Media Releas

Basel, 28 May

European Commission approves Fuzeon, first HIV-fusion inhibitor, for use in the fight against HIV

Go-ahead for Fuzeon in Europe following the recent FDA approval

Roche and Trimeris announce today that the European Commission has approved the groundbreaking anti-HIV drug Fuzeon (enfuvirtide, formerly known as T-20) for use in the European Union. Fuzeon is the first in a new class of anti-HIV medication, known as 'fusion inhibitors'; this is the first new class of HIV therapy to be approved since 1996. Fuzeon has been developed jointly by Roche and Trimeris Inc.

Fuzeon attacks HIV in a totally different way compared to existing HIV medications. Fuzeon blocks the fusion of HIV with human cells while existing drugs act once the cell is infected. As a result of the very different mechanism of action, Fuzeon is active against HIV strains that have become resistant to current therapies.

"It was twenty years ago this year that HIV was identified as the causative agent of AIDS" said Mr. William Burns, Head of Roche Pharmaceuticals. "Over the last two decades there have been significant advances in the treatment of HIV, however the virus continues to try to outsmart us. The approval of Fuzeon by the European Medicines Evaluation Agency today represents a landmark advance in the fight against HIV, bringing with it new hope for HIV-infected people living in Europe."

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"For me and my colleagues at Trimeris, who have seen Fuzeon from its discovery to becoming a therapeutic option, today's announcement of the European approval is a moment of great

excitement" said Dr. Dani Bolognesi, CEO of Trimeris Inc. "The rapid European approval demonstrates the clinical benefit and favorable safety profile of Fuzeon shown in the two pivotal phase III studies as well as the compelling need for this new therapy."

Clinical data

The regulatory submission for Fuzeon was based on data from two 24-week Phase III pivotal studies of approximately 1,000 patients, TORO (T-20/ Fuzeon vs. Optimised Regimen Only) 1, conducted in North America and Brazil, and TORO 2, conducted in Europe and Australia. These studies showed that treatment-experienced patients receiving Fuzeon as a part of an optimised background regimen (individualised combination of anti-HIV drugs) experienced greater immunologic improvements and were twice as likely to achieve undetectable plasma levels of HIV (HIV-1 RNA of <400 copies/mL) compared to patients receiving an individualised regimen alone. In addition, those patients with less advanced disease and two or more active drugs in their background regimen were more likely to achieve undetectable levels of HIV. Preliminary 48-week data was also provided to the European Authorities in support of the approval of Fuzeon. The final 48-week data will be presented at an international AIDS conference later this year.

"When I was diagnosed with HIV I thought that my life had come to an end. I was the first patient in the UK to be enrolled in a Fuzeon study, at a time when my treatment options had become limited. I now feel extremely positive about my future and I am pleased, following today's announcement, that other HIV positive patients across Europe are now able to benefit from this new class of drugs", said James Locke, a HIV-patient who was first diagnosed in 1984.

Fuzeon indication

The indication for Fuzeon in the European Union is for "use in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected patients who have received treatment with and failed on regimens containing at least one medicinal product from each of the following antiretroviral classes, protease inhibitors, non-nucleoside reverse transcriptase inhibitors and nucleoside reverse transcriptase inhibitors, or who have intolerance to previous antiretroviral regimens. In deciding on a new regimen for patients who have failed an antiretroviral regimen, careful consideration should be given to the treatment history of the individual patient and the patterns of mutations associated with different medicinal products. Where available, resistance testing may be appropriate."

The European Union approval announcement follows the granting of a positive opinion in March by the Committee for Proprietary Medicinal Products. The Food and Drug Administration (FDA) approved Fuzeon in March in the United States and the approval in Switzerland, which was announced last week. Submissions for marketing authorisations have also been made in Australia and Canada.

