Confirmed: For Black Americans, Biktarvy Effectively Controls HIV

Undetectable viral load improves longevity and prevents transmission of HIV.

July 19, 2021 By Heather Boerner

There is no reason to think Black Americans would have different outcomes on Biktarvy than their peers of other races. But data presented at the 11th International AIDS Society Conference on HIV Science confirmed it: Black people who had an undetectable viral load when they switched to Biktarvy maintained viral suppression for up to 72 weeks after changing treatment.

This randomized, open-label multicenter study followed the 30% of participants in the larger BRAAVE study who identified as African American (495 participants) for 72 weeks. At the start of the trial, all participants had an undetectable viral load, defined as less than 50 for at least six months.

One in three participants were Black women; 4% identified as both Black and Latino. Three participants were transgender; another two identified outside the gender binary. Participants started the trial with about 450 CD4 T cells and had a mean body mass index just below the cutoff for obesity. Withe regard to drug resistance, 14% had baseline resistance to nucleoside reverse transcriptase inhibitors (NRTIs), 21% had baseline non-nucleoside reverse transcriptase inhibitor (NNRTI) resistance and 13% had baseline resistance to protease inhibitors. People with resistance to integrase inhibitors were excluded from the trial.

Initially, participants were randomized 330 to 165 into one of two arms, either to receive Gilead Sciences' Biktarvy single-tablet regimen (bictegravir/emtricitabine/tenofovir alafenamide) or to stay on the HIV regimen they were already taking. At 24 weeks into the trial, the 165 people on their old regimen switched to Biktarvy, and everyone stayed on it for the next 48 weeks.

At the end of the total 72 weeks of the trial, twice as many people in the Biktarvy arm had discontinued treatment compared with the standard regimen arm—but there were also twice as many people in the Biktarvy arm, so the actual proportion of people who discontinued was the same.

After 48 weeks, almost everyone who stayed on their current treatment before switching to Biktarvy maintained an undetectable viral load, matching the experiences of those who started the study on Biktarvy. At the time of the switch, 98% of people in both arms had an undetectable viral

load; after that, 99% to 100% of people maintained viral suppression until the end of the trial. For those who started on Biktarvy, 99% had an undetectable viral load at 72 weeks.

What's more, for people with HIV that is resistant to NRTIs—even those with stubborn M184V or M1841I mutations—the results held with similarly high viral suppression. But this finding should be tempered by the fact that study participants might have had just one viral load test during follow-up.

Common side effects—including upper respiratory tract infections, headache and diarrhea—were the same as those reported in earlier clinical trials showing that Biktarvy is noninferior to standard treatment. There were no differences in adverse events based on either sex at birth or whether participants were younger or older than 50 years old.

Three participants developed high fasting blood sugar, and three saw their fasting low-density lipoprotein—that is, "bad cholesterol"—increase. These are markers clinicians use to monitor the emergence of diabetes and potential heart problems, though the study didn't report that any participants developed either condition. On the continuum of illnesses, though, no data were reported about whether anyone developed new hypertension or diabetes.

Weight changes were similar in the two groups, but depended upon which drugs people were previously using; those who were already taking tenofovir alafenamide gained less weight that those switching from teofovir disoproxil fumarate or abacavir.

"For Black Americans living with HIV, switching to [Biktarvy] was highly effective and safe through 72 weeks regardless of age, sex at birth or preexisting NRTI resistanc," the researchers concluded. "No participant had treatment-emergent resistance tostudy drugs."

Click here to read the abstract and here to read Gilead's press release.

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