 Clinical Trials." Poster Presentation. Annual Meeting. American Association for the Study of Liver Diseases, 2013.
27. M. Sulkowski, M. Rodriguez-Torres, E. Lawitz, M. Shiffman, S. Pol, R. Herring, et al. "Interim Sustained Virologic Response Rates in Treatment-Naïve HCV Genotype 1a and 1b Patients Treated for 12 or 24 Weeks with an Interferon-Free All-Oral Quad Regimen." Poster Presentation. Annual Meeting. European Association for the Study of the Liver, April, 2012.
28. M. Sulkowski, M. Rodriguez-Torres, E. Lawitz, M. Shiffman, S. Pol, R. Herring, et al. "Complete SVR4 Rates in Treatment-Naïve HCV Genotype 1a and 1b Patients Treated with an Interferon-Free All-Oral Quad Regimen." Poster Presentation. Annual Meeting. American Association for the Study of Liver Diseases, 2012.
29. Wedemeyer, H., Jensen, D., Herring, Jr., et al. "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." Poster Presentation. Annual Meeting. European Association for the Study of the Liver, 2011.
30. Jensen, D., Wedemeyer, H., Herring Jr., et al. "High Rates of Early Viral Response, Promising Safety Profile and Lack of Resistance-Related Breakthrough in HCV GT 1/4 Patients Treated With RG7128 Plus PegIFN α -2a (40KD)/RBV: Planned Week 12 Interim Analysis from the PROPEL Study." Poster Presentation. Annual Meeting. American Association for the Study of Liver Diseases, 2010.

CURRICULUM VITAE

CONTINUING MEDICAL EDUCATION COURSES (CME)

2014 Total 115.25

March 8, 2014	Saint Thomas Health <u>2014</u> Colorectal and GI Update Nashville, TN 6.75 AMA PRA Category 1 Credits
April 9 -13, 2014	European Association for the Study of the Liver The International Liver Congress™ 2014 London, United Kingdom CME Accreditation/Certificate of Attendance 27 AMA-PRACategory 1 Credits
October 16, 2014	Saint Thomas Health Healing Without Harm 2014 Nashville, TN 0.75 AMA PRA Category 1 Credits
October 20–22, 2014	2014 Annual Scientific Meeting American College of Gastroenterology Pennsylvania Convention Center Philadelphia, PA 16.25 AMA PRA Category 1 Credits
October 23-25, 2014	Becker's ASC 21 st Annual Meeting Chicago, IL CME Accreditation/Certificate of Attendance 10.5 AMA PRA Category 1 Credits
November 7-11, 2014	The Liver Meeting American Association for the Study of Liver Diseases (AASLD) Annual Meeting, Boston, MA Post Graduate Course 12 AMA PRA Category 1 Credits
November 7-11, 2014	The Liver Meeting American Association for the Study of Liver Diseases (AASLD) Annual Meeting, Boston, MA 42 AMA PRA Category 1 Credits

CURRICULUM VITAE

CONTINUING MEDICAL EDUCATION COURSES (CME)

2015 Total 99.5

April 22-26, 2015	European Association for the Study of the Liver The International Liver Congress™ 2015 Vienna, Austria CME Accreditation/Certificate of Attendance 27 AMA-PRA Category 1 Credits
July 18, 2015	Saint Thomas Health 2015 Colorectal and GI Update Nashville, TN 7.75 AMA PRA Category 1 Credits
September 25-26, 2015	Vanderbilt University School of Medicine 2015 Gastroenterology, Hepatology and Nutrition Update Nashville, TN 11 AMA PRA Category 1 Credits
November 13-17, 2015	The Liver Meeting American Association for the Study of Liver Diseases (AASLD) Annual Meeting, San Francisco, CA Post Graduate Course 6 AMA PRA Category 1 Credits
November 13-15, 2015	The Liver Meeting American Association for the Study of Liver Diseases (AASLD) Annual Meeting, San Francisco, CA 21.5 AMA PRA Category 1 Credits
November 13-15, 2015	The Liver Meeting American Association for the Study of Liver Diseases (AASLD) Annual Meeting, San Francisco, CA Basic Science Symposium 7.5 AMA PRA Category 1 Credits
December 4, 2015	ACG's Hepatitis School American College of Gastroenterology Omni Nashville Hotel, Nashville, TN 7.25 AMA PRA Category 1 Credits
December 5-6, 2015	ACG Southern Regional Postgraduate Course American College of Gastroenterology Omni Nashville Hotel, Nashville, TN 11.50 AMA PRA Category 1 Credits

CURRICULUM VITAE

2016 Total 38

April 13-17, 2016

European Association for the Study of the Liver
The International Liver Congress™ **2016**
Barcelona, Spain
CME Accreditation/Certificate of Attendance
27 AMA-PRACategory 1 Credits

September 23-24, 2016

Vanderbilt University School of Medicine
Gastroenterology, Hepatology and Nutrition Update 2016
Nashville, TN
11 AMA PRA Category 1 Credits

