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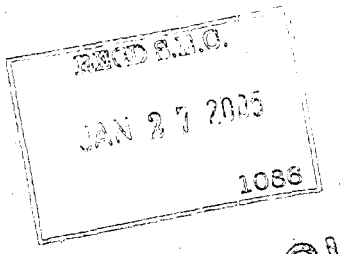

SUPPL

Basel, 21 January 2005

Pegasys receives positive opinion in the European Union for the treatment of chronic hepatitis B

First pegylated interferon to be indicated for treating chronic hepatitis B

Roche announced today that the Committee for Medicinal Products for Human Use (CHMP) has granted a positive opinion for Pegasys (peginterferon alfa-2a (40KD)) for the treatment of chronic hepatitis B. The decision is granted for both types of the disease - HBeAg-positive and HBeAg-negative chronic hepatitis B (CHB). The recommendation will now go to the EU Commission for final approval. Hepatitis B is a major public health concern with data suggesting that globally, more than 350 million people are infected with the virus and approximately one million die each year from the disease.

"Today marks another milestone in Pegasys' history as an effective antiviral agent," said Ciro Caravaggio, Head of the Hepatitis Franchise at Roche. "We set out to explore the potential of Pegasys in treating chronic hepatitis B and demonstrated its effectiveness against both forms of the virus and against the two leading medications used to treat it today, lamivudine and conventional interferon," he said. "It's also an achievement for Pegasys in that it becomes the only pegylated interferon indicated for the treatment of chronic hepatitis B."

In contrast to lamivudine, Pegasys works with a dual mode of action: it stimulates the immune system as well as inhibits virus replication. This offers physicians a new option with the advantages of a finite treatment duration and lasting remission from the disease, avoiding the burden of putting their patients on a life-long therapy.

"Studies have shown that Pegasys offers the best chance for a sustained response, in a defined treatment period, for chronic hepatitis B patients," said Professor Patrick Marcellin, Hepatologist at

F. Hoffmann-La Roche Ltd 4070 Basel, Switzerland Corporate Communications Tel. 061 - 688 88 88
Fax 061 - 688 27 75
http://www.roche.com

Hôpital Beaujon, Clichy, France and one of the lead investigators of the Phase III global studies. "Pegasys is an effective pegylated interferon, and the only one that has been studied directly against lamivudine. Its response against this agent, as well as interferon, support its use as first line therapy for chronic hepatitis B."

The studies on which the positive opinion has been granted

The CHMP positive opinion was based on one of the largest clinical development programmes in chronic hepatitis B, which included three global studies in more than 1,500 patients from 19 countries.

Pegasys has been proven twice as effective as conventional interferon for the treatment of the most common form of chronic hepatitis B, hepatitis B e antigen (HBeAg) -positive chronic hepatitis B, in a multinational phase II trial. These findings were published in the July 2003 *Journal of Viral Hepatitis.*[1]

Two large-scale multinational phase III trials, in patients with both the HBeAg-positive and HBeAg-negative forms of chronic hepatitis B, demonstrated that after 48 weeks of therapy, more patients achieved a sustained response with Pegasys than with lamivudine. Furthermore, these studies demonstrated that the addition of lamivudine to Pegasys did not improve response rates over Pegasys alone.

The phase III study results in HBeAg-negative chronic hepatitis B, which is particularly prevalent in the Mediterranean areas and is the most difficult-to-treat form of the disease, were published in September 2004 in the *New England Journal of Medicine.*[2] The results of the phase III study in patients with HBeAg-positive chronic hepatitis B were presented at the 2004 Annual Meeting of the American Association for the Study of Liver Diseases.[3] Both lead investigators have stated that the results of these trials warrant Pegasys becoming the first-line treatment for HBeAg-positive or HBeAg-negative chronic hepatitis B.

About Pegasys

Pegasys, a new generation hepatitis therapy that is different by design, has already become the worldwide market leader in hepatitis C. Pegasys has a dual immunomodulatory and antiviral mode of action. The improved pharmacokinetic profile ensures drug plasma concentrations are maintained at constant levels throughout the one week dosing interval. Pegasys therapy in chronic hepatitis B is given once weekly as a 180 µg subcutaneous injection for a 48-week period.

Pegasys has recently been approved for the treatment of chronic hepatitis B in Switzerland, Taiwan and Thailand. Approval in the US is expected this year.

Roche in Hepatitis

Roche is committed to the viral hepatitis disease area, having introduced Roferon-A for hepatitis B and C, followed by Pegasys in hepatitis C and a full development program in hepatitis B. Roche has its own brand of ribavirin, Copegus, which is used in conjunction with Roferon A or Pegasys for HCV. In addition, Roche manufactures HBV and HCV diagnostic and monitoring systems: The COBAS AMPLICOR Test, and the AMPLICOR MONITOR Test, two testing systems used to detect the presence of, and quantity of, HBV DNA or HCV RNA in a person's blood. Roche has received a positive opinion in the EU for a new indication for Pegasys and COPEGUS as a treatment for patients co-infected with HIV and HCV and it has also been filed in the United States. More than 40,000 patients worldwide continue to participate in trials with Pegasys and COPEGUS as Roche examines the unmet medical needs of hepatitis C patients. Roche's commitment to viral hepatitis also extends to its pursuit of strategic alliances and partnerships to develop new compounds for the future.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups. Its core businesses are pharmaceuticals and diagnostics. As a supplier of innovative products and services for the prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2003 the Pharmaceuticals Division generated 19.8 billion Swiss francs in prescription drug sales, while the Diagnostics Division posted sales of 7.4 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai.

