FDA to Docs: Best to Avoid Victrelis With Norvir-Boosted HIV Protease Inhibitors

April 27, 2012 By Tim Horn

Victrelis (boceprevir), Merck's hepatitis C virus (HCV) protease inhibitor, should not be combined with the following Norvir (ritonavir)-boosted HIV protease inhibitors: Reyataz (atazanavir), Prezista (darunavir) or Kaletra. This is an official warning that has been added to the Victrelis package insert by the U.S. Food and Drug Administration, according to a safety announcement by the agency on April 26.

The FDA warning follows a similar notification by Merck, issued February 8, in the wake of results from a clinical trial indicating significant drug-drug interactions between Victrelis and these HIV protease inhibitors (PIs). Though neither Victrelis nor Vertex's Incivek (telaprevir) is officially approved for the treatment of HCV in people living with HIV—coinfection studies are being conducted and yielding encouraging results—such warnings are important because some health care providers have already started prescribing these drugs for individuals living with both viruses.

"The U.S. Food and Drug Administration is notifying the public that coadministration of Victrelis along with certain ritonavir-boosted [HIV] protease inhibitors, is not recommended at this time because of the possibility of reducing the effectiveness of the medicines, permitting the amount of HCV or HIV virus in the blood (viral load) to increase," the agency warns.

Because the HCV PIs are broken down (metabolized) by the same enzyme pathway responsible for processing many ARVs, researchers have made it a priority to thoroughly explore potential drug-drug interactions and ways to circumvent potential problems.

Thus far, Incivek has been suggested to be safe to use with Norvir-boosted Reyataz and efavirenz (found in Sustiva and Atripla), though the Incivek dose needs to be increased because efavirenz reduces the blood concentration of Incivek. Significant interactions with other Norvir-boosted protease inhibitors have been documented, and thus far only Norvir-boosted Reyataz and efavirenz are being studied in combination with Incivek in the ongoing Phase II coinfection clinical trial.

As for Victrelis, researchers have known about a significant interaction with efavirenz. In turn, only Norvir-boosted PIs were permitted to be used in combination with Victrelis in Merck's Phase II

coinfection study.

But according to Merck's February letter, based on data from the Phase II study, there are significant drug interactions between Victrelis and Norvir-boosted HIV protease inhibitors that "may be clinically significant for patients infected with both chronic HCV and HIV by potentially reducing the effectiveness of these medicines when coadministered."

Specifically, Victrelis reduced mean trough concentrations—the lowest blood levels of drug, usually right before a subsequent dose is taken—of Norvir-boosted Reyataz, Kaletra and Norvir-boosted Prezista by 49, 43 and 59 percent, respectively. Average reductions of 34 to 44 percent and 25 to 36 percent were observed in average (AUC) and peak (Cmax) blood concentrations of Reyataz, Kaletra and Prezista.

While the Merck letter notes that Norvir-boosted Reyataz did not have an effect on Victrelis blood levels, Kaletra and Norvir-boosted Prezista decreased Victrelis blood levels by 45 and 32 percent, respectively.

Preliminary results from the Phase II trial have been encouraging, however, according to data presented at the 19th Conference on Retroviruses and Opportunistic Infections, held in early March in Seattle.

"In light of both the findings of the drug-drug interaction study and the clinical trial, FDA has revised the Victrelis drug label to state that coadministration of Victrelis with ritonavir-boosted Reyataz, ritonavir-boosted Prezista, or Kaletra to patients infected with both chronic HCV and HIV is not recommended at this time."

The agency says that it is aware of a planned Phase III clinical trial that will evaluate Victrelis plus pegylated interferon and ribavirin in people coinfected with HCV and HIV who are also receiving HIV therapy containing Norvir-boosted protease inhibitors. "FDA will communicate any important new information about coadministration of these drugs in coinfected patients when it becomes available."

As for people living with HIV and HCV currently using Victrelis and any of the antiretrovirals listed above, the FDA warns that treatment should not be stopped without talking to a health care provider. "Patients should contact their health care professional with any questions or concerns."

The FDA's warning is mirrored in official HIV treatment guidelines released earlier this month by the U.S. Department of Health and Human Services.

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