CURRICULUM VITAE

INVESTIGATIONAL/STUDY PROTOCOLS

1. "A Comparison of Ranitidine 300 mg hs, Ranitidine 300 mg qid in the Treatment of Duodenal Ulcer Disease." Co-Investigator.
2. "A Comparison of Ranitidine 150 mg and Ranitidine 300 mg Administered at Bedtime for Maintenance of Healed Duodenal Ulcers." Co-Investigator.
3. "Nizatidine in Preventing NSAID-Associated Ulcers." Co-Investigator.
4. "A Study of the Effect of Olestra Consumption in Patients with Ulcerative Colitis." Number 93. Co-Investigator.
5. "A Study of the Effect of Olestra Consumption in Patients with Ulcerative Colitis." Number 94. Co-Investigator.
6. "Double-Blind, Placebo-Controlled Study to Determine the Optimal bid Dose of Colloidal Bismuth Subcitrate Capsules for Duodenal Ulcer Healing and Relapse Reduction." Co-Investigator.
7. "Efficacy and Tolerability of Extended-Release Felodipine in Adult Patients with Mild to Moderate Uncomplicated Essential Hypertension." Co-Investigator.
8. "Famotidine NSAID Prophylaxis." Co-Investigator.
9. "A Double-Blind, Placebo-Controlled, Randomized, Parallel Study Evaluating Tagamet in the Relief of Duodenal Ulcer Pain." Co-Investigator.
10. "Clinical Studies for PEG Re-Introduction." Co-Investigator.
11. "A Multicenter, Prospective, Double-Blind, Randomized, Placebo-Controlled, Parallel Design Study of Controlled-Release Cimetidine for the Treatment of GERD." Co-Investigator.
12. "A Comparison of Ranitidine 300 mg and Placebo Administered at Bedtime for the Treatment of Benign Gastric Ulcers." Co-Investigator.
13. "A Comparison of Ranitidine 150 mg and Placebo Administered at Bedtime for Maintenance of Recurrent Benign Gastric Ulcers." Co-Investigator.

CURRICULUM VITAE

INVESTIGATIONAL/STUDY PROTOCOLS (continued)

14. "A Multi-Center, Double-Blind, Randomized Study to Compare the Efficacy of Asacol vs. Placebo on the Induction of Remission in Patients with Mildly to Moderately Active Chronic Ulcerative Colitis." Co-Investigator.
15. "A Multi-Center, Double-Blind, Randomized Withdrawal Study to Compare the Efficacy of Asacol versus Placebo in the Maintenance of Remission in Subjects with Ulcerative Colitis." Co-Investigator.
16. "Cefaclor AF vs. Cefaclor in Various Bacterial Infections." Co-Investigator.
17. "Nizatidine Dose Response in Gastroesophageal Reflux Disease." Co-Investigator.
18. "A Multi-Center Comparison of the Safety and Efficacy of Lomefloxacin and Cefaclor in the Treatment of Acute Exacerbation of Chronic Bronchitis." Co-Investigator.
19. "A Multi-Center, Placebo-Controlled Study Exploring Various Dosage Regimens of Cilazapril (Inhibace) in Patients with Mild to Moderate Hypertension." Co-Investigator.
20. "A Double-Blind, Dose-Ranging Study to Evaluate the Effects of Doses as Needed Up to Twice Daily of Famotidine 5 mg, 10 mg, 20 mg, or Antacid, as Compared to Placebo in the Treatment of Intermittent Heartburn." Co-Investigator.
21. "A Comparison of qid Clindinium Bromide and Placebo for the Treatment of Irritable Bowel Syndrome." Co-Investigator.
22. "Nizatidine vs. Placebo in Preventing NSAID-Associated Ulcers." Co-Investigator.
23. "A Multi-Center, Double-Blind, Randomized Withdrawal Study to Compare the Efficacy of Asacol versus Placebo in the Maintenance of Remission in Subjects with Ulcerative Colitis." Co-Investigator.
24. "A Double-Blind, Multi-Center Study Comparing Nizatidine, Magnesium Hydroxide/Aluminum Hydroxide and Placebo in the Alleviation of Heartburn." Co-Investigator.

CURRICULUM VITAE

INVESTIGATIONAL/STUDY PROTOCOLS (continued)

25. "A Comparative, Parallel, Randomized, Multi-Center Study of Rowasa (Mesalamine) Rectal Suspension Enema with Concomitant Oral Steroid Therapy vs. Cortenema with Concomitant Oral Steroid Therapy in the Treatment of Distal Ulcerative Colitis." Co-Investigator.
26. "A Multi-Center, Controlled Maintenance Study of the Efficacy and Safety of 4.0 q Rowasa (5-ASA) Rectal Suspension in Maintaining Remission in Distal Ulcerative Colitis." Co-Investigator.
27. "A Double-Blind Placebo-Controlled Study of the Efficacy and Safety of Misoprostol (Cytotec) in the Prevention of NSAID-Induced Duodenal Ulcers." Co-Investigator.
28. "Cimetidine Compared to Misoprostol in the Treatment of Gastrointestinal Symptoms and the Prevention of Mucosal Damage Associated with Chronic NSAID Therapy." Co-Investigator.
29. "Effectiveness of Sucralafate Tablets (1 gram) in Patients with Endoscopically-Documented Duodenal Ulcers." Co-Investigator.
30. "Omeprazole DU Dose Ranging/Repeated Treatment." Co-Investigator.
31. "A Double-Blind Efficacy and Safety Study of Two Regimens of Enprostil and Placebo in the Treatment of NSAID-Induced Benign Gastric Ulcers with a Post-Study Open-Label Antacid Treatment." Co-Investigator.
32. "A Double-Blind Study of Two Regimens of Enprostil and Placebo in the Maintenance of Healed NSAID-Induced Gastric Ulcers in Patients with Osteo- or Rheumatoid Arthritis." Co-Investigator.
33. "Arbacet Duodenal Ulcer Healing Study." Co-Investigator.
34. "Tagamet versus Placebo in the Treatment of Symptomatic Gastroesophageal Reflux." Co-Investigator.
35. "AHR-11190 (Zacopride) Study." Co-Investigator.
36. "Double-Blind Evaluation of Ketoprofen and Ibuprofen for the Over-the-Counter Use." Co-Investigator.

