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Gilead's Biktarvy sustains viral suppression and tolerability in Asian HIV patients

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Clinical study findings in Asian women and adult population living with HIV were presented at 2020 Asia Pacific Aids & Co-Infections Conference



Gilead Sciences, Inc. on 15 Oct 2020 announced findings from multiple studies in Asian population that evaluated the safety and efficacy of switching to once-daily, single tablet regimen, Biktarvy® (bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg tablets, B/F/TAF) from baseline regimens at the 2020 Asia Pacific AIDS & Co-Infections Conference (APACC).

A post-hoc pooled analysis from three studies demonstrated efficacy of switching to B/F/TAF from integrase strand transfer inhibitor (INSTI) based antiretroviral therapy, or a boosted protease inhibitor (PI) with two Nucleotide Reverse Transcriptase Inhibitors (NRTIs) baseline regimens, among virologically-suppressed Asian adults living with HIV. In the analysis, 100 percent of the 63 Asian adults who switched to B/F/TAF maintained virologic suppression (defined as HIV-1 RNA <50 copies/mL) with no emergent resistance, vs 95.9 percent (70/73) in those stay on baseline regimen (SBR) group, through a maximum of 48 weeks. B/F/TAF was well tolerated with no adverse events leading to discontinuation among Asian participants in the studies.

Similarly, an open-label, randomized, phase 3 study of women with HIV who were virologically suppressed (HIV-1 RNA < 50 copies/mL) on a baseline regimen (elvitegravir (E)/cobicistat (C)/F/TAF, E/C/F/tenofovir disoproxil fumarate (TDF), or atazanavir + ritonavir + F/TDF), found that virologic suppression was maintained in 100 percent of the subgroup of Asian women participants (n=48) vs 98 percent in the SBR group (53/54). B/F/TAF was well tolerated with no adverse events leading to discontinuation.

These results further demonstrate the well-established efficacy and safety profile of Biktarvy. No participant on B/F/TAF developed treatment-emergent resistance. The additional data will further define the treatment regimen.

Biktarvy® (bictegravir 50mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg; B/F/TAF) is approved in Hong Kong, Singapore, South Korea, Taiwan and Thailand as a once-daily single tablet regimen (STR) for the treatment of HIV-1 infection in adults. B/F/TAF is indicated for the treatment of HIV-1 infection in adults without present or past evidence of viral

resistance to the integrase inhibitor class, emtricitabine or tenofovir.