Safety of Fuzeon

Fuzeon is administered as a twice-daily subcutaneous injection. Local injection site reactions were the most frequent adverse events associated with the use of Fuzeon. In the TORO studies, 98 percent of patients had at least one local injection site reaction. In this treatment-experienced patient population, 3 percent of patients at 24 weeks discontinued treatment with Fuzeon as a result of injection site reactions.

An increased rate of some bacterial infections, primarily pneumonia, was seen in patients treated with Fuzeon. It is unclear if this increased incidence is related to Fuzeon use. The addition of Fuzeon to background antiretroviral therapy generally did not increase the frequency or the severity of the majority of adverse reactions. The majority of adverse reactions were of mild or moderate intensity. Hypersensitivity reactions have occasionally been associated with Fuzeon therapy and in rare cases have recurred on re-challenge.

Fuzeon – Supply and Access

There is a significant and growing need for new antiretrovirals that are active against strains of HIV that are resistant to the currently available medications. As Fuzeon represents the first new class of HIV therapy to be introduced since 1996, there is likely to be a considerable demand for the drug which may exceed initial supplies. In view of the potential for demand to exceed supply, Roche and Trimeris will carefully manage available drug to ensure that people who initiate therapy have uninterrupted supply. Increased access to Fuzeon will be in step with increased supply output. Significant investments have been made and will be further committed to increase capacity for Fuzeon production, which is expected to be fully realized early in 2004. Roche undertake to work diligently with local reimbursement bodies and health care providers to ensure the widest possible access for patients with drug resistant HIV. Fuzeon is expected to be launched in individual countries across Europe over the next few months.

Notes:

Resistance to HIV drugs

It is estimated that in a single untreated person the virus can mutate to form around a billion new and potentially different versions of HIV every day. The incidence of drug resistant HIV among already treated patients is increasing at a disturbing rate. It was recently reported in one study that up to 50 percent of patients in North America are infected with a strain of the virus that has developed resistance to one or more anti-HIV drug.

Roche in HIV

Roche is at the forefront of efforts to combat HIV infection and AIDS, committed since 1986 to groundbreaking research and development of innovative new drugs and diagnostic technology. Saquinavir was the first Protease Inhibitor (PI) and was first introduced by Roche in 1995 in the US.

As a consequence of Roche's continuous research and development, the combination of boosted saquinavir with ritonavir (1000/100 mg twice daily) has shown encouraging results in the MaxCmin 1 trial with high efficacy and an excellent safety and tolerability profile. Saquinavir/r was approved in the EU in August 2002. Viracept (nelfinavir), a leading PI is supplied by Roche outside the US and Canada. In first-line HIV therapy, Viracept delivers consistent long-term efficacy and safety. When used first line, Viracept also allows the subsequent use of both NNRTIs and other PIs for most patients due to its unique resistance pattern. Fuzeon and T-1249 are being co-developed by Roche and Trimeris.

The viral load measurements in the clinical trials for Fuzeon were performed using the AMPLICOR HIV-1 MONITOR® TEST, version 1.5. This test from Roche Diagnostics is considered to be a highly sensitive measurement of the amount of HIV circulating in a patient's blood ("viral load"). With a limited number of treatment regimens available, the accurate monitoring of viral load levels is essential to establish and monitor the effectiveness of therapeutic regimens and assess the potential onset of drug resistance.

Roche is a committed partner of the Accelerating Access Initiative to increase access to HIV care in sub-Saharan Africa and the world's Least Developed Countries. For more information

on Roche policy and pricing of HIV protease inhibitors for these regions and research in HIV, visit www.roche-hiv.com.

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 62,000 people in 150 countries. The Group has alliances and research and development agreements with numerous partners, including majority ownership interests in Genentech and Chugai.

