

## Gilead drug approved for HIV, hepatitis B in EU

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**Singapore:** European Commission granted marketing authorization for two new indications for once-daily Viread (tenofovir disoproxil fumarate) by Gilead Sciences. The first new indication permits the use of Viread in combination with other antiretroviral agents for the treatment of HIV-1 infected pediatric patients aged two years-to-less than 18 years with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line pediatric agents.

The second indication approves Viread for the treatment of chronic hepatitis B virus (HBV) infection in adolescent patients aged 12 years-to-less than 18 years with compensated liver disease and evidence of immune active disease. The authorization covers all 27 countries of the European Union (EU). Viread was approved for use in combination with other antiretroviral agents as a treatment for HIV-1 infection in adults and for chronic HBV in 2002 and 2008, respectively, and is the most-prescribed molecule for these diseases in major European countries.

"We are pleased to provide new therapeutic options for younger patients living with HIV and chronic hepatitis B and will work to make these pediatric formulations available as quickly as possible," said Dr Norbert Bischofberger, executive vice president, R&D and CSO, Gilead Sciences.

The new indications are supported by clinical data from three studies examining the use of Viread among children and adolescents with HIV and among adolescents with chronic HBV. The safety and efficacy of Viread has not been established in children less than two years of age for HIV treatment, or in children less than 12 years of age for the treatment of chronic HBV.

In an effort to accelerate the availability of pediatric formulations in low-income countries, where the majority of children with HIV live, Gilead has established incentives to encourage its Indian generic manufacturing partners to develop pediatric formulations of its HIV treatments. Through these partnerships, Gilead already makes Viread available at significantly reduced cost for adults living with HIV and chronic HBV in low-income countries.