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LONDON, UK (GlobalData), 20 April 2016 - The recent FDA approval of Gilead Sciences' drug Descovy (emtricitabine/tenofovir alafenamide [TAF]) in the treatment of human immunodeficiency virus (HIV) will boost the company's TAF-based HIV portfolio, and allow Gilead to stay on top of a fast-changing treatment landscape, according to an analyst with research and consulting firm GlobalData.

As explored in GlobalData's most recent <u>HIV report</u>, the market will see major shifts in the types of treatments administered to patients in the next few years. Indeed, fixed-dosed combinations (FDCs) and single-tablet regimens (STRs) are transforming the HIV landscape, and tenofovir disoproxil fumarate (TDF) treatments are beginning to be challenged by clinically superior TAF-based therapies.

David Fratoni, MSc, GlobalData's Analyst covering Infectious Diseases, explains: "The launch of Descovy means Gilead is now responsible for bringing three TAFs to the US market in less than six months, including Genvoya (elvitegravir/cobicistat/emtricitabine/TAF) and Odefsey (emtricitabine/rilpivirine/TAF). This commitment to building a strong TAF profile represents a remarkable milestone for Gilead's fight against HIV, cementing its leading position in the arena for now.

"Such a strategy comes at an opportune time for the company, as it encounters the rise of generic HIV regimens and branded FDCs and STRs. In fact, Gilead will have to face US and/or EU patent expirations of two of its TDF-based HIV therapies, Viread (TDF) and Truvada (emtricitabine/TDF), beginning in 2017, which will stimulate the entry of multi-tablet regimens from various generics manufacturers."

Gilead hopes to switch patients currently taking its TDF-based brands onto its next-generation TAFs over the next 6–12 months. Indeed, this will go a long way to protecting the company from imminent expiries, as it is expected that physicians will be in favor of this new regimen following a recent study showing that switching to TAF-based drugs is associated with maintenance of virological suppression, non-inferior virological efficacy, and overall tolerability.

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Fratoni continues: "Ultimately, the biggest threat to Gilead is competition from companies offering other branded drugs, not from generic manufacturers. Specifically, the strongest competitors are ViiV Healthcare and Janssen, which are currently working on a number of new HIV treatments to supplement their already-strong portfolios".

"Although GlobalData expects Gilead's three TAF-based regimens to garner a solid portion of market share over the next few years, the potentially successful outcomes of Janssen's and ViiV's clinical trials could shift market dynamics, meaning pricing factors will be key to future US market sales."