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Hong Kong Department of Health approves Biktarvy

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In clinical trials, Biktarvy demonstrated high efficacy and zero resistance through 48 weeks.

Singapore - Gilead Sciences announced that the Hong Kong Department of Health 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 . Hong Kong is the first market in Asia to approve Biktarvy.

The triple-combination, single-tablet therapy 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 provides a convenient once-daily dosing STR without regards of food. Furthermore, BIC/FTC/TAF's use is not restricted by the patient's baseline viral load, CD4 cell count or HLA-B 5701 status.

"Safety and resistance profiles are important considerations for HIV patients, as the disease requires long-term care. In addition, potent treatments with convenient dosing can potentially improve adherence and outcomes for patients in Hong Kong," said Dr Chan Kai Ming, Specialist in Infectious Disease, Consultant in Internal Medicine, Union Hospital, Hong Kong.

The approval was based upon data from four ongoing Phase 3 studies: Studies 1489 and 1490 in treatment-naïve HIV-1 infected adults, and Studies 1844 and 1878 in virologically suppressed adults. 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. The most common adverse reactions in patients taking BIC/FTC/TAF were diarrhoea, nausea, and headache.

BIC/FTC/TAF was approved by the U.S. Food and Drug Administration (FDA) on February 7, 2018 and the European Commission on June 21, 2018.