Norvir-Free Boosted Prezista Tablet in the Works

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Tibotec Therapeutics—the research and development division of Janssen Pharmaceuticals—has entered an agreement with Gilead Sciences to develop a fixed-dose combination (FDC) tablet containing its protease inhibitor Prezista (darunavir) and Gilead Sciences' experimental boosting agent cobicistat, according to a Janssen announcement.

During the past decade, a number of different HIV drugs have been combined into single pills, both to reduce the total number of pills that people with HIV take and to extend the rights of companies to exclusively sell their drugs. The most successful of these combinations, Atripla—which contains Bristol-Myers Squibb's Sustiva (efavirenz) and Gilead's Truvada (tenofovir plus emtricitabine)—was the first to combine drugs from two different companies.

Aside from Kaletra, which combines Abbott Laboratories' lopinavir and ritonavir, there are no other protease inhibitors (PIs) co-formulated with other necessary agents designed to minimize dosing requirements while at the same time boosting effectiveness. With Gilead developing an agent, cobicistat, that can be used as an alternative to Norvir (ritonavir) to boost blood levels of other PIs, some PI manufacturers have expressed interest in partnering with Gilead to develop co-formulated products that can further minimize daily pill counts.

"We are excited to be able to study and develop Prezista with an alternative boosting agent in a combination product which has the potential to reduce the number of tablets patients take," said Johan Van Hoof, MD, of Janssen. "Prezista is one of the leading protease inhibitors, and co-formulating it with cobicistat in a new combination product demonstrates our commitment to HIV and innovations that will provide new options for patients."

The deal to combine Prezista with cobicistat will depend on two criteria. First, the U.S. Food and Drug Administration (FDA) must approve cobicistat. This approval is anticipated sometime within the next year. The second, according to Janssen, is that negotiations between it and Gilead on another FDC tablet must also be complete.

This other FDC will combine Prezista and cobicistat with Gilead's Emtriva (emtricitabine) and another Gilead drug that is in early stage testing. That drug, GS-7340, requires much lower doses than Viread and is expected to remain in the body for a long time before it is eliminated. This would make it ideal to combine with other drugs.

Janssen said it will have full rights and responsibilities for manufacturing and marketing the FDC of Prezista and cobicistat, while Gilead will take full responsibility for manufacturing and marketing the FDC of four drugs.

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