Once-Daily Tenofovir Prodrug Combo Pill as Effective as Stribild

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Gilead Sciences announced promising results today from a Phase II study of its once-daily quadruple-agent combination pill, which is based on a new formulation of tenofovir, finding the new therapy has comparable efficacy to Gilead's recently approved quad combo Stribild (elvitegravir, cobicistat, tenofovir and emtricitabine), The Wall Street Journal reports.

Formerly known as GS-7340, the new tenofovir alafenamide fumarate (TAF) is a nucleotide reverse transcriptase inhibitor (NRTI); it is a prodrug formulation of well-known HIV med elvitegravir, cobicistat, tenofovir and emtricitabine (TDF), sold as Viread and found in Truvada and Atripla. (Prodrugs are usually inactive chemical compounds that become active drugs when they interact with the body's metabolic system.) Phase Ib studies found that the required dose of TAF is one-tenth that of Viread, and that it is even more potent against HIV. The TAF combo also includes elvitegravir, cobicistat and emtricitabine.

In a randomized, double-blind 48-week clinical trial among treatment naïve adults, the TAF-based therapy suppressed viral loads to undetectable in 87 percent of patients at 24 weeks, versus 90 percent of those taking Stribild. TAF showed statistically significant smaller reductions in bone mineral density in the lumbar spine. In addition, there were smaller increases in serum creatinine with TAF than with Stribild, and there were smaller decreases in calculated creatinine clearance with TAF than with Stribild. Each drug proved well-tolerated.

In a statement, Norbert Bischofberger, PhD, executive vice president of research and development and chief scientific officer of Gilead Sciences, said, "These interim findings are encouraging and warrant advancing this TAF-containing single tablet regimen into Phase III development."

For the Gilead release, click here.

For the Wall Street Journal article, click here.

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http://beta.docker.poz.com/article/HIV-TAF-Efficacy-23089-2594