Medical Xpress

Gilead's new four-in-one HIV pill, Genvoya, wins US approval

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Federal regulators have approved a new four-in-one combination pill to treat HIV, the virus that causes AIDS.

The Food and Drug Administration on Thursday approved sales of Genvoya from Gilead Sciences Inc., the top maker of HIV medicines.

The once-a-day pill combines three existing Gilead HIV drugs—Vitekta, Tybost and Emtriva—with a new version of tenofovir, the active ingredient in Gilead's widely used Viread. A chemical cousin, called tenofovir alafenamide, gets more of the drug into cells where HIV copies itself, reducing drug levels in the bloodstream and with that, side effects including kidney damage and reduced bone density.

However, patients taking the drug should be monitored for those side effects. In addition, fatal side effects including severe liver problems and a dangerous buildup of lactic acid in the blood are possible, so the drug carries a so-called black box warning, the FDA's strongest. Genvoya can also cause redistribution of fat in the body and changes in the immune system, and can interact with a number of commonly used medicines.

Gilead, based in Foster City, California, said the annual list price for Genvoya will be $31,362, about the same as for its older four-in-one HIV drug, Stribild. The company offers financial assistance to patients unable to afford that.

Tenofovir alafenamide, or TAF for short, is becoming the backbone of

Gilead's new HIV treatments. The company already has two other combination medicines that include TAF under review by the FDA.

"While exceptional progress has been made in the field of HIV, there is still a need for new treatment options that may help improve the health of people as they grow older with the disease," Gilead CEO John C. Martin said in a statement.

According to the Centers for Disease Control and Prevention, an estimated 1.3 million Americans are living with HIV, though some haven't been diagnosed yet. The bloodborne disease was once almost universally fatal, but improving treatments over the past two decades have turned it into a chronic, manageable disease for patients who have access to the medicines.

Early regimens required patients to take a dozen or more pills on a precise daily schedule. The more-recent daily combo pills have made it much easier for patients to stick to their treatment, preventing the virus from rebounding and growing resistant to the medicine.

Genvoya was approved for patients aged 12 and older who have never taken HIV medicines, and for adult patients whose HIV had been suppressed by other treatments for at least six months.

The approval was based on four late-stage studies, including a total of 3,171 patients, that compared Genvoya to other approved HIV treatment regimens. They showed Genvoya reduced blood levels of the HIV virus by about the same amount as the comparison treatments. The most common Genvoya side effect was nausea.

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