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**Fuzeon<sup>®</sup> Plus an Active Boosted Protease Inhibitor Doubles Long-Term Response in Treatment-Experienced HIV Patients**

**NUTLEY, N.J. and DURHAM, N.C. (October 5, 2004)** – Twice as many treatment-experienced patients who used Fuzeon<sup>®</sup> (enfuvirtide) with an active boosted protease inhibitor (PI) regimen experienced a significant virologic response when compared to patients on an active boosted PI regimen alone, according to new data presented at the Infectious Disease Society of America Annual Meeting in Boston. These results are particularly compelling given that they are derived from one of the largest prospective databases evaluating optimal treatment regimens selected with the assistance of resistance testing. Fuzeon, co-developed by Roche and Trimeris (Nasdaq: TRMS), is the first and only fusion inhibitor for the treatment of HIV.

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## **Study Results**

In this retrospective, subset analysis of 48-week data from the TORO Phase III studies, almost twice as many treatment experienced patients (52 percent) who took Fuzeon with an active boosted PI regimen (including at least two other active anti-HIV drugs) achieved undetectable levels of HIV (less than 400 copies/mL), compared to those receiving an active boosted PI regimen without Fuzeon (27 percent). Patients taking Fuzeon with an active boosted PI regimen also experienced a significantly greater immunological response, with a median increase of 104 cells/mm<sup>3</sup> vs. an increase of 57 cells/mm<sup>3</sup> among patients receiving an active boosted PI regimen without Fuzeon.

“Boosted PIs are a key component in the regimens of many treatment experienced patients today. This analysis allowed us to answer a crucial question which have not been well studied to date, namely whether the addition of a new class of drugs could enhance responses to boosted PI regimens in treatment experienced patients,” said Dr. Joseph Eron, Associate Professor of Medicine, University of North Carolina (UNC) at Chapel Hill. “These findings demonstrate that Fuzeon significantly enhances the treatment response in treatment experienced patients taking an active boosted PI-containing regimen, thus providing a more potent regimen against drug resistant virus.”

At the time the TORO study began, the majority of patients did not have prior treatment experience with the boosted PI lopinavir/ritonavir (Kaletra<sup>®</sup>), despite having previously taken several therapies in the protease inhibitor class. Therefore, this retrospective analysis of the TORO study database was undertaken to evaluate the 157 patients who remained sensitive to lopinavir/ritonavir. A total of 98 patients who received Fuzeon with lopinavir/ritonavir and two other active agents were compared to 59 patients who received the same regimen without Fuzeon. At baseline, patients in both treatment arms had similar median viral load and CD4 counts: HIV RNA level of 5.2 log<sub>10</sub> and CD4 count of 73 cells/mm<sup>3</sup> in the Fuzeon arm and HIV RNA level of 5.1 log<sub>10</sub> and CD4 count of 97 cells/mm<sup>3</sup> in the control arm.

### **More About Fuzeon**

Fuzeon was granted accelerated approval on the basis of 24-week data by the U.S. Food and Drug Administration in March 2003, and is also approved in the European Union, Switzerland and Canada. 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 log<sub>10</sub> copies/mL, a median CD4 cell count of less than 100 cells/mm<sup>3</sup>, and had been treated with anti-HIV drugs for an average of seven years.

**Indication:** 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-naïve patients. There are no results from controlled trials evaluating the effect of Fuzeon on clinical progression of HIV-1.

**Injection Site Reactions (ISRs):** ISRs are the most common adverse events associated with Fuzeon. In two controlled Phase III studies at 24 weeks, TORO 1 and TORO 2, 98 percent of patients had at least one local injection site reaction. 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.

Roche and Trimeris are working together to discover, develop and commercialize the next generation of HIV fusion inhibitors.

### **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 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, approved in the U.S., Canada and European Union, is the first in a new class of anti-HIV drugs called fusion inhibitors. Trimeris is developing Fuzeon and future generations of peptide fusion inhibitors in collaboration with F. Hoffmann-La Roche Ltd. For more information about Trimeris, please visit the Company's website at <http://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 12, 2004 and its periodic reports filed with the SEC.

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