AIDS Activists Call on Public to Support New FDA HIV Drug Approval Policy

February 23, 2011

The AIDS Treatment Activists Coalition (ATAC) is asking people to sign on to a letter in support of a proposed U.S. Food and Drug Administration (FDA) policy that will hopefully make it easier for drugs to be approved for heavily treatment experienced people.

The new guidance under review at the FDA is aimed at helping companies overcome a significant hurdle in HIV drug development: proving that a new drug is effective given the potency of existing drugs.

New drugs with potential for treatment-experienced patients are typically pitted against a placebo, with both the experimental drug and placebo combined with background regimens consisting of approved drugs that may fight a person's HIV. This study design worked relatively well in the past, because many people had fewer than two other active drugs in their background regimens and, in turn, it was easier to prove the benefits of a new drug compared with placebo in a relatively short period of time.

Today, given the range of potent treatment options, most background regimens studied in trials are highly effective. In turn, it can take many months to determine the efficacy of an experimental treatment, despite the fact that earlier studies not requiring background regimens suggest that the new agent works well against drug-resistant HIV.

What's more, many researchers believe it is unethical to use a background regimen that has been optimized to achieve maximal viral suppression. Doing so substantially increases the likelihood of rapid resistance to the new agent.

"Demonstrating the superiority traditionally required by the agency to prove effectiveness is now virtually impossible without conducting trials in treatment-experienced patients whose virus is not fully suppressed," explains Lynda Dee, from AIDS Action Baltimore, in her letter on behalf of ATAC.

The letter goes on to explain that "Vicriviroc, a once daily CCR5 inhibitor, and apricitabine…have recently failed to demonstrate the efficacy necessary for FDA approval even though both drugs would certainly have been a valuable addition for treatment experienced patients."

That's where the new guidance comes in. In the proposed trial design, the experimental drug

would be given to people on top of their failing regimen for a week or two, just to measure how much it was able to reduce virus on its own. At the end of the initial trial period, people would add a new active background regimen, allowing researchers to assess the longer-term durability and safety of the experimental agent without placing people at undue risk of developing resistance to the new drug.

ATAC is also asking that the FDA shorten the duration of studies required to grant full agency approval of a new drug for heavily treatment-experienced people. Rather than granting accelerated approval after 24 weeks of study data, and then full approval after 48 weeks, ATAC is asking the FDA to begin granting full approval with only 24-week studies. The group believes that older studies have documented that rates of viral suppression at 24 weeks have always held up well enough over 48 weeks that the additional time under study is no longer necessary, though continuing post-approval safety would need to be explored.

“We firmly believe that this new paradigm will ensure ethical expedited trial design with lifesaving new drugs for treatment-experienced patients [who have] limited or no available options by providing a reasonable and prudent pathway in which to develop new ARV drugs in the HAART era,” Dee concludes.

To sign on in support of these new regulations, click here.

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