

Japan approves Gilead's Biktarvy to treat HIV-1 Infection

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In Clinical Trials, Biktarvy Demonstrated High Efficacy, Few Interactions with Other Drugs and a High Barrier to Resistance Through 48 Weeks



Gilead Sciences, announced that Japan's Ministry of Health, Labour and Welfare (MHLW) 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 200 mg/tenofovir alafenamide 25 mg; FTC/TAF) dual nucleoside reverse transcriptase inhibitor (NRTI) backbone, and is the smallest INSTI-based triple-therapy STR available. Biktarvy is the first HIV product that Gilead will launch and commercialize in Japan directly through its local subsidiary, Gilead Sciences K.K.

The approval of Biktarvy is supported by data from four 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 diverse population of 2,415 participants on Biktarvy or an active comparator, including a wide range of adult age groups and races/ethnicities.

"Gilead is pleased that Biktarvy, our latest HIV treatment innovation, will be made available to people living with HIV in Japan," said John McHutchison, AO, MD, Chief Scientific Officer, and Head of Research and Development, Gilead Sciences. "In multiple clinical trials, Biktarvy has demonstrated high efficacy and a high barrier to resistance. With convenient dosing and few pre-screening or ongoing monitoring requirements, it has the potential to simplify treatment initiation, and follow-up over time."

"Gilead's operations in Japan have expanded significantly over the years and we are pleased to now be able to bring our longstanding experience and commitment as a global leader in HIV treatment to the Japanese HIV community," said Luc Hermans, M.D., President and Representative Director, Gilead Sciences, K.K. "Biktarvy adds an important new treatment option to our portfolio of medicines for people living with HIV in Japan."