CURRICULUM VITAE

INVESTIGATIONAL/STUDY PROTOCOLS (continued)

37. "A Safety and Tolerability Evaluation of Reformulated Preparation H Cream, Ointment, and Suppository in the Treatment of Hemorrhoids." Co-Investigator.
38. "A Multi-Center, Double-Blind, Safety and Efficacy Study of Azithromycin vs. Erythromycin in the Treatment of Community-Acquired Pneumonia." Co-Investigator.
39. "A Comparison of the Efficacy and Safety of Augmentin 875/125 mg po q 12 Hours versus Augmentin 500/125 mg po q 12 Hours versus Augmentin 500/125 mg po q 8 Hours in the Treatment of Bacterial Lower Respiratory Tract Infections." Co-Investigator.
40. "A 42-Day, Double-Blind, Parallel Group, Multi-Center Study to Compare the Safety and Efficacy of Three-Dose Levels of Budesonide with Placebo in Adult Patients with Distal Ulcerative Colitis/Proctitis." Co-Investigator.
41. "The Clinical Evaluation of Cisapride in the Treatment of Chronic Gastroesophageal Reflux Disease." Co-Investigator.
42. "Clarithromycin in Combination with Omeprazole or Omeprazole as a Single Agent for the Treatment of Patients with Duodenal Ulcers." Co-Investigator.
43. "A Controlled, Randomized, Double-Blind Study Comparing 2.0 and 3.0 gm/day of Dipentem with Placebo in the Treatment of Mild to Moderate Ulcerative Colitis." Co-Investigator.
44. "Fosfomycin Tromethamine versus Ciprofloxacin in the Treatment of Uncomplicated Urinary Tract Infections." Co-Investigator.
45. "A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Evaluation of Healing and Relapse Rates Following Oral GR122311X Compared with GR88502X, Ranitidine and Placebo in Patients with Duodenal Ulcer." Co-Investigator.
46. "A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Evaluation of Healing and Relapse Rates Following Oral GR122311X Compared with GR88502X, Ranitidine and Placebo in Patients with Benign Gastric Ulcer." Co-Investigator.
47. "A 42-Day, Blinded, Parallel Group, Multi-Center Study to Compare the Safety and Efficacy of One Dose Level of Budesonide with Placebo and Cortenema in Adult Patients with Distal Ulcerative Colitis/Proctitis." Co-Investigator.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

48. "A Double-Blind, Placebo-Controlled, Randomized, Parallel-Group, Multi-Center Study Evaluating Levsinex in Irritable Bowel Syndrome." Co-Investigator.
49. "A Double-Blind Parallel Group Comparison of Librax and Its Components in Patients with Irritable bowel Syndrome." Co-Investigator.
50. "A Randomized, Double-Blind, Parallel Study of the Safety and Antihypertensive Efficacy of Hydrochlorothiazide (HCTZ) in Combination with Losartan." Co-Investigator.
51. "A Multi-Center, Double-Blind Study to Evaluate the Safety and Therapeutic Efficacy of Omeprazole 20 mg a.m. or 10 mg a.m. as Compared to Placebo During 12 Months Maintenance Treatment of Patients with Duodenal Ulcer Healed Following 4 Weeks of Omeprazole 20 mg a.m." Co-Investigator.
52. "A Double-Blind, Multi-Center Study to Investigate the Efficacy of Omeprazole (20 or 40 mg Once Daily) in the Healing of and Relief of Symptoms Due to Benign Gastric Ulcers. Co-Investigator.
53. "A Double-Blind, Randomized, Multiple-Dose, Placebo-Controlled, Parallel Study to Investigate the Tolerability of MK-0591 in Patients with Ulcerative Colitis." Co-Investigator.
54. "A Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of Misoprostol in the Healing of NSAID-Induced Gastric Ulcers." Co-Investigator.
55. "A Double-Blind, Placebo-Controlled, Comparative Study of the Efficacy and Safety of Three Dosage Regimens of Misoprostol in the Prevention of NSAID-Induced Gastric Ulcers." Co-Investigator.
56. "The Efficacy and Safety of Misoprostol in the Prevention of NSAID-Induced Gastric Ulcers." Co-Investigator.
57. "Nizatidine vs. Placebo in Preventing GU Relapse in Long-Term NSAID Users." Co-Investigator.
58. "The Treatment of Inflammatory Bowel Disease with Oral Pentasa (Mesalamine): Compassionate Program." Co-Investigator.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

