# Complete One-Pill, Once-Daily Prezista-Based HIV Regimen Enters Development

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Tibotec Therapeutics—the research and development division of Janssen Pharmaceuticals—has entered yet another agreement with Gilead Sciences to develop a fixed-dose combination (FDC) tablet. Now, according to a November 15 press release, the companies will develop a complete FDC regimen containing Janssen's protease inhibitor Prezista (darunavir) and Gilead Sciences' Emtriva (emtricitabine), boosting agent cobicistat and tenofovir prodrug GS 7340.

Plans for the newest Tibotec-Gilead FDC development strategy follow a similar announcement in June indicating plans to produce a single tablet combining Prezista with cobicistat.

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.

To date, no protease inhibitors (PIs) have been co-formulated with other necessary agents to allow for complete one-pill, once-daily regimens.

The complete FDC being developed by Tibotec and Gilead will contain two approved drugs—Prezista and Emtriva—with two still-experimental agents: cobicistat and GS 7340.

Cobicistat is currently in Phase III studies and is being explored as an alternative to Norvir (ritonavir) to boost blood levels of other PIs.

GS 7340 is a "prodrug" of tenofovir (sold as Viread)—its mechanism of action is the same, but it requires a dose that is 10 times lower than Viread and provides greater effectiveness. Though Gilead announced in 2004 that it had no interest in further developing the drug, arguing that it "does not believe that GS 7340 has a profile that differentiates it to an extent that supports its continued development," the company now plans to conduct a Phase II study to explore its efficacy, in preparation for its combined formulation with Prezista, cobicistat and Emtriva.

“We are pleased to once again be partnering with Tibotec to advance and simplify HIV treatment for patients,” said Norbert Bischofberger, PhD, Gilead’s chief scientific officer, in the company’s announcement. “This is the first time we are developing a protease inhibitor–containing single-tablet regimen, and we’re able to do that based on the small milligram size of GS 7340, which is less than one tenth of the amount of the 300 mg of tenofovir disoproxil fumarate contained in Viread and Truvada.”

Gilead will be responsible for the formulation, manufacturing, registration and, subject to regulatory approval, distribution and commercialization of the single-tablet regimen worldwide. Tibotec will have the right to co-detail the single-tablet regimen in certain major markets.

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