

Supplementary data to:

Safety profile of boceprevir and telaprevir in chronic hepatitis C: Real world experience from HCV-TARGET

Stuart C. Gordon^{1,*}, Andrew J. Muir², Joseph K. Lim³, Brian Pearlman⁴, Curtis K. Argo⁵, Ananthakrishnan Ramani⁶, Benedict Maliakkal⁷, Imtiaz Alam⁸, Thomas G. Stewart⁹, Monika Vainorius⁹, Joy Peter¹⁰, David R. Nelson¹⁰, Michael W. Fried⁹, K. Rajender Reddy^{11,*} on behalf of the HCV-TARGET study group

¹Department of Internal Medicine, Division of Gastroenterology-Hepatology, Henry Ford Hospital, Detroit, Michigan, USA; ²Gastroenterology and Hepatology Research Group, Duke Clinical Research Institute, Durham, North Carolina, USA; ³Yale Liver Center, Yale University School of Medicine, New Haven, Connecticut, USA; ⁴Center for Hepatitis C, Atlanta Medical Center, Atlanta, Georgia, USA; ⁵University of Virginia, Charlottesville, VA, USA; ⁶Columbia Memorial Hospital, Hudson, NY, USA; ⁷Strong Memorial Hospital/University of Rochester, Rochester, NY, USA; ⁸Austin Hepatitis Center, Austin, TX, USA; ⁹UNC Liver Center, University of North Carolina, Chapel Hill, North Carolina, USA; ¹⁰University of Florida, Division of Gastroenterology, Hepatology and Nutrition, Gainesville, Florida, USA; ¹¹University of Pennsylvania, Philadelphia, Pennsylvania, USA

Table of Contents

HCV-TARGET investigators.....	2
Supplementary Table	5

HCV-TARGET investigators

The members of the HCV-TARGET study were as follow: *G. Abraham*, Partners in Internal Medicine, PC, Worcester, MA; *N. Afdhal*, Harvard University, Boston, MA; *I. Alam*, Austin Hepatitis Center, Austin, TX; *V. Ankoma-Sey*, Liver Associates of Texas, PA, Houston, TX; *C. K. Argo*, University of Virginia, Charlottesville, VA; *A. Aronsohn*, University of Chicago, Chicago, IL; *L. A. Balart*, Tulane University Health Sciences Center, New Orleans, LA; *A. Balistreri*, DeKalb Gastroenterology Associates, LLC, Decatur, GA; *K. L. Beavers*, Asheville Gastroenterology, Asheville, NC; *A. L. Berman*, Florida Center for Gastroenterology, Largo, FL; *D. E. Bernstein*, North Shore University Hospital, Manhasset, NY; *J. Bloomer*, University of Alabama at Birmingham, Birmingham, AL; *G. E. Catinis*, New Orleans Research Institute, New Orleans, LA; *M. R. Charlton*, Mayo Clinic, Rochester, MN; *A. G. Coates*, Gastroenterology Associates of Western Michigan, PLC, Wyoming, MI; *M. E. De Vera*, Loma Linda Transplantation Institute, Loma Linda, CA; *A. M. Di Bisceglie*, Saint Louis University, Saint Louis, MO; *R. C. Dickson*, Dartmouth-Hitchcock Medical Center, Lebanon, NH; *A. Duchini*, University of Texas Medical Branch, Gavelston, TX; *H. A. Elbeshbeshy*, Baptist Medical Center, Oklahoma City, OK; *H. El-Genaidi*, Lourdes Medical Associates, Egg Harbor Township, NJ; *G. Everson*, University of Colorado, Aurora, CO; *J. M. Fenkel*, Thomas Jefferson University, Philadelphia, PA; *E. Feysa*, Albert Einstein Medical Center, Center for Liver Disease and Transplantation, Philadelphia, PA; *M. W. Fried*, University of North Carolina at Chapel Hill, Chapel Hill, NC; *P. J. Gaglio*, Montefiore Medical Center, Bronx, NY; *J. Galati*, The Methodist Hospital, Houston, TX; *G. W. Galler*, Kelsey Research Foundation, Houston, TX; *J. A. Giron*, Orlando Infectious Disease Center, Orlando, FL; *S. C. Gordon*, Henry Ford Hospital, Detroit, MI; *M. Hassan*, University of Minnesota, Minneapolis, MN; *F. Hinestrosa*, Orlando Immunology Center, Orlando, FL; *S. Ho*, VA San Diego Healthcare System, San Diego, CA; *I. M. Jacobson*, Weill Cornell, New York City, NY; *M. E. Jones*, Tri-State Gastroenterology Associates, Crestview Hills, KY; *S. Joshi*, Ochsner Clinic Foundation, New Orleans, LA; *C. A. Kerr*, Hudson River Health Care, Peekskill, NY; *K. V. Kowdley*, Virginia Mason Medical Center, Seattle, WA; *A.*

