Media Release

Roche

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US FDA Advisory Committee unanimously recommends approval of Pegasys (peginterferon alfa-2a) in combination with Copegus (ribavirin) for treatment of hepatitis C

Roche announced today that the U.S. Food and Drug Administration (FDA) Anti-Viral Drugs Advisory Committee (AVDAC) unanimously voted to recommend marketing approval of Pegasys (peginterferon alfa-2a) in combination with Copegus (ribavirin) for the treatment of chronic hepatitis C.

AVDAC's vote to recommend approval was made after Roche presented results of two pivotal Phase III clinical trials that demonstrate combination therapy with Pegasys and Copegus is a more effective treatment for patients with chronic hepatitis C than treatment with interferon alfa-2b and ribavirin or Pegasys monotherapy.

Pegasys, in combination with Copegus, was granted six-month Priority Review Status in July of this year and Roche anticipates action on the file by the end of the year. This designation is granted to biologics and drugs that if approved, address unmet medical needs, offering a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious or life-threatening disease, according to FDA policies and procedures.

"This is a major step forward towards our approval in the United States and we are very pleased with the committee's recommendation. We commend the committee on its thorough analysis of Roche's extensive clinical development program," said William Burns, head of the pharmaceutical division at Roche. "Our studies have also led the way in being able to reduce the duration and dose

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of therapy for certain patient groups, which leads to improved safety, while not compromising efficacy."

Pegasys monotherapy was approved by the FDA on October 16, 2002 as a simple, fixed dose of 180 mcg for the treatment of adults with chronic hepatitis C who have compensated liver disease and have not previously been treated with interferon alfa. Patients in whom efficacy was demonstrated included patients with compensated cirrhosis. Clinical trials of Pegasys have shown that patients can determine at 12 weeks if they are unlikely to obtain a sustained virological response with Pegasys monotherapy.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-orientated healthcare groups. The company's two core businesses in pharmaceuticals and diagnostics provide innovative products and services, that address prevention, diagnosis, and treatment of diseases, thus enhancing people's health and quality of life. The two core businesses achieved a turnover of 19.3 billion Swiss Francs in the first three quarters of 2002 and employed about 57'000 employees worldwide.

Roche is committed to the viral hepatitis disease area, having introduced Roferon-A for hepatitis B and then C, followed by Pegasys in hepatitis C. Pegasys is also in phase III clinical development for patients infected with the HBV virus. Roche manufactures and sells the Amplicor HCV Test (v2.0) and the Amplicor HCV Monitor Test (v2.0) - two tests used to detect the presence of HCV RNA (Ribo Nucleid Acid) in a person's blood. Roche's commitment to hepatitis has been further reinforced by the in-licensing of Levovirin, an alternative antiviral. Levovirin will be studied with the objective of demonstrating superior tolerability over the current standard, ribavirin.

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