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# U.S. FDA Approves FUZEON™; First Drug to Block Entry of HIV into Immune Cells

## *FUZEON leads first new class of anti-HIV drugs since 1996*

**NUTLEY, N.J., and DURHAM, N.C. (March 13, 2003)** – Roche and Trimeris, Inc. (Nasdaq: TRMS) announced today that FUZEON™ (enfuvirtide), a novel treatment for HIV-1, has been granted accelerated approval by the U.S. Food and Drug Administration (FDA) following a six-month priority review. FUZEON in combination with other antiretroviral agents is indicated for the treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy.

FUZEON is the first fusion inhibitor, representing the first new class of anti-HIV treatments in seven years. Unlike all currently approved anti-HIV drugs, FUZEON blocks the virus from entering the human immune cell, preventing HIV replication that can devastate the immune systems of HIV infected individuals.

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"This new fusion inhibitor is a significant breakthrough and its approval is a milestone event in the HIV epidemic," said Dr. Michael Saag, Director, AIDS Outpatient Clinic, University of Alabama at Birmingham. "Patients are becoming resistant to our best therapies and they need new options. This drug attacks the virus in a new way, so it can work for patients whose virus is resistant to other therapies."

"Almost one million people in the United States are living with HIV/AIDS, and over 28,000 of those people are living here in New Jersey. Today, thanks to Roche, whose U.S. headquarters is located right here in Nutley, New Jersey, there is new hope for these patients. Today, the FDA approved FUZEON, the first in a new-class of HIV drugs called fusion inhibitors. I am extremely proud that Roche, and its 3,000 employees who live and work in New Jersey, together with their partner Trimeris Inc., are responsible for this incredible breakthrough in the treatment for HIV/AIDS," said Rep. Bill Pascrell (D-New Jersey). "New Jersey's AIDS Drug Assistance Program helps provide these life-sustaining HIV treatments to approximately 3,400 uninsured and underinsured individuals. In Congress, I've worked and will continue to work towards greater funding for this important program."

**Pivotal 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. **O**ptimized **R**egimen **O**nly) 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 optimized background regimen (individualized 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 individualized regimen alone. In addition, those patients with two or more active drugs in their background regimen were more likely to achieve undetectable levels of HIV.

Because of the public health implications, *The New England Journal of Medicine* (NEJM) will post the clinical results from the FUZEON TORO 1 study on its web site, www.nejm.org in advance of publishing the data in an upcoming issue.

"With FUZEON, what we've essentially done is to take a piece of the virus and turn it against itself. The safety and efficacy of this new molecule were demonstrated through two rigorously-designed pivotal studies conducted in a diverse treatment-experienced patient population," said Dr. Dani Bolognesi, Chief Executive Officer, Trimeris. "Together with our partner Roche, Trimeris is proud to bring this innovative new therapy to the growing number of people with HIV who are in need of new treatment options."

"FUZEON is yet another example of Roche's long-standing commitment to advancing the treatment of HIV," said George B. Abercrombie, President and Chief Executive Officer, North American Pharmaceuticals Operations, Roche. "FUZEON also represents a major advancement in the large-scale chemical synthesis of peptides. This cutting edge process has been successfully implemented at the Roche manufacturing facility in Boulder, Colorado. FUZEON adds an important dimension to our growing HIV product portfolio and opens the door for a new treatment paradigm in HIV."

**Supply and Distribution of FUZEON**

Roche and Trimeris have committed to make FUZEON available for distribution before the end of March. Because initial demand for FUZEON may exceed supply following commercial availability, Roche and Trimeris have developed and are now finalizing a US Progressive Distribution Plan to provide FUZEON to patients and to ensure uninterrupted supply to patients once they begin therapy. The details of this US Progressive Distribution Plan will be announced in the near future.

**Approved Indication**

FUZEON in combination with other antiretroviral agents is indicated for the treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy. This indication is based on analyses of plasma HIV-1 RNA levels and CD4 cell counts in controlled studies of FUZEON of 24 weeks' duration. Subjects enrolled were treatment-experienced adults; many had advanced disease. There are no studies of FUZEON in antiretroviral naive patients. There are no results from controlled trials evaluating the effect of FUZEON on clinical progression of HIV-1.

This indication is reflective of a policy shift within the anti-viral division at FDA designed to ensure that indications more closely reflect the patient populations studied.

**More About 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 Phase III clinical studies, 98 percent of patients had at least one local injection site reaction. The addition of FUZEON to background antiretroviral therapy generally did not increase the frequency or the severity of the majority of adverse events. There was less than five percent difference in the most common adverse events seen between FUZEON plus an individualized regimen of antiretroviral drugs and individualized regimen alone. The events most frequently reported in subjects receiving FUZEON plus an individualized regimen were diarrhea (26.8%), nausea (20.1%), and fatigue (16.1%). All these events were seen at a lower incidence than in subjects that received background regimen alone: diarrhea (33.5%), nausea (23.7%), and fatigue (17.4%). The most common adverse events seen more frequently in patients receiving FUZEON plus an individualized regimen than in patients who received treatment without FUZEON include headache (11.8%), peripheral neuropathy (8.9%),

dizziness (6.6%), insomnia (11.3%), depression (8.6%), decreased appetite (6.3%), asthenia (5.7%), myalgia (5.0%), constipation (3.9%) and pancreatitis (2.4%). The majority of adverse events were of mild or moderate intensity. Hypersensitivity reactions have been associated with FUZEON therapy (≤1 percent) and have recurred on rechallenge. In addition, an increased rate of bacterial pneumonia was observed in patients treated with FUZEON in the Phase III clinical trials compared to the control arm. It is unclear if the increased incidence of pneumonia is related to FUZEON use.

**Roche in HIV**

Roche is at the forefront of efforts to combat HIV infection and AIDS, committed for 15 years to groundbreaking research and development of new drugs and diagnostic technology. Roche's objective is to provide tailored treatment solutions and an improved standard of care worldwide for people living with HIV.

**About Roche**

Hoffmann-La Roche (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, diagnostics and vitamins. 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 Web site at: http://www.rocheusa.com.

**About Trimeris, Inc.**

Trimeris, Inc. (Nasdaq: TRMS) is a biopharmaceutical company engaged in the discovery, development and commercialization 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™, just approved by the FDA, is the first in a new class of anti-HIV drugs called fusion inhibitors. A Marketing Authorisation Application (MAA) has also been submitted for FUZEON in the European Union. 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 F. Hoffmann-La Roche Ltd. 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 authorizations and product commercializations; 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 S-3 filed with the Securities and Exchange Commission on September 27, 2002 and its periodic reports filed with the SEC.

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