

Quadruple therapy shows 100 percent SVR for HCV patients previously unresponsive to treatment

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Berlin, Germany, Saturday 02 April 2011: Exciting new data presented today at the International Liver CongressTM 2011 show that quadruple therapy in chronic hepatitis C (HCV) patients suppressed the emergence of resistant variants and resulted in a 100% rate of sustained virological response - undetectable HCV RNA - 12 weeks after treatment (SVR12).¹

In the quadruple therapy study, HCV patients were given four drugs in combination; pegylated Interferon-alpha (PegIFN-alpha); ribavirin (RBV); and two different direct-acting antivirals (DAAs) BMS-650032 (an HCV NS3 protease inhibitor) and BMS-790052 (an HCV NS5A replication complex inhibitor).

The current standard of care (SoC) for HCV therapy is PegIFN-alpha plus RBV - a dual therapy. The addition of DAAs (currently in phase-III clinical trials) marks the next step in treatment evolution - a triple therapy. However, the new data presented today suggests that quadruple therapy could be the next generation of treatment for chronic HCV patients.

Professor Heiner Wedemeyer, EASL'S Secretary General, said: "Quadruple therapy is possibly the future of HCV treatment; this study goes a way to confirming that. While it's expected that the first DAAs and triple therapy will be approved for use later this year, quadruple therapy appears to have a more profound effect on virological response, with less of a resistance problem."

The study may also provide new hope for a growing number of HCV patients who cannot be effectively treated for chronic <u>hepatitis</u> with current treatments.

The Phase-IIa trial looked at a cohort of 21 HCV

genotype 1 null responders (patients who have failed to respond to previous treatment), of whom 19 had an unfavourable IL28B genotype, which predisposes HCV patients to treatment failure.

Only about 30% of null responders to PegIFN-alpha/RBV treatment achieve sustained virological response (SVR) when retreated with PegIFN-alpha/RBV plus telaprevir, demonstrating a high unmet medical need.1

More information: 1. Lok A et al. Quadruple therapy with BMS-790052, BMS-650032 and peg-IFNRBV for 24 weeks results in 100% SVR12 in HCV genotype 1 null responders. Abstract presented at The International Liver CongressTM 2011.

www1.easl.eu/easl2011/program/Orals/418.htm

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