Kuo, University of California-San Diego, San Diego, CA; *P. Y. Kwo*, Indiana University, Indianapolis, IN; *S. Lidofsky*, Fletcher Allen Health Care, Inc., Burlington, VT; *J. Lim*, Yale University, New Haven, CT; *R. L. Lindenberg*, Litchfield County Gastroenterology Associates, LLC, Torrington, CT; *A. Lok*, University of Michigan, Ann Harbor, MI; *J. E. Lutz*, Bend Memorial Clinic, Bend, OR; *A. Maheshwari*, Mercy Medical Center, Baltimore, MD; *M. A. Mah'moud*, Boice-Willis Clinic, PA, Rocky Mount, NC; *M. Mailliard*, University of Nebraska, Omaha, NE; *B. J. Maliakkal*, University of Rochester, Rochester, NY; *D. Marks*, Clinical Research Consultants, Inc., Hoover, AL; *E. A. Mena*, Huntington Medical Research Institutes Liver Center, Pasadena, CA; *C. L. Meyer*, Wilmington Gastroenterology Associates, Wilmington, NC; *S. R. Mohanty*, New York Methodist Hospital, Brooklyn, NY; *G. Morelli*, University of Florida, Gainesville, FL; *A. Mubarak*, Methodist Transplant Physicians, Dallas, TX; *A. J. Muir*, Duke University, Durham, NC; *A. Mushahwar*, Center for Advanced Gastroenterology PLLC, Maitland, FL; *M. G. Mutchnick*, Wayne State University Physician Group, Detroit, MI; *S. Nair*, Methodist Healthcare University Hospital, Memphis, TN; *G. W. Neff*, Tampa General Hospital, Tampa, FL; *L. M. Nyberg*, Kaiser Permanente, San Diego, CA; *A. Paez*, Baystate Medical Center, Springfield, MA; *C. Q. Pan*, Medical Procure, PLLC, Flushing, NY; *P. Pandya*, Kansas City VA Medical Center in care of Midwest Biomedical Research Foundation, Kansas City, MO; *B. L. Pearlman*, Atlanta Medical Center, Atlanta, GA; *E. Piken*, South Bay Gastroenterology Medical Group, Torrance, CA; *P. Pockros*, Scripps Health, La Jolla, CA; *D. Pound*, Indianapolis Gastroenterology Research Foundation, Indianapolis, IN; *A. Ramani*, Mountain View Medical, Catskill, NY; *D. B. Rausher*, MD Atlanta Center for Gastroenterology PC, Atlanta, GA; *N. Reau*, University of Chicago, Chicago, IL; *G. N. Reddy*, Digestive and Liver Disease Consultants, PA, Houston, TX; *K. R. Reddy*, University of Pennsylvania, Philadelphia, PA; *F. G. Regenstein*, Saint Luke's Liver Disease and Transplant Specialists, Kansas City, MO; *M. Rodriguez-Torres*, University of Puerto Rico, San Juan, PR; *V. K. Rustgi*, Metropolitan Research, Fairfax, VA; *J. J. Santoro*, Atlantic Gastroenterology Associates, Egg Harbor Township, NJ; *E. R. Schiff*, University of Miami, Miami, FL; *S. Sedghi*, Gastroenterology Associates of Central Georgia, LLC, Macon, GA; *K. E. Sherman*, University of Cincinnati, Cincinnati, OH; *C. Smith*, University of Minnesota, Minneapolis,

