Roche

Investor Update

December 16, 2003

Roche and Trimeris submit 48-week data to U.S. FDA for full approval of Fuzeon, first and only HIV Fusion Inhibitor

Roche and Trimeris, Inc. today announced submission of 48-week efficacy and safety data from two pivotal studies of FUZEON to the U.S. Food and Drug Administration (FDA) to support its full, or traditional, approval. The data demonstrate that the utility of FUZEON in combination regimens for the treatment of HIV can be extended to at least 48 weeks. The application was submitted only nine months after the FDA granted accelerated approval for FUZEON, the first and only fusion inhibitor for the treatment of HIV, on the basis of 24-week pivotal data. Accelerated approval is a special regulatory status granted by the FDA for approval of a drug that is used to treat patients with serious or life-threatening illnesses and that provides meaningful therapeutic benefit to patients over existing treatments. Traditional approval would be granted based on the duration of response that can be achieved with FUZEON-based regimens.

"Historically, achieving a longer-term, durable response has been one of the greatest challenges in successful management of treatment-experienced HIV patients," said Dr. Joel Gallant, M.D., M.P.H., Associate Professor of Medicine and Epidemiology, Division of Infectious Disease, Johns Hopkins University, Baltimore. "The 48-week data show that regimens with enfuvirtide can substantially improve virological and immunological responses after almost a year of therapy. The best responses have been seen among treatment-experienced patients with less advanced disease, but even patients with few or no other treatment options may derive some benefit from fusion-inhibitor based therapy over the longer term."

Roche and Trimeris are successfully producing FUZEON on a large scale. The companies have continued to invest in additional manufacturing equipment and have made significant production efficiencies, both contributing to increased drug supply. There is no waiting list to receive FUZEON.

"Recently, treatment guidelines for HIV-infected patients initiating therapy were modified based on the results of a study that demonstrated superior viral suppression and durability of response with one combination of anti-HIV drugs," commented Dr. Michael Saag, Professor of Medicine, School of Medicine, University of Alabama at Birmingham. "Based on the excellent response observed in the 48-week data from the trials with enfuvirtide, a similar change in the guidelines would be expected for the use of enfuvirtide in heavily treatment-experienced patients."

Fuzeon 48-week data

The data in today's submission, which were presented at major scientific meetings throughout 2003, show that at 48 weeks, more than twice the percentage of patients on a FUZEON-containing regimen had undetectable levels of HIV (less than 400 copies/mL of blood) compared to patients on a regimen without FUZEON (30 percent vs. 12 percent). Eighty percent of patients who achieved undetectable levels of the virus at 24 weeks

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maintained this response at 48 weeks. On average, patients receiving a FUZEON-based regimen experienced an increase of twice as many CD4 immune cells from baseline as those achieved by patients on a regimen without FUZEON(increase of 91 cells/mm3 in the FUZEON arm vs. 45 cells/mm3 in the control arm) at 48 weeks. In addition, the duration of virological benefit was approximately three times longer in patients on a FUZEON-containing regimen compared to patients on regimens without FUZEON (32 weeks vs. 11 weeks). All of these results were highly statistically significant (p 0.0001).

Among patients with less advanced disease (less than 100,000 copies of HIV per mL of blood and immune cell count greater than 100 cells/mm3), almost half of patients (47 percent) receiving FUZEON-based regimens achieved undetectable levels of HIV, compared to those not receiving FUZEON (18 percent; $p< 0.05$). In this group, patients receiving a FUZEON-based regimen also experienced twice the CD4 immune cell increase from baseline compared to patients receiving a regimen without FUZEON (mean CD4 immune cell increase of 103 cells/mm3 vs. 51 cells/mm3, respectively). Patients with the most advanced disease (baseline viral load greater than 100,000 copies of HIV per mL of blood and immune cell count less than 100 cells/mm3) were more than three times as likely to achieve undetectable levels of HIV with a FUZEON-based anti-HIV drug regimen, versus patients receiving a regimen without FUZEON (15 percent vs. four percent, $p< 0.05$). Among these same patients, those taking a FUZEON-based regimen experienced twice the CD4 immune cell increase from baseline as patients receiving a regimen without FUZEON (mean CD4 immune cell increase of 84 cells/mm3 vs. 40 cells/mm3, respectively).

