Results of Boehringer Ingelheim Oral Hepatitis C Protease Inhibitor and Polymerase Inhibitor Combination Phase Ib Trial Shows Rapid Viral Response Without Use of Pegylated Int...

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BOSTON and RIDGEFIELD, Conn., Oct. 30, 2010 /PRNewswire/ -- Boehringer Ingelheim Pharmaceuticals, Inc. announced today results from a Phase Ib study, SOUND-C1, that showed the combination of two oral hepatitis C virus (HCV) compounds, the protease inhibitor BI 201335 and the polymerase inhibitor BI 207127, with ribavirin reduced viral load below the lower limit of quantifiable levels in HCV treatment-naive patients. The regimen did not include interferon through the first 28 days of treatment. These data are being presented at the American Association for the Study of Liver Diseases (AASLD) 2010 Liver Meeting in Boston, MA.

(Poster LB-7) New protease-polymerase inhibitor combination resulted in 73-100% rapid virological responses without pegylated interferonIn this randomized open-label trial, 32 treatment-naive genotype-1 HCV patients received BI 207127 in either 400mg or 600mg doses three times a day (TID), BI 201335 120mg once daily (QD) and ribavirin (RBV) (1000/1200mg daily in two doses) for 28 days. All patients had a rapid and sharp decline in HCV viral load during the first two days, followed by a slower second phase decline. In the lower and higher dose groups, 73 and 100% of patients achieved a rapid virological response (i.e. HCV RNA below lower limit of quantification after 4 weeks of treatment). One patient experienced a viral breakthrough (increase by >1 LOG10 from nadir during treatment) and one other experienced a 0.7 LOG10 increase in viral load. Both were in the lower dose group of BI 207127 and were patients with high baseline viral load. On day 29, all patients were switched to treatment with BI 201335 and PegIFN/RBV for an additional 44 weeks per the defined study protocol, and will be followed to evaluate sustained virological response.

"The current standard-of-care, PegIFN/RBV, is challenging for patients with chronic hepatitis C due to significant side effects that impact treatment adherence and has suboptimal response
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