

VIRAL HEPATITIS STUDIES @ Johns HopkinsHeather Thomas: hctomas@jhmi.edu or 410 616-2826 or pagerboxMark Sulkowski: msulkowski@jhmi.edu or cell 410 241-1966 or pagerbox

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Study	Population	Study Drug	Compensated cirrhosis allowed?	Key inclusion and/or exclusion	Open for enrollment?
GS-US-196-103: Phase 2b, Randomized, Double-Blind, Placebo-Controlled Trial Comparing 24 or 48 Weeks of GS-9190 + PEG2a + RBV to 48 Weeks of PEG2a/RBV	Naïve Geno 1	Polymerase - GS-9190	No [by FibroSURE test at screen]	18 – 65 yrs BMI < 36 HBA1C < 7 Plt > 100K WBC > 2500 Hb > 11 TSH nl	Yes
P05104: SCH 900518 + PEG2b + RBV in Previously Untreated Subjects	Naïve Geno 1	Protease – SCH900518 + Ritonavir QD	No F3 or F4 Biopsy w/in 5 yrs	18 – 55 yrs Plt > 150K TSH nl No gallstones	Late Jan 2009
VX-950-C216: A randomized, double-blind, placebo-controlled, Phase III trial of Telaprevir + PEG + RBV	Partial Responders (> 2 log ₁₀ at wk 12) or relapse Geno 1	Protease - Telaprevir	Yes Biopsy w/in 18 months	18 – 70 yrs Prior Rx well documented Plt > 90K ANC > 1200	Yes
A Phase 1, Double-blind, Randomized, Placebo-controlled, Safety and PK Dose-escalation Study of a Single Intravenous Administration of MDX-1106, a Human Monoclonal Antibody to PD-1	Non-responder or Relapse Geno 1	Anti-PD-1 antibody – IV single dose	No F3 or F4 Biopsy w/in 2 yrs	> 18 yrs Plt > 125K HB > 11 ANC > 1500	Yes
P05685: A Phase 3, Safety and Efficacy Study of Boceprevir + PEG + RBV in Subjects Who Failed Prior Treatment	Partial Responders (> 2 log ₁₀ at wk 12) or relapse Geno 1	Protease – Boceprevir	Yes Biopsy w/in 3 yrs	> 18 yrs < 125 Kg No RBV within 90 days Plt < 100K Hb < 12	Feb 2009
BI 1220.5 : daily BI 201335 + PEG2a + RBV in hepatitis C virus genotype 1 infected treatment-naïve patients	Naïve Geno 1	Protease BI 1335 QD	No	18 – 65 yrs HCV > 100,000 Plt < 100K ANC < 1500	Feb 2009