Injection site reactions (ISRs) are the most common adverse event associated with FUZEON use. A safety analysis at 48 weeks showed that aside from ISRs, the incidence of the three most common adverse events was less frequent in the FUZEON arm compared to the control arm, measured as number of events per 100 years of patient experience. These adverse events included diarrhea (37 per 100 patient-years in the FUZEON arm vs. 73 in the control arm), nausea (26 vs. 51, respectively) and fatigue (25 vs. 38, respectively). (See "Facts About FUZEON" section for complete safety information.)

For more information on FUZEON, patients and physicians can visit www.FUZEON.com or call 1-877-4FUZEON.

Facts about Fuzeon

FUZEON, co-developed by Roche and Trimeris (Nasdaq: TRMS), was granted accelerated approval on the basis of 24-week data by the U.S. Food and Drug Administration in March, and is also approved in the European Union, Switzerland and Canada. FUZEON leads the first class of anti-HIV drugs to be introduced in seven years. Unlike other HIV drugs that work after HIV has entered the human immune cell, FUZEON works outside the CD4 cell, blocking HIV from entering the cell. For this reason, FUZEON is effective in treatment-experienced patients who have developed resistance to other anti-HIV drugs, though patients may still develop resistance to FUZEON.

TORO study design

TORO 1 [T-20 (FUZEON) vs. Optimized Regimen Only] and TORO 2 are randomized, open-label trials that enrolled approximately 1,000 HIV-1 infected patients at 112 centers internationally. Patients were treatment-experienced and/or had documented resistance to each of the other three classes of anti-HIV drugs. At entry, resistance testing and patient

treatment history were used together to aid in the selection of an individualized regimen of three to five anti-HIV drugs for each patient. After selection of the regimen, patients were randomized 2:1 to receive either the regimen in combination with FUZEON (FUZEON arm) or the individualized regimen alone (control arm). At baseline, patients had a median HIV RNA level of more than 5.0 log10 copies/mL, a median CD4 cell count of less than 100 cells/mm3, and had been treated with anti-HIV drugs for an average of seven years.

Fuzeon indication and safety
FUZEON (enfuvirtide) 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. Patients may still develop resistance to FUZEON.

Injection Site Reactions (ISRs) as reported at 24 weeks: ISRs are the most common adverse events associated with FUZEON. ISRs occurred in 98% of patients studied and 3% discontinued FUZEON due to ISRs. Signs/symptoms may include pain and discomfort, induration, erythema, nodules and cysts, pruritus, and ecchymosis. Nine percent of patients had local reactions that required analgesics or limited usual activities.

Pneumonia: An increased rate of bacterial pneumonia was observed in subjects 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. Patients with HIV infection should be carefully monitored for signs and symptoms of pneumonia. Risk factors for pneumonia included low initial CD4 cell count, high initial viral load, intravenous drug use, smoking and a prior history of lung disease.

Hypersensitivity Reactions: Hypersensitivity reactions have been associated with FUZEON therapy and may recur on rechallenge. Hypersensitivity reactions have included individually and in combination: rash, fever, nausea and vomiting, chills, rigors, hypotension and elevated serum liver transaminases. Other adverse events that may be immune mediated and have been reported in subjects receiving FUZEON include primary immune complex reaction, respiratory distress, glomerulonephritis and Guillain-Barre syndrome.

Other Adverse Events: The events most frequently reported in patients receiving FUZEON plus an optimized background regimen were diarrhea (26.8%), nausea (20.1%) and fatigue (16.1%). These events were seen at a lower incidence than in patients receiving an optimized background regimen without FUZEON: diarrhea (33.5%), nausea (23.7%) and fatigue (17.4%). This list of side effects is not complete because FUZEON is still being studied.

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. The

objective is to provide tailored treatment solutions and an improved standard of care worldwide for those people living with HIV.

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, 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 R&D agreements with numerous partners, including majority ownership interests in Genentech and Chugai.

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, recently approved in the U.S. and European Union, is the first in a 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 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," "anticipate", "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 10-K filed with the Securities and Exchange Commission on March 27, 2003 and its periodic reports filed with the SEC.

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