Biktarvy Maintains High Efficacy for Three Years in Clinical Trials

The integrase inhibitor–based HIV regimen was compared with dolutegravir-based regimens.

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In a pair of clinical trials comparing Gilead Sciences' Biktarvy (bictegravir/tenofovir alafenamide/emtricitabine) with dolutegravir-based antiretroviral (ARV) regimens, Biktarvy maintained a high level of efficacy for three years. Additionally, no one on the regimen developed resistance to the components of the regimen.

Biktarvy is approved to treat HIV among those starting ARVs for the first time and those who are already on treatment for the virus and have had a fully suppressed viral load for at least three months, have no history of treatment failure and whose virus has no known resistance to the components of the regimen.

Biktarvy includes the integrase inhibitor bictegravir. Dolutegravir, another integrase inhibitor, is sold under the brand name Tivicay and is a component of the Triumeq (dolutegravir/abacavir/lamivudine), Juluca (dolutegravir/rilpivirine) and Dovato (dolutegravir/lamivudine) combination tablets.

Researchers presented 144-week findings from Study 1489 and Study 1490, a pair of randomized, double-blind, active-controlled Phase III studies, at the 17th European AIDS Conference (EACS) in Basel, Switzerland.

Between them, the two clinical trials included 1,274 first-timers to HIV treatment. In Study 1489, they were randomized to receive either Biktarvy or Triumeq (dolutegravir/abacavir/lamivudine). In Study 1490, the were randomized to receive either Biktarvy or Tivicay plus Descovy (tenofovir alafenamide/emtricitabine).

The primary result that the study authors looked for was the comparative rates of full suppression of the virus after 48 weeks of treatment. The rates were comparable between the Biktarvy arms and the two dolutegravir arms, meaning that the regimens were considered noninferior, or comparably effective.

At week 144, Biktarvy remained noninferior to the two other regimens; 82% (518 of 634) of those who received the regimen had a fully suppressed viral load, compared with 84% (265 of 315) of

those in the Triumeq arm and 84% of those in the Tivicay plus Descovy arm.

None of the participants in the two trials developed treatment failure along with the development of viral resistance to the components of the regimens.

The researchers paid special attention to kidney and bone side effects in the two studies. An older form of tenofovir, tenofovir disoproxil fumarate (TDF), can cause kidney problems and bone loss, but the tenofovir alafenamide (TAF) in Biktarvy and Descovy is safer in that regard. However, recent research has indicated that TAF is associated with increases in cholesterol.

No one stopped treatment because of kidney-related health events. Nor were there any cases in the Biktarvy group of the severe kidney diseases proximal renal tubulopathy or Fanconi syndrome.

The members of the three study groups experienced similar median declines in their estimated glomerular filtration rate (eGFR, a marker of kidney function) at week 144, including a decline of 9.2 milliliters per minute in the Biktarvy arm, compared with declines of 11.7 and 11.0 ml per minute in the Triumeq and Tivicay plus Descovy arms, respectively.

Study 1489 also assessed other markers of kidney and bone health among those taking Biktarvy and Triumeq and found that the two groups experienced similar median changes in their proteinuria (greater than normal protein in the urine) and average percentage changes in hip and spine bone mineral density since starting HIV treatment. However, there were small, statistically significant differences (meaning they are unlikely to have been driven by chance) in the median change in LDL, HDL and total cholesterol–to-HDL ratio that indicated Triumeq was safer on this front.

Biktarvy proved well tolerated through 144 weeks of treatment. One percent (6 of 634) of those receiving the regimen discontinued treatment because of adverse health events, compared with 2% (5 of 315) of those who received Triumeq and 2% (6 of 325) of those who received Tivicay plus Descovy.

Twenty-six percent (165 of 634) of those in the Biktarvy arm experienced drug-related adverse health events, compared with 42% (132 of 315) of those in the Triumeq arm and 29% (94 of 325) of those in the Tivicay plus Descovy arm. Four percent, 18% and 5% in each arm experienced nausea, respectively.

In the Biktarvy, Triumeq and Tivicay plus Descovy arms, the most commonly reported side effects included diarrhea (19%, 18% and 16%, respectively), headache (16%, 18% and 18%, respectively) and symptoms of the common cold (14%, 17% and 19% respectively).

The two clinical trials are ongoing. After the 144-week mark, participants were offered the option to receive Biktarvy for up to 96 subsequent weeks.

To read a Gilead Sciences press release about the study, click here.

To read the study abstract, click here.

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http://beta.docker.poz.com/article/biktarvy-maintains-high-efficacy-three-years-clinical-trials