59. "Evaluation of the Safety and Efficacy of Ceftibuten 400 mg q d Compared to Ceftin 250 mg bid in the Treatment of Acute Lower Respiratory Tract Infection." Co-Investigator.
60. "An Open-Label, Parallel Group, Comparative Multi-Center Trial of Ranitidine 150 mg hs versus Triple Therapy (Tetracycline, Metronidazole, Bismuth Subsalicylate) versus Ranitidine 150 mg hs Plus Triple Therapy in the Prevention of Ulcer Recurrence and Rebleeding in Patients with Helicobacter Pylori Infection and a History of Duodenal Ulcer Bleeding." Co-Investigator.
61. "A Comparison of Ranitidine 300 mg bid, Ranitidine 150 mg bid and Placebo in the Treatment of Aspirin or Nonsteroidal Anti-Inflammatory Drug Associated Gastric Ulcers in Patients with Osteo- or Rheumatoid Arthritis." Co-Investigator.
62. "A Comparison of Ranitidine 150 mg bid and Placebo in the Treatment of Aspirin or Nonsteroidal Anti-Inflammatory Drug Associated Duodenal Ulcers in Patients with Osteo- or Rheumatoid Arthritis." Co-Investigator.
63. "A Comparison of Ranitidine 150 mg bid, Ranitidine 150 mg hs and Placebo for Maintenance of Healed Aspirin or Nonsteroidal Anti-Inflammatory Drug-Associated Gastric and Duodenal Ulcers in Patients with Osteo- or Rheumatoid Arthritis." Co-Investigator.
64. "A Comparison of Ranitidine 300 mg bid, Ranitidine 150 mg bid and Placebo for Prophylaxis of Aspirin or Nonsteroidal Anti-Inflammatory Drug-Associated Gastric and Duodenal Ulcers in Patients with Osteo- or Rheumatoid Arthritis and No History of Gastric or Duodenal Ulcer." Co-Investigator.
65. "A Comparison of Ranitidine 300 mg bid, Ranitidine 150 mg bid and Placebo for Prophylaxis of Aspirin or Nonsteroidal Anti-Inflammatory Drug-Associated Gastric and Duodenal Ulcers in Patients with Osteo- or Rheumatoid Arthritis and a History of Gastric or Duodenal Ulcer." Co-Investigator.
66. "A Double-Blind Placebo Controlled Comparison of Ranitidine 150 mg qid and Ranitidine 300 mg bid in the Treatment of Erosive Esophagitis." Co-Investigator.
67. "A Comparison of Ranitidine 150 mg qid and Ranitidine 150 mg bid to Cimetidine 800 mg in the Treatment of Erosive Esophagitis." Co-Investigator.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

68. "Long-Term Safety and Efficacy of Zileuton in Patients with ulcerative Colitis in Remission." Co-Investigator.
69. "Pharmacokinetics Study of Zileuton in Patients with Moderate Ulcerative Colitis Being Treated in Study M89-371." Co-Investigator.
70. Abbott: "Dose Ranging Study of the Safety and Efficacy of Oral Doses of Abbott-64077 for Eight Weeks in Patients with Ulcerative Colitis." Co-Investigator.
71. "Safety and Efficacy of Zileuton in Patients with Ulcerative Colitis in Remission Completing Protocol M90-465." Co-Investigator.
72. "Technomed Sonolith 3000." Gallstone protocol. Co-investigator.
73. Norwich Eaton Pharmaceuticals, Inc. Protocol 850570862.70.00-3306. "An Open Label Study of Asacol in the Induction and/or Maintenance of Remission of Inflammatory Bowel Disease." Co-investigator.
74. Amgen Clinical Grants Protocol 980102. "A Clinical Study of Infergen, in Hepatitis C Patients Who Receive an Initial Course of Therapy with Infergen 9 mcg (12 Weeks) and Retreatment with Infergen 15 mcg (24 Weeks) for Nonresponders." Principal Investigator: Robert W. Herring, Jr., M.D.
75. Amgen Clinical Grants Protocol Number 980170. "Efficacy of Infergen for Chronic Hepatitis C in Patients who are Non-Responders and Relapsers to Combination Therapy with Intro-A + Ribavirin. A Multi-Center Trial" Principal Investigator: Robert W. Herring, Jr., M.D.
76. Amgen Clinical Grants Protocol Number 980181. "Introductions Therapy Using 9 mcg vs 15 mcg of Infergen Daily for HCV Patients who have Failed Previous Interferon Therapy". Principal Investigator: Robert W. Herring, Jr., M.D.
77. Amgen Clinical Grants Protocol Number 980276. "Daily Induction Therapy with Infergen for HCV Patients who are Naive to Interferon Therapy. Principal Investigator: Robert W. Herring, Jr., M.D.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

