Gilead Submits Application for FDA Approval for a New Single-Pill HIV Regimen

November 24, 2010

Gilead announced November 23 that is has submitted a new drug application (NDA) to the U.S. Food and Drug Administration for a single-pill once-daily tablet that combines Tibotec's experimental drug rilpivirine (TMC278) with Gilead's Truvada (tenofovir and emtricitabine). If approved, it would become the second all-in-one, single-pill HIV regimen available in the United States.

During the past decade, the number of antiretroviral pills that a person must take has grown smaller and smaller. This trend culminated in 2006 with the release of Atripla, which contains the non-nucleoside reverse transcriptase inhibitor (NNRTI) Sustiva (efavirenz), with two nucleoside reverse transcriptase inhibitors (NRTIs), tenofovir and emtricitabine. The manufacture and marketing of the drug represented another first in the history of HIV drug development, which was the partnership of two independent drug companies, Bristol-Myers Squibb—the maker of Sustiva—and Gilead.

Now, a new second-generation NNRTI, rilpivirine, is in the last stages of development. In clinical trials reported so far, it has shown similar potency to Sustiva, but with fewer side effects. Once again, Gilead will be partnering with another company, in this case Tibotec (a subsidiary of Johnson & Johnson), which is developing rilpivirine as a stand-alone drug as well.

The submission of an NDA is the start of the final process for FDA approval. Historically, most AIDS drugs have been approved within a year of NDA submission. Gilead and Tibotec filed paperwork for European approval of the drug on September 3.

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