Selzentry (Maraviroc) Shows Promise as an Alternative to Truvada as PrEP

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The antiretroviral Selzentry (maraviroc) may eventually become an alternative to Truvada (tenofovir/emtricitabine) as pre-exposure prophylaxis (PrEP) against HIV, having performed well in a safety and tolerability study comparing the medications. Researchers conducted a Phase II, prospective, randomized, double-blind, multisite trial comparing various combinations of Selzentry and the two drugs in Truvada among 406 high-risk men who have sex with men (MSM) in the United States. Results were presented at the 2016 Conference on Retroviruses and Opportunistic Infections (CROI) in Boston.

The study was not designed to test the effectiveness of Selzentry as PrEP.

The participants were eligible if they reported having had condomless intercourse with an HIV-positive man or a man with an unknown HIV status during the previous 90 days, and if results of lab tests showed adequate safety parameters, including kidney function. The men were recruited at 12 U.S. sites, including one in San Juan, Puerto Rico. Sixty-two percent of the participants were white, 28 percent were black, 22 percent were Latino, and 10 percent were other races.

The men, who were all instructed to take three tablets daily, were divided into four groups, which received either: Selzentry plus two placebo tablets; Selzentry, Emtriva (emtricitabine) and a placebo; Selzentry, Viread (tenofovir disoproxil fumarate, or TDF) and a placebo; or Viread and Emtriva (in other words, Truvada divided into two tablets) plus a placebo.

During the 48-week study, participants were scheduled to return for follow-up visits at weeks 2, 4, 8 and every 8 weeks thereafter. A total of 340 (84 percent) of the participants completed the 48-week follow-up.

Five participants contracted HIV during the study, including two men who had no detectable study drug in their plasma at any of the study visits (one man was taking Selzentry alone, the other Selzentry and Viread). The remaining three men were all taking Selzentry alone and had low or variable levels of drug in their systems during the study visits.

An entry inhibitor, Selzentry works by blocking HIV's ability to connect to the CCR5 coreceptor on

the surface of CD4 immune cells. Not all HIV latches onto this coreceptor, however; some virus connects to the CXCR4 coreceptor. The three men who took Selzentry alone and who had low or variable levels of drug in their systems all had so-called R5 virus that attaches to the CCR5 receptor, and none had drug resistance.

A random subset of 122 participants received random tests to determine their adherence to the study drugs. Ninety-three percent of the tests showed detectable drug levels.

The rates of grades 2 to 4 adverse health problems did not differ between the study arms. Creatinine clearance, an indication of kidney function, dropped by an increment of 3 to 8 mL per minute among the participants between the study's outset and week 48; again, there was no difference between the study arms in this change.

Bone density tests of the participants are pending.

The researchers concluded that Selzentry as PrEP had comparable safety and tolerability to Truvada. They feel that the drug should be moved into advanced trials.

A Phase III trial of Selzentry as PrEP is currently under discussion. (There are three phases in the clinical trials process that are required before the U.S. Food and Drug Administration can consider an approval.)

To read a POZ feature about when we can expect to see PrEP 2.0, click here.

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