78. "An Open-Label Study of Cyto Tab for the Treatment of Active Crohn's Disease." Protocol Number Tab 019-01. Therapeutic Antibodies, Inc., Nashville, Tennessee. Co-Investigator: Robert W. Herring, Jr., M.D.
79. "Clinical Protocol for a Multicenter Double-Blind, Parallel Group Study Comparing the Incidence of Clinically Significant Upper Gastrointestinal Adverse Events Associated with SC-58635 400 mg to that of Diclofenac 75 mg BID in Patients with OsteoArthritis or Rheumatoid Arthritis IND #48,395" Protocol Number N49-98-02-102. G. D. Searle and Company, Skokie, Illinois. Co-Investigator: Robert W. Herring, Jr., M.D.
80. "Safety, Tolerance, and Efficacy of Treatment with Subcutaneous rHuIL-10 (SCH 52000) in Subjects with Steroid-Dependent Crohn's Disease" Protocol Number C97-455-35. Schering-Plough Research Institute. Co-Investigator: Robert W. Herring, Jr., M.D.
81. "A Double-Blind Randomized Placebo Controlled Study of the Safety and Efficacy of Three Doses of Oral Aliminase in the Treatment of Active Ulcerative Colitis" Protocol Number 9084. Carrington Laboratories, Inc. Co-Investigator: Robert W. Herring, Jr., M.D.
82. "A 14-day, Evaluator-blinded, Randomized, Multicenter Gastrointestinal Endoscopy Study of Orally Administered Risedronate 5 mg/day vs. Alendronate 10 mg/day in Healthy Postmenopausal Women" Protocol Number 1998054. Proctor and Gamble Pharmaceuticals, Inc., Cincinnati, Ohio. Co-Investigator: Robert W. Herring, Jr., M.D.
83. "A Multicenter, Double-Blind, Placebo Controlled, Parallel Study Group Comparing the Incidence of Gastroduodenal Ulcer Associated with Valdecoxib 10 mg and 20 mg QD with that of Ibuprofen 800 mg TID and Diclofenac Sodium 75 mg, Taken for 12 Weeks in Patients with Osteoarthritis" Protocol Number N91-98-02-048. G. D. Searle and Company. Co-Investigator: Robert W. Herring, Jr., M.D.
84. "A Multicenter, Double-Blind, Placebo-Controlled, Randomized Comparison Study of the Efficacy and Upper Gastrointestinal Safety of Valdecoxib 5 mg, 10 mg, and 20 mg QD and Naproxen 500 mg BID in Treating the Signs and Symptoms of Osteoarthritis of the Knee" Protocol Number N91-99-02-053. G. D. Searle and Company. Co-Investigator: Robert W. Herring, Jr., M.D.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

85. "A Randomized, Double-Blind, Placebo-Controlled, Dose Finding, Multicenter Study to Assess the Efficacy, Safety and Tolerability of tegasevod Given Orally at Three Dose Levels (.4 mg, 1 mg or 4 mg daily) and Placebo in Patients with Non-Erosive Gastro-Esophageal Reflux Disease (GERD)" Protocol Number CHTF9190202. Norartis Pharmaceuticals Corporation. Co-Investigator: Robert W. Herring, Jr., M.D.
86. "A 12 Week, Randomized, Double-Blind, Placebo- and Positive Controlled, Parallel-Group, Multicenter, Dose-Ranging Study of Darbufelone Mesylate (CI-1004) in Patients with Osteoarthritis of the Knee" Protocol Number 1004-031. Park-Davis Pharmaceutical Research. Co-Investigator: Robert W. Herring, Jr., M.D.
87. "A Two-Period, Double-Blind, Placebo-Controlled Trial to Evaluate the Effects of Re-treatment of Prucalopride on the Efficacy and Safety in Subjects with Chronic Constipation" Protocol Number PRU-USA-28. Janssen Research Foundation. Co-Investigator: Robert W. Herring, Jr., M.D.
88. "A 24 Week Randomized, Open Label Study of Health Care Resource Use, Quality of Life and Productivity with Alosetron 1mg Twice Daily Versus Traditional Therapy in Females with Non-constipated Irritable Bowel Syndrome." Protocol Number S3B30020. Principal Investigator.
89. "A Twelve Week Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Tolerability of Alosetron Hydrochloride 1mg Twice Daily for Control of Bowel Urgency in Females with Non-Constipated Irritable Bowel Syndrome in an Independent Practitioner Association (IPA) Model." Protocol Number S3B40031. Principal Investigator.
90. "A Study to Evaluate the Safety and Efficacy of TAK-637 (30mg BID, 60mg BID, and 120mg BID) Versus Placebo in Subjects with Irritable Bowel Syndrome, Incorporating Amendment No. 1. Protocol Number TAK-637-99-201. Principal Investigator.
91. "A double-blind, placebo-controlled trial to evaluate the effects of 1mg Prucalopride tablets, given once-daily, on efficacy and safety in subjects with chronic constipation." Protocol Number PRU-USA-35. Principal Investigator.
92. "Aciphex (Rabeprazole sodium) The F.A.S.T. Trial for the healing and relief of symptoms of erosive esophagitis or ulcerative GERD." Protocol Number RAB-USA-4. Principal Investigator.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

