

Gilead HIV/AIDS 'blood booster' gets EU nod

26 September 2013 | Regulatory | By BioSpectrum Bureau



Singapore: Gilead Sciences has recieved European Commission marketing authorization approval for once-daily Tybost (cobicistat 150 mg tablets), a pharmacokinetic enhancer that boosts blood levels of certain HIV medicines.

Tybost is indicated as a boosting agent for the HIV protease inhibitors atazanavir 300 mg once daily and darunavir 800 mg once daily as part of antiretroviral combination therapy in adults with HIV-1 infection.

"Gilead is pleased to offer HIV patients who rely on protease inhibitors a new boosting option to help facilitate once-daily dosing, which is an important factor in supporting treatment adherence,― said Mr Norbert Bischofberger, executive VP, R&D and chief scientific officer, Gilead Sciences.

The EU approval of Tybost is supported by 48-week data from a pivotal phase III study (study 114), which found that Tybost was non-inferior to ritonavir when administered with an antiretroviral regimen of atazanavir plus Truvada (emtricitabine 200 mg and tenofovir disoproxil (as fumarate) 245 mg) in HIV-infected treatment-naÃ-ve adults.