Trimeris, Roche Pull No-Needle Fuzeon Bid

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By AIDS Reader [1]

Trimeris and its partner Roche said they are withdrawing an application to sell their injectable AIDS drug Fuzeon (enfuvirtide) in a needle-free device. "While the device has shown potential benefit for some patients, we don't believe it's the real alternative delivery option for all patients," said Michelle Zupancic, vice president, HIV, at Roche (Vollmer S. News & Observer [Raleigh]. October 4, 2007).

Trimeris anticipated good results from the device, Biojector, which delivered doses of the drug in a manner similar to that of syringes but caused fewer welts. The partners had hoped to begin marketing kits with the drug and the device a year ago. Approval by the FDA was delayed, however, over concerns about nerve pain and bruising.

Sharon Seiler, a biotech analyst with Punk Ziegel, suggested that with advanced, new HIV/AIDS pills reaching the market, 4-year-old Fuzeon is past its prime. Trimeris has worked to develop a next-generation form of Fuzeon, but it has also laid off half of its employees and changed its corporate leadership in response to the drug's disappointing sales. [CDC HIV/Hepatitis/STD/TB Prevention News Update, Friday, October 5, 2007]

Obesity a Problem in HIV Population

The weight loss and wasting syndrome long associated with AIDS has now been replaced by obesity for some HIV-positive persons whose infection has not progressed to AIDS, according to a new study (Chang A. Associated Press. October 4, 2007).

Doctors report there is a growing need for HIV patients to be screened for obesity, which raises the risk of diabetes, high blood pressure, and high cholesterol levels. "We used to worry that they would lose weight and become wasted," said Dr Nancy Crum-Cianflone of San Diego's TriService AIDS Clinical Consortium. "Maybe we should redirect our concerns to making sure they are maintaining a healthy, normal weight."

At the height of the US AIDS epidemic, many patients experienced wasting syndrome (the uncontrollable loss of more than 10% of body weight) along with symptoms such as diarrhea and fever. Medical advances have resulted in more HIV patients living longer than their counterparts 2 decades ago, causing them to be prone to the same habits as uninfected US persons: poor eating choices and lack of exercise.

After observing that her patients were steadily getting fat, Crum-Cianflone decided to study how prevalent obesity was in the HIV population. She and her colleagues analyzed the medical records of 663 HIV patients at Navy hospitals in San Diego and in Bethesda, Md. The researchers looked at duration of HIV infection and whether patients had a history of diabetes or high blood pressure.

Sixty-three percent of the patients were overweight or obese, while just 3% were underweight, and none were considered to be "wasted." Among those with fully developed AIDS, about 30% were overweight or obese, the researchers found.

The numbers are especially striking considering that most of the study participants were in the
military and tended to be in better shape. Previous research has suggested that about 40% of HIV patients are overweight.

The study did not show a link between excess weight and AIDS drugs. Patients who gained weight tended to put on an average of 13 lb over a decade. Those who become infected younger, were infected for a longer time, or had high blood pressure were more likely to get fat.

The rise in obesity among HIV patients appears to mirror the US population in general. "These folks are, in more ways than not, becoming like everyone else," said Dr Michael Saag, director of the AIDS Center at the University of Alabama at Birmingham, who was not connected with the study. "If they're overeating, they're going to get fat." [CDC HIV/Hepatitis/STD/TB Prevention News Update, Thursday, October 4, 2007]

**New AIDS Drugs Will Simplify Care of Rural Children**

Families in rural areas in particular will benefit from new child-friendly formulations of AIDS drugs, a World Health Organization (WHO) official recently told attendees at a Harvard Medical School conference. The complicated dosing requirements of current AIDS drugs are "the reason so few kids are on treatment outside of capitals," said Charlie Gilks, head of treatment in WHO's HIV Division (Appel A. Inter Press Service. September 28, 2007).

The benefits of getting modern AIDS drugs to infected children early are evident in Brazil where "in the 1980s, just 25% of children infected with HIV survived after 3 years of treatment. Today it is 80%," Gilks said.

The new pills combine 2 or 3 antiretroviral drugs in a single tablet and are accompanied by a simple dosing chart. The pills are scored so they can easily be cut in half for very small children; they can also be crushed and mixed with food.

Under the WHO plan, the drugs will be distributed to entire families, with adults taking them at higher doses. This is key because the HIV-infected children with the best chance of survival are those whose mothers are well enough to care for them, Gilks said.

Most of the world's children who need HIV treatment live in sub-Saharan Africa, Gilks said. Despite improvements in recent years, the drugs are reaching only 21% of South African children who need them.

The WHO has been working for more than a year on the new formulations in combination with the European Union and the Bill Clinton Foundation. They still must be approved by the drug boards of various nations however, and "it's been a nightmare dealing with the regulators," Gilks said. [CDC HIV/Hepatitis/STD/TB Prevention News Update, Wednesday, October 3, 2007]

**Feds Help Atlanta Firm Hunt for AIDS Vaccine**

Given encouraging initial data, the NIH recently awarded a vaccine research firm $15 million to help continue investigations in a candidate HIV vaccine's development (Schneider C. Atlanta Journal-Constitution. September 28, 2007).

"We've done a significant amount of testing on humans with positive results," said Don Hildebrand, president of Atlanta-based GeoVax. "We've had a high percentage of people respond positively so far."

