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Once-a-day pill for AIDS expected to help millions

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In a landmark step in the fight against HIV and AIDS, the Food and Drug Administration announced Wednesday the approval of a single-tablet, once-a-day, three-drug pill that is expected to improve and lengthen the lives of millions of patients worldwide.

One of the three drugs in the new combo pill was developed by a trio of Emory University scientists and sold last year in a record $525 million intellectual property rights deal.

U.S. Secretary of Health and Human Services Mike Leavitt called the three-drug pill cocktail --- to be called Atripla --- a "key breakthrough" and said it would be on the market in 96 days. Taking just one pill a day would simplify medication for patients who now have to remember to take from two to 15 pills a day.

Raymond F. Schinazi, an infectious disease expert and one of the Emory scientists who discovered one of the three drugs, emtricitabine --- now sold as Emtriva --- was jubilant at the announcement, which he said marked the crowning achievement of 20 years of battling HIV infection and AIDS.

"The big advantage is you have a tremendously powerful drug, like having an H-bomb for the HIV virus," he said. "You blow it to smithereens with one simple pill --- the virus doesn't know how to escape."

He added that "people should live a lot longer or maybe even a normal life span."

Schinazi, 56, a professor of pediatrics at Emory, discovered the drug in 1996 with fellow researchers Dennis Liotta, 57, a professor of chemistry, and Woo-Baeg Choi, a chemist who now owns FOB Synthesis of Atlanta, a small pharmaceutical company.

Last July, in what Emory called the largest known intellectual property deal involving an American university, Emory sold 65 percent of the royalties on Emtriva to Gilead Sciences of California and 35 percent to Royalty Pharma, a New York firm that brokered the deal. Though Emory received most of the money, the deal made millionaires of the three men.

Because Emory sold all future rights to the drug, it will not make any additional money from Atripla.

Emtriva was approved by the FDA in July 2003 to treat HIV infection in combination with other anti-retroviral agents.

Dr. Andrew C. von Eschenbach, acting FDA commissioner, said in a teleconference that the single pill dosage

marked a landmark in the treatment of the virus and demonstrates how scientists and publicly owned companies can work together in the war against AIDS.

Emtriva is one of three components of the new drug, being cooperatively manufactured by Gilead and Bristol-Myers Squibb. The other drugs in the single pill will be Viread and Sustiva. Emtriva and Viread are components of the drug Truvada, which was approved by the FDA for HIV treatment in August 2004.

"This drug could soon become the leading HIV drug in the world, because it simplifies treatment from the two or more pills now required each day," Schinazi said.

Liotta said the pill will likely cost about $1,200 a month.

He said the single pill may have a third benefit --- prevention.

In experiments using monkeys given the three ingredients and then injected with HIV, "it was completely effective," he said. "There's good reason to believe that this would be the case in humans."

Liotta called the approval "a great accomplishment" but said "our work will go on at full speed" to come up with even better medications.

Dr. Melanie Thompson, principal investigator for the AIDS Research Consortium of Atlanta, said all of the ingredients of the single pill are currently on the market but must be taken in multiple tablets.

"The potency of the new combination pill is greater," she said. "The other combination had to be taken twice a day, and taking it once will be better. Some drugs used in the past stopped working when the virus got resistant to different drugs. This is certainly different from patients taking 15 or 20 pills a day."

Frank Oldham Jr., executive director in Washington of the National Association of People with AIDS, was ecstatic at the FDA's announcement.

"It is an amazingly fantastic, lifesaving breakthrough," he said. "I know people who are taking 30 to 60 pills a day. This new pill will save many lives."

The ability to take just one pill a daily will be most beneficial in developing countries, von Eschenbach said, and will make access and compliance more effective.

Dr. Murray Lumpkin, FDA deputy commissioner for international and special programs, said current therapies involving several pills a day make it hard for people in the Third World to receive treatment, and the single pill will make it easier.

"We are getting to the holy grail that is not a cure for AIDS," but close, he said. "This will meet the logistical needs of developing countries."

Lumpkin said in a randomized trial of 511 people, about 80 percent "had complete control of the virus" after a year.

The new single-dose tablet can be taken alone or in combination with other anti-retroviral products, the FDA said. It combines the active ingredients of Sustiva (efavirenz), Emtriva (emtricitabine) and Viread (tenofovir

disoproxil fumarate).

The collaboration between two drug companies to manufacture and distribute Atripla is the first of its kind in the HIV/ AIDS field. It was approved in just under three months.

Because the three components of Atripla have been in use for some time, their effects are well known, the FDA said. The Atripla labeling includes a warning that the drug can cause a buildup of lactic acid in the body called lactic acidosis, and that it should not be used by pregnant women with HIV.

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