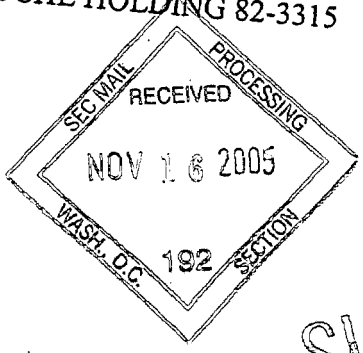
# Group News


Roche

SUPPL

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## Early results show Pegasys working where Peg-Intron has failed

**Study results provide hope for hepatitis C patients who could not be cured of their disease**

Early results evaluating re-treatment strategies using Pegasys plus Copegus show benefit in patients who had been unsuccessfully treated with another pegylated interferon (Peg-Intron plus ribavirin). This means that hope may be at hand for the large and growing group of patients who could not initially be cured of their hepatitis C virus. Preliminary results from the large international trial called REPEAT[1] show that 47% of patients treated with the standard combination of Pegasys plus Copegus have undetectable amounts of virus or have a significant reduction in viral load at the important 12 week assessment. In addition, 64% of patients who received an innovative induction dose of Pegasys achieved this early viral response.

The results presented today at the American Society for the Study of the Liver (AASLD) reflect findings from the first 12 weeks of therapy from this ongoing study. These early results typically act as an excellent indicator of whether or not a person will be cured of their disease after completing the full course of therapy.

"These are very positive results for patients who have not responded to previous therapy," said Professor Patrick Marcellin, from the Hôpital Beaujon, France and one of the lead investigators of the study. "Previously these patients would have been considered difficult to treat; now there is hope for a cure."

"This is a further example of Roche defining new treatment strategies resulting in optimal therapeutic approaches for the hepatitis C patient population," said Eduard Holdener, Global Head Pharma Development at Roche. "These new results have pioneered a new solution for patients who have not responded to first-line treatments."

One of the biggest challenges in the treatment of hepatitis C patients is to find treatment options for those who do not respond to primary treatments. These new data become available at a time when a report from a large study mandated by the US health authority demonstrated that Peg-Intron was not able to generate sustained viral response in more than 50% of patients receiving Peg-Intron as a first line treatment.[2]

The key findings of the 12 week results from the REPEAT study published at AASLD include:

- Amongst patients receiving a standard dose of Pegasys (180 mcg) given with Copegus for the first 12 weeks of therapy, 47% achieved an early viral response, defined as having a significant drop in viral load or being virus free
- Amongst patients receiving the induction dose of Pegasys (360 mcg) given with Copegus for the first 12 weeks of therapy, 64% achieved an early viral response, defined as having a significant drop in viral load or being virus free
- Interim safety data also presented at the conference indicate that the innovative induction dose of Pegasys for 12 weeks given with Copegus is tolerated as well as the standard dose of Pegasys plus Copegus[3]
- The 12 week results from all 942 patients who received treatment in the trial will be presented in the late breaking session during AASLD

The final results of the REPEAT study are expected to be available in 2007.

Creating hope from despair

"Imagine being told that you might be cured of a disease when you thought there was no chance," said Maureen Bromage from the Eddystone Trust, Plymouth, UK. "Treatment options, like those being tested in the REPEAT trial, are needed for patients who have been unable to clear the virus after their first treatment" she said.

About REPEAT

The study presented at AASLD is known as REPEAT – REtreatment with PEgInteferon alfa2a in PATients not responding to prior peginterferon alfa2b/ribavirin combination therapy. Its purpose is to evaluate the efficacy and safety of Pegasys and Copegus combination therapy in patients who were unable to be cured using PegIntron combination therapy. In this innovative study, Pegasys and Copegus are given for the traditional 48 week period or a longer 72 week period, as well as with or without an induction dose of Pegasys for the first 12 weeks of therapy. 950 patients were randomised in the REPEAT study from Europe, North America and Latin America.

Pegasys – The Right Solution for More Patients

Pegasys is the most frequently prescribed pegylated interferon for patients infected with hepatitis C. An extensive clinical study programme has demonstrated its safety and efficacy in the broadest range of patients including those with difficult-to-treat disease. The benefits of Pegasys are derived from its unique 40 kilodalton branched PEG molecule which ensures sustained viral control for patients throughout the once-weekly dosing interval.

In addition to becoming the only treatment approved for hepatitis C patients who are co-infected with HIV, Pegasys is also the only approved medication in the EU for hepatitis C patients with 'normal' levels of alanine aminotransferases (ALT) - a patient population previously thought not to benefit from treatment. Pegasys also been approved in over 40 countries around the world for the treatment of chronic hepatitis B including the EU, Switzerland, Hong Kong, New Zealand, Taiwan and Thailand and is the only pegylated interferon with this indication.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of drugs for cancer and transplantation and a market leader in virology. In 2004 sales by the Pharmaceuticals Division totalled 21.7 billion Swiss francs, while the Diagnostics Division posted sales of 7.8 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).



Further information:

About hepatitis C: www.health-kiosk.ch/start_hepa

About Roche in virology: www.roche-hiv.com

References:

1. Marcellin, P et al. "Efficacy Analysis of the 12-week induction period of the REPEAT study" Study presented at the 56th Annual Meeting of the American Association for the Study of Liver Diseases.
2. Jacobson I, Brown N, Fridlich B et al. Weight-Based Ribavirin Dosing (WBD) Increases Sustained Viral Response (SVR) in Patients With Chronic Hepatitis C (CHC): Final Results of the WIN-R Study, A US Community Based Trial. Abstract number LB03 at: 56th Annual Meeting of the American Association for the Study of Liver Diseases,

San Francisco, CA, Nov. 11 -15, 2005.
3. Marcellin, P et al. "Interim safety analysis of patients enrolled in the randomized, international REPEAT study. Study presented at the 56th Annual Meeting of the American Association for the Study of Liver Diseases.

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