’Quad’ Stribild Combo Tablet Approved by FDA

August 27, 2012 By Tim Horn

Stribild, the once-daily four-in-one fixed-dose combination (FDC) tablet formerly known as the “Quad,” has been approved for people living with HIV initiating antiretroviral (ARV) therapy for the first time, according to announcements by Gilead Sciences and the U.S. Food and Drug Administration released on Monday, August 27.

The tablet contains two new antiretrovirals—the integrase inhibitor elvitegravir and the novel pharmacokinetics enhancer cobicistat (needed to boost blood levels of elvitegravir)—as well as the nucleotide/nucleoside analog pair Truvada (tenofovir and emtrictabine).

The approval of Stribild is supported by 48-week data from two Phase III clinical trials (Studies 102 and 103) in which the single-tablet regimen was found comparable to Atripla and Norvir (ritonavir)-boosted Reyataz plus Truvada.

Like labels of many other ARVs, Stribild’s package insert carries a Boxed Warning alerting people living with HIV and their health care providers that the drug can cause a build up of lactic acid in the blood and severe liver problems, both of which can be fatal. The Boxed Warning also states that Stribild is not approved to treat chronic hepatitis B virus infection.

Common side effects observed in clinical trials include nausea and diarrhea. Serious side effects include new or worsening kidney problems, decreased bone mineral density, fat redistribution and changes in the immune system (immune reconstitution syndrome, IRIS).

Stribild’s label gives advice to health care providers on how to monitor patients for kidney or bone side effects.

Stribild’s per-patient annual wholesale acquisition cost (WAC) is $28,500, according to a Gilead spokesperson. The per-patient WAC for Atripla (efavirenz plus tenofovir and emtricitabine), Gilead’s current leading once-daily FDC tablet, is $21,000.

A patient assistance program—Gilead’s U.S. Advancing Access initiative—will provide assistance to people living with HIV who do not have insurance or who need financial assistance to pay for their ARVs, including Stribild. Patients may contact Advancing Access at 1-800-226-2056 between 9:00 AM and 8:00 PM (Eastern Time) to see if they are eligible for the program.

For people living with HIV who have private insurance, Gilead’s co-pay program provides assistance with out-of-pocket expenses for Gilead’s HIV medications, including Stribild, starting at the first dollar. Additionally, Gilead is working closely with the ADAP Crisis Task Force, as the company has done for each of its other HIV medications, to provide discounts to state AIDS Drug Assistance Programs (ADAPs) that will help ensure access to Stribild for people living with HIV who receive medications through these programs.

Applications for marketing approval of Stribild are pending in Australia, Canada and the European Union.

In the developing world, Gilead has granted multiple Indian manufacturing partners and the Medicines Patent Pool the right to develop generic versions of Stribild and distribute them to 100 developing countries. These agreements include a complete technology transfer of the manufacturing process for the single tablet regimen.

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