Gilead’s HIV ’Quad’ Tablet Now Before FDA for Approval Review

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Gilead Sciences has submitted paperwork to the U.S. Food and Drug Administration (FDA) for marketing approval of the “Quad,” a complete once-daily, single-tablet regimen.

The Quad, as the fixed-dose combination tablet has casually come to be known, contains four Gilead compounds: elvitegravir, an experimental integrase inhibitor; cobicistat, an experimental boosting agent that enables elvitegravir once-daily dosing; along with tenofovir and emtricitabine, typically used together as Truvada.

Gilead’s new drug application in support of approval, the company said in an October 28 announcement, is supported by 48-week data from two Phase III studies in which the Quad met its primary objective of non-inferiority as compared to Atripla or to a regimen containing Norvir (ritonavir)–boosted Reyataz (atazanavir). Preliminary data from Study 102 and Study 103, respectively, were reported earlier this year and will be revealed, in detail, at a conference early next year.