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European approval for Roche's Pegasys personalises treatment for a subgroup of hepatitis C patients: chance for cure with only four months of treatment

Roche also announces start of NCORE study to determine best length of treatment in patients who do not experience a rapid response

Roche announced today that the European Commission has approved a shortened, 16-week course of treatment with Pegasys (peginterferon alfa-2a (40 KD)) plus Copegus (ribavirin) for certain hepatitis C patients.

The four-month treatment course will be for patients with particular strains of chronic hepatitis C (genotype 2 or 3) who have low virus levels before starting treatment, and who show a rapid virological response by clearing the virus from the blood within the first 4 weeks of treatment. This shorter treatment duration with Pegasys/Copegus will provide patients with the full benefits of therapy while reducing unnecessary drug exposure.

This is good news for eligible patients as previously, all patients with genotype 2 or 3 hepatitis C (HCV) received 24 weeks of Pegasys/Copegus therapy, regardless of their baseline virus levels and response while on treatment.

The approval marks an important milestone in a new treatment concept in hepatitis C, which is called "response-guided therapy" and seeks to customise regimens for patients based on how well they respond to treatment. Response-guided therapy is enabled by the use of Roche's highly sensitive, real-time PCR diagnostic tests, which accurately measure the levels of virus in the patient's blood. The automated COBAS AmpliPrep/COBAS TaqMan HCV Test is the newest and most advanced Roche product for measuring hepatitis C virus levels. The test is widely used in many global markets, and is pending FDA approval in the United States.

"Response-guided therapy in hepatitis C is an excellent example of how Roche is uniquely positioned to

individualise healthcare and deliver real benefit to patients, physicians and healthcare payers by combining the power of innovative pharmaceuticals and diagnostics,” said William M. Burns, CEO, Roche Pharmaceuticals Division. “This approval for 16 weeks of treatment in genotype 2 and 3 patients with a rapid response demonstrates the value of using diagnostic tools to determine an individual treatment regimen and hopefully will encourage more eligible patients to come forward for treatment. Together with the start of yet another large clinical study with Pegasys, NCORE, these initiatives underscore Roche’s commitment to advancing the treatment of hepatitis and making personalised medicine a reality”.

Shortening the Treatment Duration for Many

This approval is based on data from several studies that show shorter treatment duration in patients who have a rapid response to Pegasys/Copegus results in high cure rates, similar to those achieved with the currently-approved 24 weeks of therapy.¹⁻⁴ An analysis of a major study (ACCELERATE) which evaluated the efficacy and safety of 16 weeks vs. 24 weeks of treatment with Pegasys/Copegus in patients with genotype 2 or 3 HCV -- showed that a similar number of patients achieved a cure (82% versus 90% respectively). In patients with low virus levels before treatment and a rapid virological response (undetectable virus 4 weeks after starting treatment), the cure rates for 16 and 24 weeks of treatment were essentially identical (89% vs. 94%).⁵

“This EU approval is important, as it means that we can tailor a patient’s treatment with Pegasys based on an early marker of response without a loss in the regimen’s effectiveness” said Prof Stefan Zeuzem, Chief of the Department of Medicine I at the Johann-Wolfgang Goethe University Hospital in Frankfurt, Germany. “This is good news for doctors, who now have the reassurance of offering a shorter treatment regimen, and for patients themselves, who will have the possibility to be cured with only 16 weeks of treatment”.

NCORE Study Commenced to Determine If Genotype 2/3 Patients Without a Rapid Virological Response Need Longer Treatment

Roche also announced the launch of the NCORE study (ENhancement of Cure Through Treatment Extension Guided by On-Treatment ResponsE in Patients Infected with G2/3 Hepatitis C; Roche study protocol number MV21371). The study aims to further improve treatment outcomes by examining whether genotype 2 and 3 patients who do not have a rapid virological response at 4 weeks should have treatment with Pegasys and Copegus extended to 48 weeks.⁶ This global study will enrol approximately 400 patients at 90 centres in seven countries.

About Hepatitis C

The hepatitis C virus (HCV) is transmitted primarily through blood or blood products. HCV chronically affects 180 million people worldwide, which makes it over four times more prevalent than HIV.^{7,8} It is a leading cause of cirrhosis, liver cancer and liver failure, despite the fact that many patients can be cured.

About Roche

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