For Immediate Release: March 13, 2003

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Project Inform Press Statement on the FDA Approval of Fuzeon

Trimeris, Inc. and Hoffman La Roche announced on Thursday afternoon that the FDA had granted approval for the marketing of Fuzeon, the companies' new fusion inhibitor (previously known as T20). While Project Inform applauds the availability of a new class of drugs, especially one that works in people who have failed most other therapies, the expected price of the drug is so high that it's hard to celebrate the announcement. "There's no guarantee, perhaps not even a likelihood, that most of the people who truly need this drug will be in a position to get it," said Martin Delaney, Founding Director of Project Inform. "The AIDS Drug Assistance Program (ADAP) is facing a financial crisis without even considering the addition of Fuzeon, and the cost of the drug will be a hard blow to already strapped Medicaid budgets."

The cost of Fuzeon was announced for Europe a few weeks ago at approximately $20,500 US. Even if substantial new rebates are given to the ADAP program, the drug will likely remain out of reach. Ryan Clary, Senior Policy Advocate for Project Inform, said "For many state ADAP programs, the only option may be to take other drugs off the formulary or make other major changes to the program if they really hope to add Fuzeon. This would pit one set of patient needs against another's." Project Inform even questions whether all private insurance and HMO programs will cover the drug.

Martin Delaney continued, "We acknowledge that this is an extraordinarily difficult and expensive drug to manufacture, but it really doesn't matter what we believe. Regardless of the cause of the high price, or even the efficacy of the drug, the effect is the same: a great number of people will be denied access. When development of of Fuzeon first began, a number of scientists were not hopeful about its future. They told us that either the drug could not be manufactured in sufficiently large quantities, or if it was, it could not be made at a price the health care system could afford. Trimeris and Roche have more or less solved the first problem, but they have failed to conquer the second. They have given us a drug reminiscent of the French/British Concorde supersonic airliner – a wondrous machine that no can afford. What we need is a 747."

Nothing should please patients and treatment advocacy groups like Project Inform more than having a new drug targeted at a new part of HIV's life cycle. But the pricing issue hangs like a dark cloud over what should have been a celebration of progress. ACT-UP New York, for example, staged a demonstration Thursday morning at Roche's headquarters in New Jersey, one of very few such actions in recent years (pictures of the demonstration are available at http://www.ultinet.net/~kfo/roche.html).

Several meetings have already occurred with the companies over pricing issues, including meetings of Roche's senior executives with Roche's HIV community advisory board, several state ADAP directors and the Fair Pricing Coalition. No satisfactory solutions have been reached

and given the companies' position on cost recovery and pricing, none seem likely. However, discussions will continue in hopes of finding at least some way to get the drug for people who are denied access through state ADAP programs and other payers. The high price will actually work against the manufacturer, since the cost may limit sales and thus make it much more difficult for them to recover their costs.

Brenda Lein, Director of Information and Advocacy at Project Inform, concluded, "We must struggle to make sure we are never again put in such a no-win situation. Right now, the manufacturers have not offered a workable solution to the problems created here. I don't know what we'll be able to tell people who need the drug right now. It will be no comfort to them to know how expensive the drug is to produce or how little of it will be made. For those who truly need it, access to Fuzeon is literally a matter of life and death. The companies must find a way to make the drug accessible to all those in need. Without that, we are simply worsening what is already a two-tiered health care system."

Project Inform is the nation's leading HIV/AIDS treatment information and advocacy source. Established in 1985 as a national, non profit, community-based organization, Project Inform serves people living with HIV/AIDS, their healthcare and service providers and their families and friends through its national, toll-free treatment hotline; the PI Perspective and other publications (including a growing quantity of information in Spanish); Project WISE, focusing on women's HIV/AIDS treatment information and advocacy issues; on-line services; educational Town Meetings and technical assistance programs; and research and drug access advocacy programs.

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