About Trimeris

Trimeris, Inc. (Nasdaq: TRMS) is a biopharmaceutical company engaged in the discovery, development and commercialisation of novel therapeutic agents for the treatment of viral disease. The core technology platform of fusion inhibition is based on blocking viral entry into host cells. Fuzeon, recently approved by the FDA and now in the European Union, is the first in a new class of anti-HIV drugs called fusion inhibitors. Trimeris' second fusion inhibitor product candidate, T-1249, has received fast track status from the FDA and is in Phase I/II clinical testing. Trimeris is developing Fuzeon and T-1249 in collaboration with Roche. For more information about Trimeris, please visit the company's website at www.trimeris.com.

Trimeris Safe Harbor Statement

This document and any attachments may contain forward-looking information about the Company's financial results and business prospects that involve substantial risks and uncertainties. These statements can be identified by the fact that they use words such as "expect," "project," "intend," "plan," "believe" and other words and terms of similar meaning. Among the factors that could cause actual results to differ materially are the following: there is uncertainty regarding the success of research and development activities, regulatory authorisations and product commercialisations; the results of our previous clinical trials are not necessarily indicative of future clinical trials; and, our drug candidates are based upon novel technology, are difficult and expensive to manufacture and may cause unexpected side effects. For a detailed description of these factors, see Trimeris' Form 10-K filed with the Securities and Exchange Commission on March 27, 2003 and its periodic reports filed with the SEC.

Material available

Film footage is available for broadcast journalists from The NewsMarket at www.thenewsmarket.com. Video is compressed in MPEG2 and is available for download to your FTP server.

Furnished under Rule 12g3-2(b)
ROCHE HOLDING 82-3315

Media Release

Basel, 2. June, 2003

Increased potential for cure for people with aggressive blood cancer

Three-year follow up data from GELA study shows greatly improved long term survival for aggressive non-Hodgkin's lymphoma patients treated with MabThera

Data presented today at the American Society of Clinical Oncology (ASCO) annual meeting showed that patients with an aggressive form of the blood cancer, non-Hodgkin's lymphoma (NHL), who were treated with MabThera plus standard chemotherapy (CHOP), have an improved chance of survival after three years compared with those treated with standard chemotherapy alone. These results offer significant hope for people with the aggressive form of NHL, one of the most common types of blood cancer of the lymphatic system. Current medical opinion indicates that if patients survive past the two-year landmark their chance of a cure can be up to 90%[1].

Results from the pivotal GELA Study (Groupe d'Etude des Lymphomes de l'Adulte) have shown that three-year event free survival for patients treated with MabThera plus CHOP is 53%, compared to 35% for patients treated with CHOP alone[2]. Moreover, 62% of those patients receiving MabThera plus CHOP were still alive 3 years after treatment compared to 51% of the patients who were treated with chemotherapy alone. Importantly, MabThera did not increase the toxicity of therapy when compared to chemotherapy alone[2].

"These results represent a real breakthrough for people with aggressive NHL. This combination therapy is the first treatment in 20 years to offer patients a great improvement in long term survival," commented principal GELA study investigator Professor Bertrand Coiffier, head of the Department of Hematology, Hospices Civiles de Lyon, France. "It confirms that MabThera plus CHOP is the gold standard treatment for this aggressive form of cancer. It is the only recent

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treatment in aggressive NHL proven to increase survival and potentially offer a cure without an increase in toxicity. People with aggressive NHL must be treated with this combination wherever possible."

MabThera works by 'seek and destroy' action, which unlike chemotherapy specifically targets tumour cells, therefore it does not cause the unpleasant side effects associated with traditional chemotherapy. Approximately 1.5 million people worldwide have NHL, 55% of them have the aggressive form of the disease, which if left untreated can be fatal within six months. The remaining 45% suffer from indolent NHL, where tumour cells divide slowly and patients may live for many years, however currently there is no cure. The causes of NHL remain unknown, however it is more common than leukaemia and worldwide is the 3rd fastest growing form of cancer, after skin melanoma and lung cancer[3].

