Approval Application for Gilead's Novel Booster Cobicistat Filed with FDA

June 28, 2012

A day after Gilead Sciences filed a New Drug Application (NDA) for its integrase inhibitor elvitegravir, the company announced on June 28 that it has submitted the necessary paperwork to the U.S. Food and Drug Administration requesting approval for its experimental pharmacoenhancing agent cobicistat (GS-9350).

If found to be safe and effective by the agency, cobicistat may be given marketing clearance to be used in combination with various antiretroviral medications, notably Reyataz (atazanavir) and Prezista (darunavir), as an alternative to low-dose Norvir (ritonavir) to boost their blood levels and allow for simplified dosing.

The company's "Quad" fixed-dose combination tablet—containing cobicistat, the experimental integrase inhibitor elvitegravir, and the nucleoside reverse transcriptase inhibitors tenofovir and emtricitabine—was recently recommended for approval by the FDA's Antiviral Drugs Advisory Committee for people living with HIV starting ARV therapy for the first time.

The NDA for cobicistat, supporting its use as a separate drug in combination with approved ARVs, is based on 48-week data from a Phase III study in which the agent was found to be comparable to Norvir when both boosters were administered with a background regimen of Reyataz plus Truvada (emtricitabine plus tenofovir).

The application is also supported by data demonstrating that cobicistat boosts blood levels of atazanavir and darunavir similar to ritonavir.

Gilead entered into an agreement with Janssen Therapeutics in June 2011 for the development of a fixed-dose combination tablet containing cobicistat and Prezista. In October 2011, Gilead announced an agreement with Bristol-Myers Squibb to develop a fixed-dose combination of cobicistat and Reyataz.

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