# Merck Warns of Victrelis and HIV Protease Inhibitor Interactions

February 8, 2012

The hepatitis C protease inhibitor Victrelis (boceprevir) has some significant drug-drug interactions with common Norvir (ritonavir)–boosted protease inhibitor (PI) combinations, according to preliminary data from a clinical trial and a warning issued to health care providers by Merck on February 6.

Drug-drug interactions between HIV antiretrovirals (ARV) and the recently approved hepatitis C PIs Victrelis and Incivek (telaprevir) are an essential area of study, given that roughly one third of people living with HIV are coinfected with hepatitis C virus (HCV) and may wish to use either Victrelis or Incivek to boost the efficacy of pegylated interferon and ribavirin treatment. While neither Merck's Victrelis nor Vertex's Incivek is officially approved for people coinfected with HIV and HCV—coinfection studies are still being conducted—some clinicians have already started prescribing these drugs for their patients living with both viruses.

Because the HCV PIs are broken down (metabolized) by the same enzyme pathway responsible for processing many ARVs, thoroughly exploring potential drug-drug interactions and ways to circumvent potential problems has been a research priority.

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, there is a significant interaction with efavirenz. In turn, only Norvir-boosted PIs are permitted to be used in combination with Victrelis in Merck's Phase II coinfection study.

New data from this study, however, indicate that there are significant drug interactions between Victrelis and Norvir-boosted PIs that "may be clinically significant for patients infected with both chronic HCV and HIV by potentially reducing the effectiveness of these medicines when coadministered," the February 6 letter from Merck warns.

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 (darunavir) 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.

“Merck does not recommend the coadministration of Victrelis and ritonavir-boosted HIV protease inhibitors,” the letter states.

For health care providers who have already prescribed Victrelis together with a Norvir-boosted protease inhibitor, Merck says they “should discuss these findings with those patients, and closely monitor those patients for HCV treatment response and for potential HCV and HIV virologic rebound.”

It is important to note that neither Victrelis nor Incivek is expected to interact with Merck’s Isentress (raltegravir)—an integrase inhibitor that is a preferred first-line treatment option for use in combination with other ARVs by the U.S. Department of Health and Human Services—and that interaction studies to confirm this hypothesis are being conducted.

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