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ASIA EDITION

Singapore Health Sciences Authority approves Biktarvy to treat HIV-1

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Gilead Sciences, Inc. has announced that the Singapore Health Sciences Authority has approved Biktarvy® (bictegravir 50mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg; BIC/FTC/TAF), a once-daily single tablet regimen (STR) for the treatment of HIV-1 infection in adults.

The triple-combination, single tablet regimen combines the potency of the novel integrase strand transfer inhibitor (INSTI) bictegravir, with the demonstrated safety and efficacy profile of a guideline recommended dual nucleoside reverse transcriptase inhibitor (NRTI) backbone - Descovy® (emtricitabine 200 mg/tenofovir alafenamide 25 mg; FTC/TAF). BIC/FTC/TAF has convenient once-daily dosing, does not require testing for HLA-B 5701, and has no food intake or baseline viral load or CD4 count restrictions.

The approval was based on data from four studies: Studies 1489 and 1490 in HIV-1 infected adults with no antiretroviral treatment history, and Studies 1844 and 1878 in HIV-1 virologically-suppressed adults who switched to Biktarvy. The trials are comprised of a population of 2,414 participants, and BIC/FTC/TAF met its primary efficacy objective at 48 weeks in all four studies, with no participants in any of the four BIC/FTC/TAF studies developing treatment-emergent virologic resistance. There were no cases of renal discontinuation, proximal renal tubulopathy or Fanconi syndrome in the BIC/FTC/TAF arms at 48 weeks.

Additional ongoing studies not included in the marketing authorization application involve dedicated studies in women, adolescents and children.

BIC/FTC/TAF was approved by the U.S. Food and Drug Administration (FDA) on February 7, 2018, the European Commission on June 21, 2018 and the Hong Kong Department of Health on September 26, 2018.