MN; *J. R. Spivey*, Emory University, Atlanta, GA; *T. R. Stainbrook*, DuBois Regional Medical Center, DuBois, PA; *R. K. Sterling*, Virginia Commonwealth University, Richmond, VA; *A. D. Stone*, Commonwealth Clinical Studies, Brockton, MA; *M. S. Sulkowski*, Johns Hopkins, Baltimore, MD; *G. Szabo*, University of Massachusetts, Worcester, MA; *N. A. Terrault*, University of California-San Francisco, San Francisco, CA; *H. Tobias*, Concorde Medical Group PLLC, New York, NY; *H. E. Vargas*, Mayo Clinic, Phoenix, AZ; *D. A. Warner*, Daniel Warner Consultative Medicine, Daytona Beach, FL; *A. Williams*, Liver Wellness Center, Little Rock, AR.

Supplementary Table

Supplementary Table 1. Key baseline characteristics, patient disposition, sustained virologic response, safety profile, and anaemia management in patients with cirrhosis.

	Patients with cirrhosis but no history of decompensation (n = 712)	Patients with cirrhosis and a history of decompensation (n = 76)	All patients with cirrhosis (n = 788)
Key baseline characteristics			
History of varices, n/N (%)	210/418 (50)	47/67 (70)	257/485 (53)
History of ascites, n (%)	33 (5)	31 (41)	64 (8)
Mean MELD score (range)	8.1 (6.0-21.0)	9.6 (6.0-17.0)	8.2 (6.0-21.0)
Mean APRI (range)	2.5 (0.2-17.1)	3.5 (0.4-12.3)	2.6 (0.2-17.1)
History of diabetes, n (%)	137 (19)	18 (24)	155 (20)
Mean platelets (range) (x10 ³) count per µl	125 (25-447)	96 (32-262)	122 (25-447)
Mean albumin (range), g/dl	3.9 (1.0-5.0)	3.5 (1.9-4.8)	3.9 (1.0-5.0)
DAA, n (%)			
Boceprevir	134 (19)	6 (8)	140 (18)
Telaprevir	578 (81)	70 (92)	648 (82)
Patient disposition during treatment, n (%)			
Completed therapy	372 (52)	31 (41)	403 (51)
Discontinued early	335 (47)	45 (59)	380 (48)
Adverse event	150 (21)	29 (38)	179 (23)
Lack of efficacy	153 (21)	14 (18)	167 (21)
Lost to follow-up	21 (3)	1 (<1)	22 (3)
Other	11 (2)	1 (<1)	12 (2)

Missing EOT data	5 (<1)	0	5 (<1)
Sustained virologic response, n (%; 95% CI)	306 (43; 39-47)	36 (47; 36-59)	342 (43; 40-47)
Adverse events, n (%)	688 (97)	74 (97)	762 (97)
Anaemia	488 (69)	63 (83)	551 (70)
Rash	399 (56)	38 (50)	437 (55)
Anorectal symptoms	250 (35)	27 (36)	277 (35)
Infection	122 (17)	16 (21)	138 (18)
Decompensating event	41 (6)	18 (24)	59 (7)
Dysgeusia	31 (4)	2 (3)	33 (4)
Serious adverse events, n (%)	92 (13)	25 (33)	117 (15)
Anaemia	29 (4)	8 (11)	37 (5)
Infection	30 (4)	7 (9)	37 (5)
Decompensation	8 (1)	6 (8)	14 (2)
Rash	5 (<1)	1 (<1)	6 (<1)
Anorectal symptoms	4 (<1)	1 (<1)	5 (<1)
Dysgeusia	0	0	0
Anaemia management, n (%)			
Ribavirin dose reduction	345 (48)	40 (53)	385 (49)
Epoetin use	290 (41)	38 (50)	328 (42)
Blood transfusion	106 (15)	16 (21)	122 (15)
Ribavirin interruptions	23 (3)	3 (4)	26 (3)
Deaths, n	2	1	3