national news

A new option

The FDA admits nevirapine onto the AIDS-drug roster, while a herpes drug is nixed due to serious risks

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by Bob Roehr

A Food and Drug Administration advisory panel unanimously recommended approval of the AIDS drug nevirapine at its June 7 meeting at Silver Spring, Md. Final approval seems assured, and the drug may be available in pharmacies as early as the end of June.

Nevirapine was developed by Boehringer Ingelheim Pharmaceuticals and will be marketed under the trade name Viramune. It disrupts the HIV virus at the same point in its replication cycle as do the nucleoside analogs (AZT, 3TC, d4T, ddI, ddC). But it is the first in a new class of drugs known as non-nucleoside reverse transcriptase inhibitors. It binds to a different site of virus RNA to stop replication.

Clinical trials show the drug to be easily absorbed and tolerated by the body. The most significant side effect is skin rash, though it is seldom severe enough to discontinue use. Resistance quickly develops when used as a monotherapy, as is often the case with AIDS drugs. The drug is being recommended for use in combination.

Trials of nevirapine in triple combination with AZT and ddI have produced sustained elevations in CD4 count and drops in viral load that approach those of combinations using protease inhibitors. It appears to have its greatest effect on those with a CD4 count between 50 and 350 and lesser impact on either side of that range.

There is no clinical data on combination use with other nucleoside analogs. However, the chemical profile of nevirapine leads researchers to believe it is safe and will have parallel synergy in those combinations. There is, however, potential for harmful drug interactions with protease inhibitors. Patients and physicians are advised not to try these combinations until clinical data become available.

Martin Delaney of Project Inform in San Francisco called nevirapine "another pathway towards that goal of undetectable virus, one that has very low side effect risk."

Spencer Cox of the Treatment Action Group in New York City called nevirapine "an important option without very much information on how to use it." He believes that "people are going to be making decisions [on whether to use it or not] based on everything from toxicity profile, prior anti-viral history and cost."

Delaney sees "the issues are shifting away from active therapies. Now the goal is to sort out clinical management of the disease."

The company has not said how it will price the new drug, but indications are that it will be comparable to the nucleoside analogs and significantly lower than the protease inhibitors.

Ernest Hopkins of the National Association of People with AIDS, calls it "a significant funding challenge. Health care access will be the issue for us as more and more people begin to enroll in treatment therapy."

Delaney says, "It will actually offer some relief in the [government AIDS Drug Assistance Programs]. There may be a way to get to the goal of suppressing the virus without initially incurring the cost of the protease inhibitors."

Cox warns, "It is probably going to require some compromise from activists that we haven't had to make in the past—figuring out when it is time to let a drug fall off the formulary, as well as hopefully bringing in some new money to pay for new products." He cites the use of expensive growth hormone in people with very advanced disease as "a hard question that sounds mean just [in] asking it."

On June 6 the panel considered and rejected the application for Sorvudine, a treatment for herpes zoster. The drug is as effective as current medications and offers the convenience of taking a pill once a day as opposed to four pills five times a day.

The problem is a fatal interaction with an anti-cancer drug. Experience in Japan, where the drug is commercially available, has resulted in numerous cases of patients obtaining the medications from different physicians who were unaware of the other prescription. The patients died from the drug interaction.

"I know there were people in the community, particularly the AIDS community, who were looking forward to that one-dose drug," said NAPWA's Hopkins. But he applauded the panel's recommendation as appropriate. "There was no way they could agree to put the drug on the market because of the potential for fatalities."

The panel recommended further study to see if there is a way to approve restricted distribution so as to safeguard the public.