Approval of Gilead and Tibotec's New Combo HIV Pill Hits Snag

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Gilead Sciences announced January 25 that the U.S. Food and Drug Administration (FDA) has refused to accept the company's New Drug Application (NDA) supporting the approval of a new three-in-one HIV drug that combines Tibotec's rilpivirine (TMC278) with Gilead's Truvada (tenofovir plus emtricitabine).

The company expects to be in a position to resubmit the NDA by the end of March, once it is ready to provide additional information requested by the FDA. The agency is interested in the chemistry and manufacturing of the three-in-one drug, notably its methodology of establishing acceptable levels of an impurity related to emtricitabine that was found while testing the combination tablet.

Gilead's chief scientific officer, Norbert Bischofberger, told Bloomberg news that FDA's refusal to accept the filling will actually help ensure that the drug will still receive a priority six-month review.

"I am confident that this will result in only a minor delay in bringing this important new treatment to patients," said John Martin, Gilead's chief executive officer.

While Gilead is responsible for manufacturing the combination pill and getting its FDA approval, Tibotec—a subsidiary of Johnson & Johnson—remains responsible for manufacturing rilpivirine as a stand-alone drug. Gilead's reported manufacturing problem has affected the FDA review only of the combination pill.

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