Media Office contacts

Phone: +41 61 688 8888 / e-mail: basel.mediaoffice@roche.com

- Baschi Dürr
- Alexander Klauser
- Daniel Piller (Head of Group Media Office)
- Katja Prowald (Head of Science Communications)
- Martina Rupp

References

[1] Cooksley WG, Piratvisuth T, Lee SD, et al. Peginterferon alpha-2a (40 kDa): an advance in the treatment of hepatitis B e antigen-positive chronic hepatitis B. J Viral Hepat 2003; 10:298-305.

[2] Marcellin P, Lau GK, Bonino F, et al. Peginterferon alfa-2a alone, lamivudine alone, and the two in combination in patients with HBeAg-negative chronic hepatitis B. N Engl J Med 2004; 351:1206-17.

[3] Lau GK, et al. Peginterferon alfa-2a (40KD) (PEGASYS®) monotherapy and in combination with lamivudine is more effective than lamivudine monotherapy in HBeAg-positive chronic hepatitis B: results from a large, multinational study. Hepatology, 2004; Vol. 40 (4); Suppl. 1:171A

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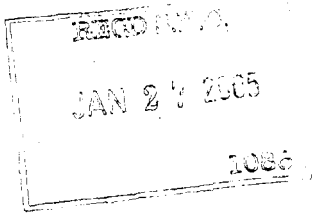

Basel, 21. January 2005

Roche to launch publicly accessible databases for clinical trials

Enhanced transparency through electronic databases for clinical trial protocol registration and reporting of results

Roche announced today that it is establishing a global clinical trial protocol registry to disclose information about new Phase II to Phase IV studies at or before their start. In addition, the company will create a global clinical trial results database for key results from completed trials. The new registry and results database will enable the coordination of data Roche publishes and ensure that ultimately, there is one global source for all Roche-sponsored clinical trial data. Both the clinical trial registry and results database, which will be hosted by an independent, neutral entity, will be available to the public via a website by the end of the first quarter 2005. The name of the organisation will be announced in due time.

Ed Holdener, Head of Global Pharma Development at Roche, commented: "Transparency on the results of its clinical studies has always been important to Roche. At the same time, it is important that we protect the safety and the rights of patients, and secure the quality and integrity of the data and related conclusions. Our current policy on the publication of clinical trial data will be further enhanced and consolidated by the creation of one electronic source of information. This clear and transparent approach is in the best interest of all parties involved."

The Roche approach is in accord with and even exceeds the information disclosure principles published earlier this year by the European Federation of Pharmaceutical Industry Associations (EFPIA).

Roche has always been dedicated to transparency in clinical trials and publishes both positive and negative results of late stage development trials. The company is now committed to creating both a clinical trial results database to ensure health care providers have ready access to new

F. Hoffmann-La Roche Ltd. CH-4070 Basel Corporate Communications Tel. 061 - 688 88 88
Fax 061 - 688 27 75
http://www.roche.com

information and a clinical trial registry to help patients and their physicians find clinical trials that may be appropriate for them.

Clinical trial information will be added in a staged approach on the results database and will ultimately include protocol information from all Phase II to Phase IV clinical trials completed on or after October 1, 2004. In addition, data from all Phase II to Phase IV clinical trials for products marketed on or after October 1, 2002 will be included retrospectively.

The clinical trial protocol registry

The clinical trial registry will serve as a global repository for information on ongoing Phase II through Phase IV clinical studies. It will contain information in layman's terms about each trial to inform the public, in particular patients and healthcare professionals, as to the trial's purpose and conditions of participation.

The clinical trial results database

The clinical trial results database will ensure the fair and balanced reporting of all Roche-sponsored clinical trials that might affect the practice of medicine.
Roche will also provide links to its global registry and database in local registries and databases, as appropriate and study results published in scientific journals will be referenced.

Strict adherence to regulations of clinical trials

Roche works to ensure that all its activities are performed in accordance with ethical and regulatory requirements. Moreover, Roche is strongly committed to verifying adherence to compliance policies. Adequate and ongoing peer review is a key prerequisite for maintaining high ethical standards in Roche's clinical trials and development activities.

In addition, Roche adheres to the "Declaration of Helsinki", a statement developed by the World Medical Association on ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Roche also strictly follows the rules of good clinical practice (GCP), which ensure the protection of patients' safety and rights.

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Further information

Roche and clinical trials: www.roche.com/sus_res_clin

Clinical trials: www.roche.com/sci_events_facets_clinical#sci_events_facets_clinical_text-Anchor3

EFPIA position statement: http://www.efpia.org/4_pos/sci_regu/Clinicaltrials2005.pdf

Declaration of Helsinki: www.wma.net/e/policy/b3.htm

Media Relations Contacts

Phone: +41 61 688 88 88 / e-mail: basel.mediaoffice@roche.com

- Baschi Dürr
- Alexander Klauser
- Daniel Piller (Head Roche Group Media Office)
- Katja Prowald (Head Science Communications)
- Martina Rupp

Roche Media Relations Contact in the US

Ms Darien Wilson, *ext.* 973 562 2232