



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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