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

November 1, 2011

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.

© 2026 Smart + Strong All Rights Reserved.

http://beta.docker.poz.com/article/quad-fda-nda-21387-1143