93. "A double-blind, placebo-controlled, randomized, multicenter study to investigate the safety and efficacy of 2 mg TID of cilansetron over 12 weeks in diarrhea-predominant irritable bowel syndrome subjects." Protocol Number S2413006. Sub-Investigator.
94. "A phase III, multi-national, multi-site, double-blind, placebo controlled, 28 week study to assess the safety and efficacy of the engineered human anti-TNF_{CX} antibody, CDP571 (10mg/kg), in patients with active Crohn's disease. Protocol Number CDP571-015. Sub-Investigator.
95. "Prevention of sporadic colorectal adenomas with celecoxib." Protocol Numbers NCI #N01-CN-95015, Searle #IQ4-99-02-005, WIRB 991136. Sub-Investigator.
96. "Pegylated interferon and ribavirin for HCV treatment failure." Schering. Protocol Number 202-02-00. Principal Investigator.
97. "Comparison of PEG interferon alfa-2b plus ribavirin given as a fixed dose or on a weight optimized basis for treatment of chronic hepatitis C in previously untreated adult subjects BB-IND#-9243." Schering. Protocol Number 244-11-00. Principal Investigator.
98. "A prospective, randomized, multicenter, open label comparative safety study of pegasys vs. pegasys plus ribavirin treatment vs. a twelve week treatment delay in patients with chronic hepatitis C." Roche. Protocol Number NR16161. Principal Investigator.
99. "Daily induction therapy with infergen for HCV infected patients who are naive to interferon therapy." Amgen. Protocol Number 980276. Principal Investigator: Robert W. Herring, Jr., M.D.
100. "A phase III study of the comparison of entecavir to lamivudine in chronic hepatitis B subjects with incomplete response to current lamivudine therapy." Protocol Number AI463-026. Principal Investigator.
101. "A phase III study of the safety and antiviral activity of entecavir vs lamivudine in adults with chronic hepatitis B infection who are negative for hepatitis B E antigen." Protocol Number AI463-027-182. Principal Investigator.
102. "A phase III study of the safety and antiviral activity of entecavir vs lamivudine in adults with chronic hepatitis B infection who are positive for hepatitis B E antigen." Protocol Number AI463-022-177. Principal Investigator.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

103. "A multi-center randomized trial comparing daily induction dose Intron-A plus ribavirin followed by daily rebetron versus standard rebetron in patients who have not previously been treated with interferon." Schering. Protocol Number 173-08-99. Principal Investigator: Robert W. Herring, Jr., M.D.
104. "A randomized multicenter trial of PEG-interferon alfa 2b plus ribavirin +/- amantadine in patients with chronic hepatitis C (Lawitz)." Schering. Protocol Number 252-02-01. Principal Investigator: Robert W. Herring, Jr., M.D.
105. "Use of Peginterferon alfa-2b and Ribavirin for Treatment of Patients with Chronic Hepatitis C with Normal ALT Levels. Schering. Principal Investigator: Robert W. Herring, Jr., M.D.
106. A Comparison of the Safety and Efficacy of Two Doses of Peg-Interferon alfa-2b (Peg-Intron: 1.5 mcg/kg vs. 3.0 mcg/kg) in Combination with Ribavirin (Rebetol) for Treatment of Chronic Hepatitis C Patients. Schering. Principal Investigator: Robert W. Herring, Jr., M.D.
107. 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. Schering. Principal Investigator: Robert W. Herring, Jr., M.D.
108. Does Induction Peg-Intron In Combination with Rebetol Enhance The Sustained Response Rates in Patients With Chronic Hepatitis C. Schering. Principal Investigator: Robert W. Herring, Jr., M.D.
109. 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. Schering-Plough Research Institute. Principal Investigator: Robert W. Herring, Jr., M.D.
110. REPEAT (**RE**treatment with **PE**gasys® in **PAT**ients Not Responding to Prior Peginterferon alfa-2b Ribavirin Combination Therapy). F. Hoffmann-La Roche Ltd./Inc/AG. Roche Global Business. Clinical Phase III. Project Phase IV. Principal Investigator: Robert W. Herring, Jr. M.D.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

111. Protocol ML18179: A Prospective, Multicenter, Open-Label, Comparative, 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., M.D.
112. Protocol #M02-404 Abbott Crohn's Sub-Investigator: Robert W. Herring, Jr., M.D.
113. Protocol #M02-690 Abbott Crohn's Sub-Investigator: Robert W. Herring, Jr., M.D.
114. Protocol #CDP870-033 Celltech Crohn's Sub-Investigator: Robert W. Herring, Jr., M.D.
115. Protocol #5326-07 Synta Crohn's Flare Sub-Investigator: Robert W. Herring, Jr., M.D.
116. Protocol #RM01-2018 Romark Crohn's Flare Sub-Investigator: Robert W. Herring, Jr., M.D.
117. Protocol #CL-C002-00 Inflabloc Crohn's Flare Sub-Investigator: Robert W. Herring, Jr., M.D.
118. Protocol #SPI/0211SIB-431 Sucampo IBS Constipation Sub-Investigator: Robert W. Herring, Jr., M.D.
119. Protocol #197-02-218 Otsuka Ulcerative Colitis Flare Sub-Investigator: Robert W. Herring, Jr., M.D.
120. Protocol #197-02-219 Otsuka Ulcerative Colitis Flare Rollover Sub-Investigator: Robert W. Herring, Jr., M.D.
121. Protocol #197-02-220 Otsuka Ulcerative Colitis Remission Sub-Investigator: Robert W. Herring, Jr., M.D.
122. Protocol #MPUC3003 Salix Ulcerative Colitis Remission Sub-Investigator: Robert W. Herring, Jr., M.D.
123. Protocol #CHTF919D2302 Novartis Dyspepsia Sub-Investigator: Robert W. Herring, Jr., M.D.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

