Gilead Files Approval Request for Integrase Inhibitor Elvitegravir

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Gilead Sciences has filed a New Drug Application for elvitegravir, its experimental integrase inhibitor, for use in combination with other antiretrovirals (ARVs) for treatment-experienced people living with HIV, according to a company news announcement.

The filing means Gilead currently has two ARVs under review by the U.S. Food and Drug Administration (FDA). The company's "Quad" fixed-dose combination tablet—containing elvitegravir, the novel boosting agent cobicistat 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 application for elvitegravir, supporting its use as a separate drug in combination with other HIV medications, is backed by 96-week data from a Phase III study in which once-daily elvitegravir was comparable to Merck's twice-daily integrase inhibitor Isentress (raltegravir), each administered with a background regimen that included a fully active Norvir (ritonavir)–boosted protease inhibitor and a second ARV.

Approval of elvitegravir could be granted before the end of 2012. The approval of the Quad is expected sometime this summer.

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