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**FDA Issues Approvable Letter In Response to Application for  
Use of FUZEON® with Needle-Free Injection Device**

**NUTLEY, N.J. and MORRISVILLE, N.C. (Nov. 23, 2005)** – Roche and Trimeris (Nasdaq: TRMS) announced that today the companies have received an approvable letter from the U.S. Food and Drug Administration (FDA), in response to their request for inclusion of information about the Biojector® 2000 (B2000) needle-free injection device in the FUZEON® (enfuvirtide) labeling. In the approvable letter, FDA has requested additional information from the ongoing ENF-404 or WAND (**W**ith **A** **N**eedle-Free **D**evice) study, a randomized, open-label, two-way, cross-over study assessing the tolerability of the B2000 device for administration of FUZEON.

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The B2000, made by Bioject Medical Technologies Inc., is a needle-free, CO<sub>2</sub>-powered injector that disperses liquid medication beneath the skin. FUZEON is the first and only entry inhibitor available for the treatment of HIV and is currently approved for administration with a needle and syringe.

Roche and Trimeris filed a supplemental New Drug Application (sNDA) in May 2005 based on data from the T20-405 study, a single-dose pharmacokinetic study of FUZEON administered by a nurse via the B2000 needle-free device, compared to standard needle-syringe administration. In August 2005, Roche and Trimeris announced the initiation of the FUZEON WAND (**W**ith **A** **N**eedle-Free **D**evice, or ENF-404) study, an eight-week trial designed to assess patient acceptance and experience of FUZEON administration via the B2000 needle-free device compared to the standard needle and syringe. The primary endpoints of this study are tolerability and injection site reactions. This trial is currently enrolling and final data are expected in the second half of 2006.

Healthcare providers and patients can call Roche/Trimeris at 877-4FUZEON (877-438-9366) or visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for details regarding participation in the FUZEON WAND study.

### **Facts About FUZEON**

FUZEON is the first and only fusion inhibitor for the treatment of HIV. 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. FUZEON was granted accelerated approval by the U.S. Food and Drug Administration (FDA) in March 2003 on the basis of 24-week data, and was granted traditional (full) approval on Oct. 15, 2004 on the basis of long-term 48-week data.

*Injection Site Reactions (ISRs):* ISRs are the most common adverse events associated with FUZEON. ISRs occurred in 98% of patients studied and 4% discontinued FUZEON due to ISRs. Signs/symptoms may include pain and discomfort, hardened skin, redness, bumps, itching and swelling. Eleven 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:* Systemic 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 (32%), nausea (23%) and fatigue (20%). These events were seen at a lower incidence in patients taking a FUZEON-based regimen compared to those receiving an optimized background regimen without FUZEON when taking into account the uneven number of patients in each arm and the length of time they are in that arm. As measured in number per 100 patient years, the incidence was: diarrhea (38 per 100 patient-years in subjects receiving FUZEON-based regimens vs. 73 per 100 patient-years in patients who did not receive FUZEON), nausea (27 vs. 50, respectively) and fatigue (24 vs. 38, respectively).

### **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 – More Than a Century in the U.S. and the World**

Founded in 1896 and 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 one of the world's leaders in diagnostics, the leading supplier of pharmaceuticals for cancer, as well as 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 many fronts to improve people's health and quality of life. Roche employs roughly 65,000 people in 150 countries, including approximately 15,000 in the United States.

Roche's U.S. operations celebrate their American Centennial in 2005. In another milestone this year, Roche was named in January to *Fortune* magazine's list of Best Companies to Work for in America. One of an increasingly rare breed of major healthcare companies that still bear their original name, Roche today has more than a dozen U.S. sites located in California, Colorado, Indiana, New Jersey and South Carolina, as well as in Puerto Rico. Roche has alliances and research and development agreements with numerous partners, including majority ownership interests in Genentech and Chugai. Roche's Pharmaceuticals Division offers a portfolio of leading medicines in therapeutic areas including cancer, HIV/AIDS, hepatitis C, transplantation, dermatology and influenza. Roche's Diagnostics Division supplies a wide array of innovative testing products and services to researchers, physicians, patients, hospitals and laboratories world-wide. For further information, please visit our worldwide and U.S. Web sites (Global: <http://www.roche.com> and U.S.: <http://www.roche.us>). 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 Web site 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," "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 11, 2005 and its periodic reports filed with the SEC.

### **About Bioject Medical Technologies Inc.**

Bioject Medical Technologies Inc., based in Bedminster, New Jersey, and Portland, Oregon, is an innovative developer and manufacturer of needle-free drug delivery systems. Needle-free injection works by forcing medication at high speed through a tiny orifice held against the skin. This creates a fine stream of high-pressure fluid penetrating the skin and depositing medication in the tissue beneath. The Company is focused on developing mutually beneficial agreements with leading pharmaceutical, biotechnology, and veterinary companies.