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European Commission approval of new indication for Roche's Pegasys offers hepatitis C patients a second chance for a cure

Pegasys is the first and only pegylated interferon to be approved for treatment of up to 72 weeks in treatment-experienced patients

Roche announced today that the European Commission has approved Pegasys (peginterferon alfa-2a [40 KD]) plus Copegus (ribavirin) for the retreatment of hepatitis C patients who were not successfully treated with an initial course of interferon alpha (pegylated or non-pegylated), either alone or in combination with ribavirin.

Although exciting advances in the treatment of hepatitis C have been made in recent years, a significant number of patients do not achieve treatment success (sustained virological response [SVR], widely equated to cure¹) with their first treatment. This results in a large and growing population of patients who urgently need alternative treatment solutions. Today's approval provides a significantly broader indication for Pegasys and establishes a new standard of care for treatment-experienced patients with the most difficult-to-treat virus.

“This new indication for Pegasys plus Copegus is another demonstration of Roche's commitment to extend the promise of a cure to as many chronic hepatitis C patients as possible,” said William M. Burns, CEO, Roche Pharmaceuticals Division. “Our approach is to optimise and individualise treatment to increase patients' chance of success with Pegasys and Copegus, while establishing them as the backbone for combination with novel agents in development, both by Roche and through external partnerships and collaborations”.

The Pegasys label for treatment-experienced patients contains several aspects of Personalised Healthcare, a major focus for Roche which seeks to tailor medicines for better disease management:

- The recommended length of Pegasys treatment for patients is based on their virus genotype and type of prior treatment. For patients with genotype 1 virus who did not respond to initial

treatment with pegylated interferon and ribavirin, it is recommended that they be retreated with Pegasys for an extended period of 72 weeks. Pegasys is now the first and only pegylated interferon to be approved for a 72-week treatment duration in this patient population. For all other treatment-experienced patients, the recommended treatment period is 48 weeks.

- The label recommends that after 12 weeks of treatment, a patient's virus levels be measured to determine whether a full course of treatment is likely to result in a cure.

A large, Roche-sponsored study called REPEAT demonstrated that 72 weeks of retreatment with Pegasys plus Copegus doubled the chance of achieving a cure, compared to 48 weeks, in patients who were prior non-responders to PegIntron (peginterferon alfa-2b) and ribavirin. Furthermore, the study showed that 57% of patients who responded by week 12 (defined as HCV RNA levels of less than 50 IU/mL) went on to achieve a cure with 72 total weeks of retreatment.

“The high predictability of response at week 12 with Pegasys plus Copegus should be an important factor when considering whether to retreat hepatitis C,” said Prof Patrick Marcellin, Professor of Hepatology at the University of Paris and Head of the Viral Hepatitis Research Unit in Hôpital Beaujon, Clichy, France. “It means that physicians and patients will be able to determine -- after only three months -- whether treatment is likely to result in a cure”.

The safety profile for Pegasys plus Copegus in prior non-responders was similar to that seen in patients being treated for the first time. Further analyses of the 72-week treatment in REPEAT showed a favourable benefit/risk ratio for the longer duration, because more patients were able to achieve a cure than with 48 weeks of therapy.²

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.³⁻⁴ It is a leading cause of cirrhosis, liver cancer and liver failure, despite the fact that many patients can be cured. In Europe alone, HCV is estimated to cause more than 86,000 deaths every year.⁵

A recent study examining the HCV-related burden of disease in 22 European countries estimated that 7.3-8.8 million people are infected with HCV, representing 1.1-1.3% of the population. The report also found that no uniform HCV surveillance exists at the European level, and that authorities need to work on an EU-wide,

consistent surveillance system for HCV.⁶

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 the world's biggest biotech company and an innovator of 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 the world leader in in-vitro diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2007 sales by the Pharmaceuticals Division totalled 36.8 billion Swiss francs, and the Diagnostics Division posted sales of 9.3 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested over 8 billion Swiss francs in R&D in 2007. Worldwide, the Group employs about 80,000 people. Additional information is available on the Internet at www.roche.com.

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Further information

-About Hepatitis, Roche Health Kiosk: www.health-kiosk.ch/start_hepa.htm

-About Pegasys and Hepatitis: www.roche.com/products/product-details.htm?type=product&id=86

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2. Marcellin P, Craxi A, Brandão-Mello C, Di Bisceglie A. A 72-week treatment duration with peginterferon alfa-2a (40KD) (PEGASYS) plus ribavirin (COPEGUS) has a favorable risk:benefit ratio in non-responders to pegylated interferon alfa-2b (12KD) plus ribavirin: findings of the multinational REPEAT study. Abstract presented at the American Association for the Study of Liver Disease; 31 October 2008; San Francisco, California, USA.
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4. World Health Organization. Initiative for Vaccine Research, Viral Cancers, Hepatitis C. 2006. (Accessed July 24, 2006, at http://www.who.int/vaccine_research/diseases/viral_cancers/en/index2.html.)
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