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FDA Advisory Committee Backs Controversial HIV Prophylactic

LONDON, UK (GlobalData), 11 May 2012 - In a controversial decision on May 10, the FDA antiviral drugs advisory committee backed Gilead Sciences' drug Truvada to prevent the transmission of HIV. The committee voted in favour of prophylactic Truvada in three populations: HIV-uninfected men who have sex with men (19-3), in HIV-uninfected partners in relationships with infected partners (19-2), and for individuals at risk of acquiring HIV through sexual activity (12-8). Although awareness of HIV and AIDs has significantly increased throughout recent decades, the disease remains a global epidemic requiring better preventative strategies. Yet the possibility that on June 15 the FDA will approve Truvada for pre-exposure prophylaxis (PrEP) has provoked strong and divided opinions from infectious disease experts and activists.

It might initially be surprising that groups with vested interests in HIV control would be vehemently opposed to a PrEP drug like Truvada. Truvada is already approved for the treatment of HIV, but a number of experts have expressed serious concern regarding its use as PrEP. A major argument against the use of Truvada or any PrEP strategy is whether at-risk patients will stop using other preventative methods like condoms. As Truvada's efficacy depends on consistent daily administration, there is concern that non-adherence will fail to prevent HIV transmission in people who would otherwise use a condom during sex. Other opponents fear that treating HIV-naïve patients with Truvada will result in the evolution of a drug-resistant HIV strain, making the disease even more difficult to treat and control. Finally, Truvada treatment is not free from side effects, and it is questionable whether otherwise healthy individuals will be willing to endure these when they are already reluctant to use a condom to prevent HIV transmission.

These concerns are all certainly valid, but evidence from clinical trials shows that PrEP Truvada is efficacious at preventing HIV transmission in three high risk populations. The FDA advisory committee considered the 2499 subject iPrEx study, which found that men who have sex with men (MSM) who took PrEP Truvada had 43.8% of of fewer infections than men taking a placebo. MSM are currently the main driver of HIV infection in the United States, and efficacy within this group is particularly important to control HIV-AIDS in this country. In addition, the committee considered data showing that Truvada decreased infection rates by 63% in men and women at high risk of infection in Botswana. Truvada has also demonstrated clinical efficacy in couples with a single infected partner. The drug decreased transmitted infections by 62% in serodiscordant Kenyan couples, and combination treatment with the HIV drug tenofovir resulted in a 73% reduction in infections. Despite opponents' concerns of severe side effects, Truvada's safety profile is actually fairly good. Adverse effects associated with Truvada include diarrhea, headache, depression, weight loss, and nausea; however these were mild to moderate and occurred in less than 7% of patients.

While these results show that Truvada is still less effective than using a condom, it is clearly evident that populations and high risk for HIV infection do not have a 100% adherence rate to this strategy. Therefore an orally administered, once daily pill like Truvada can seem like an appealing addition to the anti-HIV arsenal. Its proven efficacy and absence of severe side effects have already been enough to win over the antiviral drugs advisory committee, despite the valid and numerous concerns of PrEP opponents. Although the FDA does not necessarily need to follow the advice of its advisory committee, it almost always does. Since the committee voted in favour of PrEP Truvada with a clearly overwhelming majority, GlobalData anticipates that the FDA will approve Truvada for all three PrEP indications. Truvada generated sales of $2.88 million in 2011, but FDA approval of the Truvada brand extension could significantly increase these numbers in 2012 as the CDC estimates 415,000 Americans are at high risk for contracting HIV. However, GlobalData shares concerns with PrEP Truvada's opponents regarding patient non-adherence and the evolution of drug-resistant viral strains, and watches the impact of this drug on HIV epidemiology with great interest.

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-NOTES TO EDITORS-

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This expert insight was written by Dr. Cheryl Strelko, Oncology and Infectious Diseases Analyst for GlobalData. If you would like an analyst comment or to arrange an interview, please contact us on the details below.

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