Clinical Trial of Triple-Drug Combination Pill 572-Trii Begins

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ViiV Healthcare and Shionogi & Co. announced Thursday, February 3, that the first patient has been enrolled into a study exploring the safety and efficacy of 572-Trii, the companies' fixed-dose combination pill containing the experimental integrase inhibitor S/GSK1349572 (S/GSK-572) and Epzicom (lamivudine plus abacavir).

"We are seeking to create an integrase-based, once-daily fixed-dose combination that helps meet patient needs," says Dominique Limet, ViiV Healthcare's chief executive officer. "We know that even with the successes of current therapies, patients still need additional treatment options, and we will continue to evaluate existing and pipeline compounds for new combination therapies."

The international clinical trial, dubbed SINGLE, is a randomized and blinded two-arm study comparing once-daily 572-Trii with once-daily Atripla (efavirenz plus tenofovir and emtricitabine). The study will include about 800 people living with HIV who are starting antiretroviral therapy for the first time.

The primary objective for the SINGLE study will be to demonstrate the antiviral activity of 572-Trii, compared with Atripla, over 48 weeks. Secondary objectives include the assessment of the tolerability, long-term safety and antiviral and immunologic activity of 572-Trii once-daily, compared with Atripla, over 96 weeks. Investigators will also evaluate viral resistance in patients experiencing virologic failure.

To learn more about the study and enrollment sites, including one in Wilton Manors, Florida, click here.