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China NMPA approves Biktarvy to treat HIV-1 Infection

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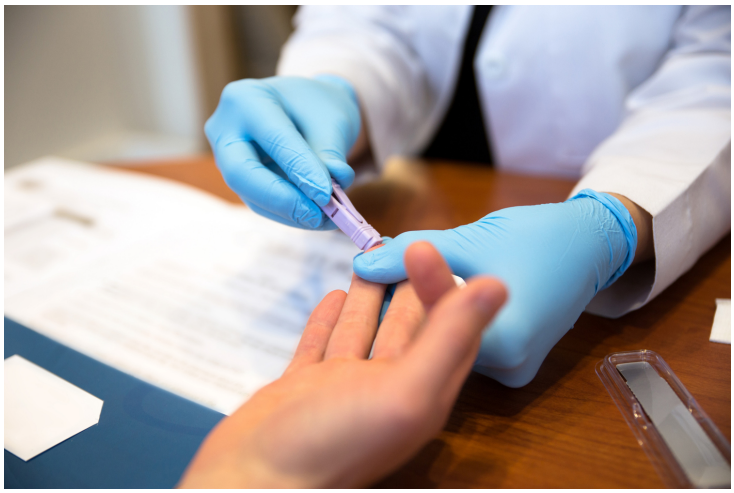
Biktarvy demonstrated high efficacy and a high barrier to resistance in clinical trials through 48 weeks



Gilead Sciences, Inc. has announced that the China National Medical Products Administration (NMPA) has approved Biktarvy® (bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg, BIC/FTC/TAF), a once-daily single tablet regimen (STR) for the treatment of HIV-1 infection.

Biktarvy combines the novel, unboosted integrase strand transfer inhibitor (INSTI) bictegravir with the demonstrated safety and efficacy profile of the Descovy® (emtricitabine 200mg/tenofovir alafenamide 25mg; FTC/TAF) dual nucleoside reverse transcriptase inhibitor (NRTI) backbone and is the smallest INSTI-based triple-therapy STR available. In China, Biktarvy 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.

“Biktarvy offers high rates of efficacy, high barriers to resistance and a demonstrated tolerability profile, underscoring its role as an important new treatment option for a broad range of patients in China,” said Professor Taisheng Li, Director of Infectious Disease Department, Peking Union Medical College Hospital.

In 2018, there were approximately 150,000 people newly diagnosed with HIV in China. The number of diagnoses has increased significantly in recent years, partially due to expanded screening. At the same time, the number of people living with HIV and receiving antiretroviral treatment has also increased steadily. The government of China has provided free antiretroviral treatment to all persons living with HIV since 2003.

Biktarvy met its primary efficacy objective of non-inferiority at 48 weeks across all four studies. Through 48 weeks, no participants in any of the four studies developed treatment-emergent virologic resistance while taking Biktarvy, and no patients discontinued Biktarvy due to renal, bone or hepaticadverse events. The most common adverse reactions in patients taking Biktarvy through 48 weeks were diarrhea, nausea and headache.