MabThera was discovered by IDEC Pharmaceuticals Corporation and was jointly developed by IDEC, Genentech, Inc, Roche and Zenyaku Kogyo Co. Ltd of Japan. In July 1998, Genentech granted Roche exclusive marketing rights for MabThera outside the USA. (marketed as Rituxan in USA, Japan and Canada). MabThera is the Roche World-Wide Prescription Group's largest prescription product just four years after its first launch.

Roche in Oncology

Roche is a world leader in oncology. Its franchise includes Herceptin (breast cancer), MabThera (non-Hodgkin's lymphoma), Xeloda (colorectal cancer, breast cancer) NeoRecormon (anaemia in various cancer settings), Roferon-A (leukaemia, Kaposi's sarcoma, malignant melanoma, renal cell carcinoma) and Kytril (chemotherapy and radiotherapy-induced nausea). Roche Oncology has four research sites (two in the US, Germany and Japan) and four HQ Development sites (two in the US, UK and Switzerland) dedicated to Oncology.

Roche also offers a broad portfolio of tumor markers for prostate, colorectal, liver, ovarian, breast, stomach, pancreas and lung cancer, as well as a range of molecular oncology tests running on the LightCycler. Within its Integrated Cancer Care Unit the company develops new tests which will have a significant impact on disease management of cancer patients in the future.

About Roche

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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 62,000 people in 150 countries. The Group has alliances and research and development agreements with numerous partners, including majority ownership interests in Genentech and Chugai.

References:

1. Fisher et al, New Eng. Jrnl Med., April 1993, 328:1002-6
2. Abstract #2395: GELA study comparing CHOP and R-CHOP in Elderly Patients with Diffuse Large B-Cell Lymphoma: 3 year median follow-up with an analysis according to co-morbidity factors. This phase III study was conducted by Groupe d'Etude des Lymphomes de l'Adulte (GELA), a large cancer co-operative group of more than 110 institutions in France, Belgium and Switzerland. The study analysed 399 previously untreated elderly patients (60 to 80 years old) with aggressive non-Hodgkin's lymphoma. Patients were randomised to receive standard CHOP chemotherapy or MabThera plus CHOP.
3. World Health Report 2000: World Health Organisation (www.who.int)

For B-roll footage (including an interview with principal GELA study investigator, Professor Bertrand Coiffier) please go to www.thenewsmarket.com <http://www.thenewsmarket.com> and enter 'MabThera' in the search function.

Roche

Investor Update

June 03, 2003

One-Year Pivotal Study Results Show Valcyte™ Comparable to Cytovene® in Preventing Cytomegalovirus Disease in Organ Transplant Recipients
Simpler Valcyte Dosing Regimen Improves Patient Convenience

Washington, D.C., June 2, 2003 Valcyte (valganciclovir) is comparable to Cytovene (ganciclovir) Capsules in reducing the incidence of cytomegalovirus (CMV) disease in solid organ transplant recipients, according to results of a twelve-month pivotal phase III study presented today at the American Transplant Congress, joint meeting of the American Society of Transplantation and the American Society of Transplant Surgeons.
"These data demonstrate what physicians already hypothesized from the safety and efficacy profile of Valcyte seen in HIV patients," said Mark David Pescovitz, MD, Professor of Surgery and Microbiology/Immunology, Indiana University Medical Center. "Valcyte was comparable to our standard therapy and we believe the once-daily regimen will be easier for patients to take."
Valcyte is indicated for the treatment of CMV retinitis in AIDS patients. A supplemental NDA for the prevention of CMV disease in solid organ transplant recipients was filed with the U.S. FDA in Nov. 2002 and is currently under review.
Valcyte is the pro-drug of Cytovene, which is currently the most widely prescribed anti-CMV medication worldwide. As a pro-drug, Valcyte is rapidly converted to ganciclovir in the body. However, the availability of ganciclovir from Valcyte is ten times greater than the availability of ganciclovir from Cytovene capsules and Valcyte has a more convenient dosing regimen. Valcyte achieves bioavailability of 60%, while Cytovene capsules have a bioavailability of 6%.

