

Basel, 20 October 2003

## **Pegasys becomes the first pegylated interferon approved in Japan for the treatment of hepatitis C**

**More than one million Japanese infected by the virus**

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Roche and Chugai Pharmaceutical Co., Ltd (Chugai), a member of the Roche Group, announced today that Chugai received approval to market Pegasys (peginterferon alfa-2a) in Japan for the treatment of chronic hepatitis C.

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The decision by the Ministry of Health, Labour and Welfare marks the approval of the first pegylated interferon in Japan, the world's second largest hepatitis C market'. Pegasys was recommended for approval on 8. August 2003 and Chugai is awaiting reimbursement clearance to launch it in Japan.

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"There are approximately 1.5 million people in Japan who have chronic hepatitis C and until today, the available medications have been either conventional interferon alone or combined with ribavirin," said William M Burns, Head of Roche's Pharmaceutical Division. "We believe the Japanese health authorities recognize that there are significant benefits from Pegasys therapy, as it was designated 'fast track' approval and this has occurred in under a year."

Patients will require a single once weekly injection of 180 mcg of Pegasys which is the approved dose regardless of body weight. This compares to the current practice of two initial weeks of daily injections of conventional interferon, followed by injections three times weekly. Burns noted: "We are confident that physicians in Japan will find Pegasys an effective, better tolerated and easier preparation to use as have other physicians across the globe. The trend everywhere has been rapid market adoption – a clear sign of the value this medication provides to patients."

*Handwritten signature and date: DW 10/29*

### **About Pegasys**

Pegasys, a new generation hepatitis C therapy that is different by design, provides significant benefit over conventional interferon therapy in patients infected with HCV 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 constant viral suppression. Pegasys also distributes more readily to the liver (the primary site of infection) than conventional interferon. Pegasys is the only pegylated interferon available as a ready-to-administer solution.

Pegasys has been introduced in more than 80 countries including Europe, North and South America and the Asia-Pacific region. In the US market, where Pegasys was first approved as monotherapy in October 2002 followed by a combination approved two months later, Pegasys has now achieved approximately 40% of total prescriptions.

### **Extensive development program**

Pegasys is supported by the most extensive global development program ever undertaken for a hepatitis C treatment. Three global trials were conducted with monotherapy from 1997 to 1999 while two pivotal trials with combination therapy with Copegus (Roche ribavirin) were conducted between 1998 and 2002. In monotherapy, Pegasys has achieved an overall 39% sustained virological response compared to a 19% response with conventional interferon.

### **About Roche**

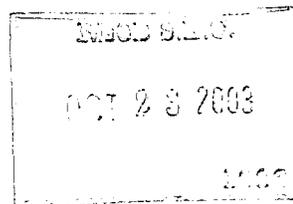
Headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is number one in the global diagnostics market and is the leading supplier of pharmaceuticals for cancer and a leader in virology and transplantation. As a supplier of 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 employs roughly 65,000 people in 150 countries. The Group has alliances and research and development agreements with numerous partners, including majority ownership interests in Genentech and Chugai.

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<sup>1</sup> IMS data, March 2003. The value of the interferon market in Japan has grown on average by 13% per year over the past four years.

# Media Release



Basel, 22 October, 2003

## Unique agreement between Roche and Aspreva to develop CellCept in autoimmune diseases

Roche and Aspreva Pharmaceuticals Corporation today announced a collaboration to develop CellCept (Mycophenolate Mofetil/ MMF) in several autoimmune diseases.

CellCept is the leading immunosuppressant in transplantation. In over a decade of clinical experience CellCept has demonstrated that it provides potent immunosuppression, preventing organ rejection without the long-term toxic effects associated with other therapies.

Organ rejection is an immune reaction with many parallels to autoimmune disease. CellCept's unique mode of action and positive efficacy and safety data in the transplant market suggest it could also benefit many autoimmune disease patients.

For several years physicians have been increasingly interested in investigating the use of CellCept in a variety of autoimmune diseases. Some of the most promising results so far have been seen in lupus (a disease causing chronic skin rash and affecting other body systems), myasthenia gravis (a disorder characterized by weakening of the muscles and fatigue, notably affecting the muscles of the mouth and throat), pemphigus vulgaris (a skin disease characterized by blisters that heal poorly) and autoimmune hepatitis.

Through the new collaboration, Aspreva will now build upon this evidence base by undertaking a global clinical program that will form the basis of formal regulatory submissions for CellCept in autoimmune diseases. This enables Roche to maintain focus on CellCept's core market, transplantation, while extending the potential benefits of CellCept to a broader patient population.

Under the terms of the deal Aspreva Pharmaceuticals has obtained exclusive worldwide rights (excluding Japan) to develop and market CellCept in autoimmune disease applications. Roche will register and invoice such sales as may result and will share the proceeds with Aspreva.

"By bringing together the complimentary expertise of our two organizations, we are better able to enhance the value of this key Roche brand. Roche will stay focused on serving the needs of transplant patients, and Aspreva will undertake the specialized development necessary to expand the use of CellCept into autoimmune disease," said William M. Burns, Head of Roche's Pharmaceuticals Division.

Richard Glickman, Chairman and CEO of Aspreva Pharmaceuticals said: "Roche is an ideal partner for Aspreva. We share the same philosophy of providing high quality evidence based medicine that can help address the needs of underserved patient populations."

There are more than 80 clinically distinct autoimmune diseases which collectively affect an estimated 5-8% of the population. In the US alone, as many as 22 million people are affected. Most of these conditions are highly debilitating and under-treated, creating significant social and financial burdens.

New data on CellCept in autoimmune diseases will be presented at the meeting of the American College of Rheumatology, Orlando, USA 25 - 28<sup>th</sup> October 2003. This will include a plenary session describing the potential role of CellCept in lupus nephritis, the most serious complication of systemic lupus erythematosus.

#### About CellCept

CellCept was first approved in 1995 for renal transplant, and the indications for CellCept now also include heart, liver and pediatric kidney transplants. In the USA CellCept is the leading branded transplant medicine for the prevention of rejection, and it has been used to treat approximately 593,000 transplant patients worldwide. In over a decade of clinical experience CellCept has demonstrated that it provides potent immunosuppression, preventing organ rejection without the long-term toxic effects associated with other therapies. CellCept prevents immune reactions through a unique mode of action which is highly relevant for many autoimmune disease patients.

#### About Autoimmune Diseases

Autoimmune diseases occur when the immune system attacks the body's own cells rather than invading microorganisms. There are more than 80 clinically distinct autoimmune diseases, each affecting the body in different ways. Presentation of these diseases can also vary from patient to patient with the same condition. For example, in lupus many parts of the body are affected, especially the skin, joints, blood, and kidneys. But the extent to which each is affected can vary from patient to patient. lupus nephritis – damage to the kidneys caused by autoantibodies - is the most serious complication of systemic lupus erythematosus. It can lead to kidney failure requiring dialysis or transplant.

Corticosteroids are still the mainstay of treatment for many autoimmune diseases and physicians have to constantly balance the requirement for best possible disease control with the drug related morbidities associated with long term steroid exposure. For example, no treatments have been approved for lupus in over for 30 years, and the current standard of care, the cancer drug cyclophosphamide, is associated with significant drug related morbidity.

#### **About Roche**

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#### **About Aspreva**

Aspreva Pharmaceuticals is a specialty pharmaceutical company focused on addressing the needs of underserved patient populations by developing new indications for approved medicines. Aspreva's asset partnering program allows its partners to maintain core brand focus while extending the benefits of their medicines to a broader patient population.

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