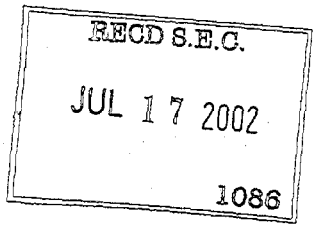
# *Media release*


SUPPL

Basel, 15 July 2002

## Priority review for Pegasys combination treatment of hepatitis C granted by US FDA

**Pegasys and Copegus clinical data address existing unmet medical needs**

Roche announced today that the U.S. Food and Drug Administration (FDA) has granted a six-month Priority Review Status to the Biologics License Application (BLA) and the New Drug Application (NDA) for Roche's combination therapy of Pegasys, peginterferon alfa-2a (40KD), and Copegus (Roche's own ribavirin) tablets, for the treatment of chronic hepatitis C in patients without cirrhosis and with cirrhosis with compensated liver disease. Roche filed the BLA and NDA for Pegasys and Copegus in June, 2002 and approval action is expected by the end of the year.



Priority designation is only granted to biologics or drug products that address unmet medical needs offering significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious or life-threatening disease according to the FDA.

"The FDA's priority review designation for this application is an acknowledgement that Pegasys in combination with our Copegus provide new and important benefits to patients over the currently available treatments in the United States," said William M. Burns, Head of Pharma for Roche worldwide.

In addition, the FDA is also reviewing Pegasys monotherapy data and the approval process is underway. Pegasys combination therapy data filed with the FDA includes findings from two landmark clinical trials: a head-to-head study against the standard of care, interferon alfa-2b and ribavirin; and a trial to evaluate the dose of ribavirin and duration of therapy in patients with genotype 1 and genotype non-1. Roche's Pegasys combination filing also includes data regarding predictability of a patient's response at week 12 to Pegasys combination therapy.

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***Extensive development program***

Pegasys is supported by the most extensive development program ever undertaken for a hepatitis C

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treatment, having been studied in nearly 20,000 patients ranging from those with the most difficult to treat form of the disease (genotype 1) and those with cirrhosis (scarring of the liver), to other special populations, such as in individuals co-infected with HIV and patients with end-stage renal disease.

*About Pegasys*

Pegasys, peginterferon alfa-2a (40KD), a new generation hepatitis C therapy that is different by design, is unique in providing benefit over existing therapy in patients of all genotypes. The benefits of Pegasys are derived from its new generation large 40 kilodalton branched-chain polyethylene glycol (PEG) construction, which allows for true seven-day viral suppression and is preferentially distributed to the liver, the primary site of infection. Pegasys is administered once weekly in an easy-to-use pre-filled syringe with one starting dose for everyone.

In June Pegasys monotherapy and combination therapy was granted marketing authorization by the European Commission, making it immediately available in all European Union countries and paving the way for approvals in Central and Eastern European countries. Pegasys has been approved in 24 other countries since its first approval in Switzerland in August 2001. It is now also available in Argentina, Brazil, Bahrain, Belarus, Cambodia, Chile, Columbia, Costa Rica, Dominican Republic, Egypt, El Salvador, Ecuador, Guatemala, Israel, Kuwait, Mexico, Morocco, Panama, Peru, Russia, Syria, United Arab Emirates, Uruguay and Venezuela.

*About Roche*

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups in the fields of pharmaceuticals, diagnostics and vitamins. Roche's innovative products and services address needs for the prevention, diagnosis and treatment of disease, thus enhancing people's well-being and quality of life.

Roche is committed to the viral hepatitis disease area, having introduced Roferon-A for hepatitis C, followed by Pegasys in hepatitis C, with studies currently being conducted on its efficacy in hepatitis B. Roche also manufactures the COBAS AMPLICOR® HCV Test, v2.0 and the AMPLICOR HCV MONITOR™ Test, v2.0 - two tests used to detect the presence of, and quantify, HCV RNA 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.

# *Media Release*



Basel, 16 July 2002

## Xenical label change to incorporate new data on overweight and obese patients with type 2 diabetes granted by European Commission

Roche announced today that the European Commission has granted a label change for the company's leading weight loss medication, Xenical (orlistat). The new label includes additional and important information on the benefits of Xenical for overweight and obese patients with type 2 diabetes. The decision was based on the positive opinion adopted by the Committee for Proprietary Medicinal Products (CPMP) and is another important endorsement of a Roche application in the European Union this year.

Nine out of ten people with type 2 diabetes are overweight and weight management is the first-line treatment of type 2 diabetes. Even a modest reduction of initial body weight improves blood sugar control in patients with type 2 diabetes and also reduces the severity of cardiovascular risk factors such as high blood pressure and high cholesterol levels.

Xenical clinical studies show that:

- Overweight or obese patients with type 2 diabetes taking Xenical lost up to three times more weight than those on diet alone;
- More overweight or obese patients with type 2 diabetes taking Xenical had clinically significant improvements in blood sugar control than those on diet alone;
- Xenical significantly improves fasting plasma glucose in overweight or obese patients with type 2 diabetes within two weeks of starting treatment;
- Xenical may reduce the need for anti-diabetic medications in overweight patients with type 2 diabetes; and
- Additional data has also shown that Xenical can improve certain risk factors for cardiovascular disease, such as blood pressure and cholesterol levels in diabetic patients.

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It is estimated that there are at least 150 million people in the world with diabetes and that type 2 diabetes accounts for 90 per cent of all cases. This figure is expected to double over the next 25 years.

"This label change for Xenical marks an important step forward as it will allow physicians to address one of the core issues associated with type 2 diabetes – excess weight." commented William M. Burns, head of the pharmaceutical division at Roche.

**About Xenical**

Xenical is the only available weight loss medication that works locally in the gut to prevent dietary fat absorption by around 30 per cent and effectively promotes weight loss. It is an effective therapy that not only helps patients lose weight, but also helps them maintain their weight loss. Xenical is well tolerated and unlike appetite suppressants, it does not act on the brain. Since it was first marketed in 1998, there have been more than 13.6 million patient treatments with Xenical world-wide. Xenical is licensed for weight management in 149 countries around the world. For further information please go to: www.managingyourweight.com

**About Xenical Weight Management Programmes**

Roche has developed Xenical weight management programmes (WMPs) for healthcare professionals to use with their patients. The programme aims to help patients set and reach realistic weight goals while modifying their dietary intake and behaviour in the long-term. The programmes are individually tailored to help people achieve their weight loss goals, and maintain weight loss, through healthy eating, physical activity, behaviour modification and pharmacotherapy.

Roche provides free patient support programmes in around 50 countries worldwide to help support people taking Xenical. Recent data demonstrated that patients enrolled in Xenical WMPs can significantly improve the levels of weight loss achieved and can increase their overall satisfaction and compliance with treatment.

**About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-orientated healthcare groups in the fields of pharmaceuticals, diagnostics and vitamins. Roche's innovative products and services address prevention, diagnosis and treatment of diseases, thus enhancing people's well-being and quality of life.

**Roche International Award for Obesity Journalism**

The Roche International Award for Obesity Journalism is a new initiative to recognise excellence in overweight and obesity reporting. For more information and submission details, please visit www.managingyourweight.com/formedia/formedia_ja.cfm or contact obesityjournalism@shirehealthinternational.com.