124. Protocol #ITOFDO4-01 Axcan Dyspepsia Sub-Investigator: Robert W. Herring, Jr., M.D.
125. Protocol #D9612L00084 Astra-Zeneca Gerd Sub-Investigator: Robert W. Herring, Jr., M.D.
126. Protocol #M02-404 Abbott Crohn's Sub-Investigator: Robert W. Herring, Jr., M.D.
127. Protocol #M02-690 Abbott Crohn's Sub-Investigator: Robert W. Herring, Jr., M.D.
128. Protocol #CDP870-033 Celltech Crohn's Sub-Investigator: Robert W. Herring, Jr., M.D.
129. Protocol #CL003-282 Chemocentryx Crohn's Flare Sub-Investigator: Robert W. Herring, Jr., M.D.
130. Protocol #CL-C002-00 Infabloc Crohn's Flare Sub-Investigator: Robert W. Herring, Jr., M.D.
131. 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., M.D.
132. Protocol AG1003-003. "A Randomized, Double-blind, Placebo-controlled Study of AGI-003 (Arverapamil) in the Treatment of Irritable Bowel Syndrome with Diarrhea (IBS-D)". Principal Investigator: Robert W. Herring, Jr., M.D.
133. Protocol E3810-G000-303. "A Randomized Double-Blind Parallel Study of Rabeprazole Extended Release 50 MG versus Esomeprazole 40 mg for Healing and Symptomatic Relief of Mild to Moderate Erosive Gastroesophageal Reflux Disease". Principal Investigator: Robert W. Herring, Jr., M.D.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

134. 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-Naïve Patients with Chronic Hepatitis C Genotype I Virus Infection”. Principal Investigator: Robert W. Herring, Jr., M.D.
135. Protocol E3810-G000-301. “A Randomized Double-Blind Parallel Study of Rabeprazole Extended Release 50 mg versus Esomeprazole 40 mg for Healing and Symptomatic Relief of Moderate to Severe Erosive Gastroesophageal Reflux Disease”. Principal Investigator: Robert W. Herring, Jr., M.D.
136. Protocols CI-PSI-5268-06-305 and 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 Week 48 in Nucleoside Treatment-Naïve Subjects with HbeAg Positive (-305) and HbeAg Negative (-306) Chronic Hepatitis due to Hepatitis B Virus”. Principal Investigator: Robert W. Herring, Jr., M.D.
137. 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 Principal Investigator: Robert W. Herring, Jr., M.D.
138. 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 Principal Investigator: Robert W. Herring, Jr., M.D.
139. 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) Principal Investigator: Robert W. Herring, Jr., M.D.
140. NV22688B-row Long Term Monitoring Study to Evaluate the Persistence of Direct Acting Antiviral (DAA) Treatment Resistant Mutations or the Durability of Sustained Viral Response (SVR) in patients treated with DAA-containing regimens for Chronic Hepatitis C Infection (CHC) Principal Investigator: Robert W. Herring, Jr., M.D.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

141. 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
Principal Investigator: Robert W. Herring, Jr., M.D.
142. MCH-02-001 A Phase II Double-Blind, Placebo-Controlled Study of Two Doses of EPA-E in Patients With NASH Principal Investigator: Robert W. Herring, Jr., M.D.
143. 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
Principal Investigator: Robert W. Herring, Jr., M.D.
144. ML21301 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” Principal Investigator: Robert W. Herring, Jr., M.D.
145. Roche, Protocol NV21928B: “An Open-label, Multicenter, protocol providing with Pegasys® as monotherapy or in combination with Copegus® for patients Chronic Hepatitis C who have participated in previous Roche or Roche partner protocols”.
Principal Investigator
146. 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” Primary Investigator
147. 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” . Primary Investigator

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

148. 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 Peginterferon alfa plus Ribavirin Combination Therapy”. Primary Investigator
149. Gilead, Protocol GS-US-248-0120: A Phase 2 Randomized, Open-Label Study of GS-5885 Administered Concomitantly with GS-9451, Tegobuvir and Ribavirin (RBV) to Treatment-Naïve Subjects with Chronic Genotype 1 HCV Infection” Primary Investigator
150. 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”. Primary Investigator
151. Schering-Plough; Protocol P05063: Site #003 “Long-Term Follow-Up of Subjects in a Phase 1, 2, or 3 Clinical Trial in Which Boceprevir or Narlaprevir was Administered for the Treatment of Chronic Hepatitis C” Principal Investigator
152. 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.” Primary Investigator
153. 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”. Primary Investigator
154. 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 Peginterferon and Ribavirin (RBV) in Treatment-Experienced Subjects with Chronic Genotype 1 HCV Infection”. Primary Investigator

