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Roche's Pegasys receives EU approval for the treatment of chronic hepatitis C in children five years of age and older

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Medicines Agency (EMA) has expanded the approval of Pegasys (peginterferon alfa-2a) plus ribavirin for the treatment of chronic hepatitis C virus (HCV). The new label includes children and adolescents five years of age and older, who have not received treatment and who have tested positive for the virus.¹ Pegasys in combination with the antiviral ribavirin is the foundation of treatment for chronic HCV in adults. The medicine was first approved in the European Union over ten years ago.¹

“Hepatitis C can ultimately lead to the development of advanced liver disease if left untreated. This approval provides doctors and parents of children as young as five with a treatment combination for this infection,” said Hal Barron, MD, Roche’s Head of Global Product Development and Chief Medical Officer.

Mother-to-child transmission of HCV is the most common route of acquiring the infection in children,^{2,3} with approximately 65,000 children estimated to live with chronic HCV in Europe.⁴⁻⁶ While the minority of children (4–10%) born to infected mothers become infected, 80% of these children will develop chronic disease.^{2,3} Most children infected with chronic HCV do not have any symptoms, but the disease is progressive and can lead to advanced liver damage (cirrhosis), liver cancer and end-stage liver disease.^{2,3,7}

The approval of Pegasys plus ribavirin provides an important additional treatment option for these children.

About the study

The expanded EMA approval is based on a randomised controlled trial involving 114 children between the ages of five and 17 years with chronic HCV. The study assessed the efficacy of Pegasys in combination with ribavirin, as compared to treatment with Pegasys alone. The study showed that treatment with Pegasys plus ribavirin achieved sustained viral response (undetectable HCV ribonucleic acid [RNA] in the blood 24 weeks after completion of treatment) in over half of the children treated (53%), compared with 21% of children who received Pegasys alone.⁸ The majority of patients were infected with HCV genotype 1, a difficult-to-treat

genotype. These results in children and adolescents are consistent with the pattern of response rates seen in adults infected with HCV genotype 1 treated with this combination of medicines.⁹

About Pegasys

Pegasys is approved for the treatment of a broad range of adult patients, including those with chronic HCV, human immunodeficiency virus (HIV)/HCV co-infection and chronic hepatitis B. Pegasys is a modified form of interferon, a naturally occurring protein produced by the body to fight viruses. The medicine is made by attaching a branched 40KD polyethylene glycol chain to interferon alfa, which allows the interferon to be absorbed more slowly and stay active in the body longer. Pegasys is administered as a once-a-week injection at a dose of 180µg in adults and is dosed according to Body Surface Area (BSA) in children.

Personalised healthcare in hepatitis C

In a rapidly changing treatment landscape, tests that can detect and measure the amount of virus in the blood (HCV RNA) are important to optimise the treatment choices and treatment durations. Roche provides a diagnostic test which helps tailoring treatment to patients of all age groups. This is a good example of personalised healthcare, delivering real benefit to patients by combining pharmaceuticals and diagnostics.

About hepatitis C

Hepatitis C is transmitted primarily through blood or blood products. Hepatitis C chronically infects approximately 150 million people worldwide,⁷ with 3–4 million people newly infected with the virus each year.¹⁰ HCV is a leading cause of cirrhosis, liver cancer and liver failure, despite the fact that many patients can be cured. Approximately nine million people carry the virus in Europe, with the virus estimated to cause more than 86,000 deaths every year in this region alone.¹¹

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, infectious diseases, inflammation, metabolism and neuroscience. Roche is also the world leader in *in vitro* diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2012 Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche

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