Study Details
The 12-month randomized trial involved 364 high-risk kidney, kidney-pancreas, liver and heart transplant recipients whose donors were seropositive for CMV, although they themselves did not have antibodies to CMV. The goal of the study was to compare the efficacy and safety of Valcyte to Cytovene in preventing CMV disease; the study was designed and powered to establish non-inferiority of Valcyte to Cytovene.
The study showed that the incidence of CMV disease during the first 12 months post transplant was 17.2% in patients treated with Valcyte compared to 18.4% in Cytovene-treated patients. The CMV viral load was significantly lower in the Valcyte group while on therapy, but the measurable viral load was comparable in both treatment groups (49% on Valcyte vs. 50% on Cytovene) by 6 months. There were no deaths considered related to the drug (6.1% vs. 6.3%, respectively).
There was a greater incidence of neutropenia and leucopenia in the VALCYTE arm and a greater incidence of anemia in the CYTOVENE arm; these differences were not statistically significant. The most frequent adverse events were diarrhea, tremor, graft rejection, and headache.
Adult patients were grouped by organ type and then randomized by a 2 to 1 ratio to Valcyte 900 mg twice a day or Cytovene 1000 mg three times a day. Therapy started within ten days post transplant and continued through day 100 with regular follow up to twelve months.

About CMV

Cytomegalovirus disease is an opportunistic infection caused by the cytomegalovirus, which can complicate and interfere with transplant recipients' full recovery. Although the virus is present in about half of the worldwide population, in patients with a suppressed immune system, such as transplant recipients or HIV-positive patients, the virus is able to reactivate. In transplant patients, the most common clinical manifestations of CMV disease are CMV pneumonia, CMV hepatitis, and CMV gastrointestinal disease, and frequently involve the transplanted organ. In contrast, CMV retinitis is the most common manifestation of the disease in HIV patients.

About Valcyte

Valcyte is indicated for the treatment of CMV retinitis in AIDS patients. Valcyte is the oral pro-drug of Cytovene and received FDA approval on March 30, 2001 after a priority review. The drug became available for sale in June 2001. A supplemental NDA for Valcyte in the prevention of CMV disease in solid organ transplant recipients was filed with the U.S. FDA in Nov. 2002 and is currently under review.

Since Valcyte is rapidly converted to ganciclovir after administration, adverse reactions known to be associated with Cytovene can be expected with Valcyte. Both products can produce hematologic toxicity, including anemia, depressed white blood cell counts, and to a lesser extent, depressed platelet counts. In animal studies ganciclovir was carcinogenic, teratogenic and adversely affected sperm production. In AIDS patients on certain antiretroviral regimens, didanosine (ddI) blood levels can be significantly increased when taken with Valcyte, and the hematologic abnormalities may be exacerbated if the product is taken with AZT. Other side effects occurring with a frequency of greater than 5% include diarrhea, nausea (with or without vomiting), abdominal cramping, fever, headache and peripheral neuropathy. Kidney function can be affected, and dose adjustment is necessary with altered renal function.

About Roche

Hoffmann-La Roche Inc. (Roche), based in Nutley, N.J., is the U.S. prescription drug unit of the Roche Group, a leading research-based health care enterprise that ranks among the world's leaders in pharmaceuticals and diagnostics. Roche discovers, develops, manufactures and markets numerous important prescription drugs that enhance people's health, well-being and quality of life. Among the company's areas of therapeutic interest are: dermatology; genitourinary disease; infectious diseases, including influenza; inflammation, including arthritis and osteoporosis; metabolic diseases, including obesity and diabetes; neurology; oncology; transplantation; vascular diseases; and virology, including HIV/AIDS and hepatitis C.

For more information on the Roche pharmaceuticals business in the United States, visit the company's website at: http://www.rocheusa.com. See full prescribing information for complete information on contraindications, warnings, precautions and other adverse reactions of Valcyte and Cytovene.

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