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

155. Gilead, Protocol GS-US-248-0122: “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”. Primary Investigator
156. Gilead, Protocol GS-US-248-0123: “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”. Primary Investigator
157. Gilead, ProtocolGS-US-334-0110: “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” Primary Investigator
158. Gilead, Protocol GS-US-334-0108: “ 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” Primary Investigator
159. 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”. Primary Investigator
160. 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”. Primary Investigator
161. Achillion, Protocol ACH102-007: “A Phase 2a Trial to Evaluate the Safety, Tolerability and Efficacy of 12 Weeks of Sovaprevir, ACH-0143102 and Ribavirin in Treatment-Naïve Subjects with Chronic Hepatitis C Genotype-1 Viral Infection” Primary Investigator
162. Gilead, GS-US-334-0109: “An Open-Label Study of GS-7977 + Ribavirin with or without Peginterferon Alfa-2a in Subjects with Chronic HCV Infection who participated in prior Gilead HCV Studies” Primary Investigator

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

163. Gilead, GS-US-334-0107: “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” Primary Investigator
164. 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” Primary Investigator
165. 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” Primary Investigator
166. 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” Primary Investigator
167. 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” Primary Investigator
168. 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” Primary Investigator
169. 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” Primary Investigator

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

170. Abbott (Abbvie), Protocol M14-002: “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)” Primary Investigator
171. 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 Primary Investigator
172. Merck; 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 Peginterferon alfa-2b and Ribavirin in Treatment-Naive Patients with Chronic Genotype 1 Hepatitis C Virus Infection” Primary Investigator
173. 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” Primary Investigator
174. 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” Primary Investigator
175. 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” Primary Investigator
176. Ferring International Pharmascience Center US, Inc.; Protocol 000080: “A double-blind, Randomised , Placebo-controlled,Phase 3Trial 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”. Primary Investigator
177. 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”. Primary Investigator

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

178. Hologic Incorporated; 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”. Primary Investigator
179. 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”. Primary Investigator
180. 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” Primary Investigator
181. 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”. Primary Investigator
182. 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”. Primary Investigator
183. 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” Primary Investigator
184. 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” Primary Investigator

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

185. 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”. Primary Investigator
186. 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”. Primary Investigator
187. 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” Primary Investigator
188. 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) Primary Investigator
189. 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” Primary Investigator
190. 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” Primary Investigator
191. 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” Primary Investigator

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

192. 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” Primary Investigator
193. 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)” Primary Investigator
194. 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” Primary Investigator
195. 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” Primary Investigator
196. 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” Primary Investigator
197. Gilead: Protocol # GS-US-342-1446 “An Open Label Study of Sofosbuvir/GS-5816 Fixed-Dose Combination in Subjects with Chronic HCV Infection” Primary Investigator
198. 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” Primary Investigator
199. 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” Primary Investigator

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

200. 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” Primary Investigator
201. 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” Primary Investigator
202. Genentech: 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” Primary Investigator
203. Genentech: Protocol # GA28951 “An Open-Label Extension and Safety Monitoring Study of Moderate to Severe Ulcerative Colitis patients previously Enrolled in Etrolizumab Phase III Studies” Primary Investigator
204. 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” Primary Investigator
205. 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” Primary Investigator
206. Braintree Laboratories Inc.: Protocol # BLI400-301 “A Safety and Efficacy Evaluation of BLI400 Laxative in Constipated Adults” Primary Investigator
207. 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”. Primary Investigator

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

208. 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”. Primary Investigator
209. 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”. Primary Investigator
210. 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
211. 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 ”. Primary Investigator
212. 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”. Primary Investigator
213. 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”. Primary Investigator.
214. 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”. Primary Investigator.

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

215. 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” Primary Investigator.
216. 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)”. Primary Investigator
217. 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”. Primary Investigator
218. 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”. Primary Investigator
219. 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)”. Primary Investigator
220. 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” Primary Investigator
221. 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)” Primary Investigator
222. 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)” Primary Investigator

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

223. 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” Primary Investigator
224. 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” Primary Investigator
225. 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)”. Primary Investigator
226. Ardelyx, Inc.: Protocol # TEN-01-303 “An Open Long-Term Safety Study of Tenapanor for Treatment of Constipation-Predominant Irritable Bowel Syndrome (IBS-C)”. Primary Investigator
227. 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” Primary Investigator
228. 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” Primary Investigator
229. 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)” Primary Investigator
230. 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” Primary Investigator
231. 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” Primary Investigator

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

232. 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)” Primary Investigator
233. 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)” Primary Investigator
234. 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” Primary Investigator
235. 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” Primary Investigator
236. Braintree Laboratories Inc.: Protocol # BLI400-303 “An Open Label Study of Chronic Use of BLI400 Laxative in Constipated Adults” Primary Investigator
237. 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” Primary Investigator
238. 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” Primary Investigator
239. 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” Primary Investigator

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INVESTIGATIONAL/STUDY PROTOCOLS (continued)

240. Gilead: Protocol # GS-US-418-3899 “A Long-Term Extension Study to Evaluate the Safety of Filgotinib in Subjects with Ulcerative Colitis” Primary Investigator
241. 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” Primary Investigator
242. Gilead: Protocol # GS-US-419-3896 “A Long-Term Extension Study to Evaluate the Safety of Filgotinib” Primary Investigator