The experimental inoculation is meant to stimulate a person's immune system to fight HIV infection, said Hildebrand. About 140 people are participating in 4 independent national studies of the vaccine, he said, characterizing its development as in the middle stages.

The NIH grant will move the vaccine's development forward by months or years, Hildebrand said. With the help of the funding, GeoVax will perform phase 2 human clinical trials, planned for 2008, to see whether the vaccine prevents HIV or helps keep HIV infection from progressing to AIDS. A recent vaccine candidate by Merck & Co was found not to be effective, and the study was halted.

GeoVax developed its vaccine with the CDC, the NIH, and the firm's majority stakeholder, Emory University.
Provinces Undermine Beijing's Goals on AIDS
Since 2003, China's government has promised free HIV testing and, for the poor, antiretroviral treatment. But AIDS experts and Chinese HIV-infected patients say control and corruption inherent in a 1-party system prevent national AIDS policies from gaining much traction at the local level (Fan M. Washington Post. September 19, 2007).

In some hospitals, HIV/AIDS is deliberately misdiagnosed to cover up the problem or the the hospital fails to offer testing. Judges, all appointed by the Communist Party, get political signals not to take certain cases, said one Henan High Court official speaking anonymously. "Courts in Henan stopped getting involved in AIDS cases 2 years ago," he said. Many of the poor in Henan contracted HIV through government-approved blood-buying operations during the 1990s and were promised free antiretroviral drugs.

Inaction by some local officials has, experts fear, allowed HIV to race from high-risk injection drug users and sex workers to the general population. There were 18,543 new HIV cases reported in the first 6 months of this year, almost as many as in all of 2006, according to the official New China News Agency.

Little of the funds contributed to non-governmental organizations (NGOs), which often face restrictive scrutiny from wary officials, reaches them, activists say. Contributions are "far from enough to allow NGOs to have meaningful and comprehensive, preventative programs," said Wan Yanhai, a former Health Ministry official and now an AIDS activist. "Most of the money is taken away by government or government-controlled NGOs, and no one knows how it's being spent."

The government also recently forced the cancellation of 2 AIDS conferences and raided the Henan offices of an AIDS group. [CDC HIV/Hepatitis/STD/TB Prevention News Update, Monday, October 1, 2007]

Pillboxes Help HIV-Positive Stick to Drug Regimens
Simple plastic pillbox organizers can help HIV-infected patients improve their adherence to antiretroviral therapy, according to a study by Dr David R. Bangsberg of San Francisco General Hospital and colleagues (Reuters. September 12, 2007).

Although pillboxes are inexpensive and commonly used to help patients adhere to their drug regimens, no studies had examined whether they can help AIDS patients take their medications as prescribed. The researchers followed 245 HIV-positive men and women who were taking at least 3 different medicines from 1996 to 2000. They conducted periodic adherence checks by performing unannounced pill counts every 3 to 6 weeks.

The study authors used statistical techniques to compare adherence for participants who chose to use pillbox organizers with those who elected not to. Sixty-one percent of the individuals opted to use the organizers for at least 1 month during the study period.

Three different statistical models found that pillbox users increased their drug adherence by up to 4.5%. In addition, they had significantly lower HIV RNA levels in their blood and were almost twice as likely to have an HIV RNA level of 400 copies/mL or less. Pillbox users were 11% less likely to progress to AIDS during the course of the study than were non-users.

Antiretroviral regimens are simpler now than when the study was conducted, the authors noted, so it is not clear whether the organizers would be equally helpful for current patients. However, "given the simplicity and low cost of the intervention, clinicians should consider including pillbox organizers in their routine treatment of chronic disease." "Pillbox organizers should be a standard intervention to improve adherence to antiretroviral therapy," the authors concluded.


Warning Is Sent to AIDS Vaccine Volunteers
South African researchers have begun telling participants in the HIV vaccine trial conducted by Merck & Co that the vaccine may have increased their risk of HIV infection (Timberg C. Washington
In September, researchers shut down the trial of Merck's vaccine because it was proving ineffective compared with a placebo. The South African trial of Merck's vaccine was conducted separately and had its own ethics board. South African researchers have begun "unblinding" the trial, telling the 801 mostly heterosexual volunteers in Durban, Cape Town, and Soweto whether they received the placebo or the vaccine. Most are being notified by cell phone text messaging.

Merck developed the vaccine, a genetically manipulated cold virus containing HIV elements, in conjunction with the NIH. The hope was that the vaccine would stimulate the immune system, making HIV infection less likely or at least delaying the progression of infection to AIDS. While scientists say the vaccine itself could not have caused HIV infection, it could have caused immunological changes that made recipients more susceptible to infection on later exposure to HIV.

The ethics board in the United States, which monitored all other trial sites involving 3000 volunteers who are mostly gay men and women, has not decided whether to unblind the trial, said Mark Feinberg, Merck's vice president for medical affairs and policy. Continuing research could be compromised by doing so, he said. Nonetheless, individual participants wishing to know whether they received a placebo or the vaccine will be told, he said. Researchers are telling all participants that the vaccine could increase their risk of HIV infection. "Given the complexity of the issue, we feel the best conclusions will be reached when all the data are analyzed in their entirety," said Feinberg.


[Links:]