HCV-TARGET

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APRIL 2013 INTERIM ANALYSIS

Presented at the 48th Annual Meeting of the European Association for the Study of the Liver • April 24-28, 2013

The Hepatitis C Therapeutic Registry and Research Network, or HCV-TARGET, is an international research consortium created to inform the ongoing transformation of hepatitis C treatment and research. Led jointly by the University of Florida and the University of North Carolina at Chapel Hill, HCV-TARGET includes 103 academic and community sites in 31 states, Puerto Rico, Canada and Europe as well as partnerships with multiple industry sponsors, regulatory agencies and the patient advocacy community. As more patients get tested for hepatitis C and as new treatments enter the market, HCV-TARGET aims to objectively reflect, inform and improve the hepatitis C patient experience across diverse populations.

Disclosures: HCV-TARGET is conducting an investigator-initiated observational study jointly sponsored by UF and UNC and funded in part by Vertex; Merck; Kadmon; and Genentech through PEGBASE: An Observational Study. Co-PI Dr. Michael W. Fried (UNC) receives research grant support and serves as ad hoc consultant to Genentech, Vertex, Merck, Gilead, Bristol Myers Squibb and Abbott. Co-PI Dr. David R. Nelson (UF) receives grant support from Genentech, Kadmon, Merck, Vertex Pharmaceuticals, Gilead, Boehringer Ingelheim and Abbott/Abbvie; and payment for the development of educational presentations from Clinical Care Options, Rush University Medical Center, Practice Point Communications and Chronic Liver Disease Foundation.

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APRIL 2013 INTERIM ANALYSIS SUMMARY

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A Longitudinal, Observational Study of North American Patients with Chronic Hepatitis C Treated with Boceprevir or Telaprevir (#574)

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HCV-TARGET is a consortium of academic (n=44) and community (n=59) medical centers conducting an ongoing study characterizing the use of FDA-approved direct-acting antiviral agents across a broad spectrum of clinical practices in the U.S., Canada and Europe (ClinicalTrials.gov Identifier: NCT01474811). HCV-TARGET releases interim analyses each spring and fall to improve information on populations represented and underrepresented in phase III clinical trials and identify and remediate educational gaps and adverse event management.

Aim: To evaluate the safety and efficacy of triple therapy in a broad population of patients treated in North America, including patients with cirrhosis and other underrepresented populations

Methods for interim evaluation of available data through April 2013:

- Data from sequentially enrolled patients treated with boceprevir or telaprevir captured within a common database utilizing novel, standardized source data abstraction
- Demographic, clinical, adverse event, and virological data collected throughout treatment and post-treatment follow-up
- Whole blood for DNA and serum from specified time points stored at a central biorepository

PATIENT CHARACTERISTICS

Patient Characteristics at Time of April 2013 Analysis	Total (n= 1457)	Telaprevir (n=1079)	Boceprevir (n=342)
Age, years (Mean) 18-39 years (n,%) 40-64 years 65 and older	62 years 123 (8%) 1160 (80%) 104 (7%)	59.5 years 92 (9%) 887 (82%) 73 (7%)	67.1 years 31 (9%) 270 (79%) 31 (9%)
Gender Male/Female	60%/40%	60%/40%	62%/38%
BMI	29.4	29.7	28.8
Race or Ethnicity Caucasian African-American Asian Hispanic	1056 (72%) 300 (21%) 22 (2%) 95 (7%)	790 (73%) 223 (21%) 16 (1%) 76 (7%)	245 (72%) 72 (21%) 6 (2) 18 (5%)
HCV Genotype 1a 1b 1 (No subtype) 2,3,4	842 (58%) 283 (19%) 204 (14%) 16 (1%)	639 (59%) 207 (19%) 152 (14%) 11 (1%)	192 (56%) 70 (20%) 45 (13%) 4 (1%)
Cirrhosis	550 (38%)	437 (41%)	106 (31%)
Prior treatment status Naïve Treatment-experienced	720 (49%) 714 (49%)	526 (49%) 547 (51%)	182 (53%) 154 (45%)

INTERIM FINDINGS

Key findings from the interim evaluation of North American data available through April 2013:

- The safety and on-treatment efficacy of telaprevir and boceprevir in the real-world setting are comparable to that observed in registration trials
- Although no new safety signals were observed, anemia emerged as the most relevant adverse event impacting clinical care
  - Ribavirin dose reductions were frequent and minimized the use of EPO and/or transfusions
- Patients with cirrhosis were at increased risk for severe anemia (22% vs 14% in non-cirrhotics) and early treatment discontinuation due to adverse events (12% vs 7%)
  - Hepatic decompensation occurred in 11% of patients with cirrhosis (vs. 1% for non-cirrhotics) and 2 of these died from sepsis-related events
  - Predictors of these adverse outcomes are under investigation
- Patients continue to be followed to assess sustained virologic response rates for the entire cohort