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FDA nod for Gilead's HIV drug

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Gilead Sciences has announced today that the US Food and Drug Administration (US FDA) has approved Genvoya(elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg or E/C/F/TAF) for the treatment of HIV-1 infection. Genvoya is the first TAF-based regimen to receive FDA approval.

Genvoya is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA levels less than 50 copies per mL) on a stable antiretroviral regimen for at least six months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Genvoya. No dosage adjustment of Genvoya is required in patients with estimated creatinine clearance greater than or equal to 30 mL per minute.

Genvoya has a boxed warning in its product label regarding the risks of lactic acidosis/severe hepatomegaly with steatosis, and post treatment acute exacerbation of hepatitis B.

TAF is a novel targeted prodrug of tenofovir that has demonstrated high antiviral efficacy similar to and at a dose less than one-tenth that of Gilead's Viread(tenofovir disoproxil fumarate, TDF), as well as improvement in surrogate laboratory markers of renal and bone safety as compared to TDF in clinical trials in combination with other antiretroviral agents. Data show that because TAF enters cells, including HIV-infected cells, more efficiently than TDF, it can be given at a lower dose and there is 91 percent less tenofovir in the bloodstream.

Genvoya was studied in a Phase 3 HIV clinical program in more than 3,500 patients across 21 countries, including treatment-naÃ¯ve, virologically suppressed, renally impaired and adolescent patients. The approval is supported by 48-week data from two Phase 3 double-blind studies (Studies 104 and 111) among 1,733 treatment-naÃ¯ve patients in which the regimen met its primary objective of non-inferiority compared to Stribild (elvitegravir 150 mg, cobicistat 150 mg, emtricitabine 200 mg and

tenofovir disoproxil fumarate 300 mg or E/C/F/TDF). In the combined analysis of the studies, 92.4 percent of Genvoya patients and 90.4 percent of Stribild patients had HIV-1 RNA levels less than 50 copies/mL at Week 48. Tests of certain renal and bone laboratory parameters also favored Genvoya over Stribild.

"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," said Dr John C Martin,chairman and CEO, Gilead Sciences. "For more than 25 years, Gilead has been committed to changing the trajectory of HIV management and we are now pleased to introduce Genvoya, the first in a portfolio of TAF-based products that have the potential to advance the long-term treatment of HIV."