Improved safety and efficacy among women who switched from a multi-pill antiretroviral drug regimen

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Results from the first phase 3 HIV study to enroll only women show improved safety and efficacy of the drug Stribild over multi-pill antiretroviral drug regimens. The research was presented at ASM's 55th Interscience Conference of Antimicrobial Agents and Chemotherapy (ICAAC/ICC).

Results from the Women's Antiretroviral Efficacy and Safety Study (WAVES), the first randomized, double-blind antiretroviral (ARV) trial to enroll only women, show that women receiving the drug Stribild had a statistically higher rate of HIV suppression compared to the group that received ritonavir-boosted atazanavir plus Truvada. Additionally, no one receiving Stribild developed resistant mutation to HIV-1, compared to three women in the comparator group.

Data from this study provides specific safety and efficacy profiles for women regarding two approved regimens. "The optimal selection of HIV treatment should be evidence-based and WAVES provides clinical safety and efficacy data to assist women and their clinicians in the informed selection of antiretroviral treatment regimens," said study author Sally Hodder, MD, Director of the West Virginia Clinical and Translational Science Institute

The trial enrolled 575 HIV-1 infected women from Africa, Asia, Europe, Latin America and North America. The median age of study

participants was 35 years old, 48 percent were black and the majority reported unprotected heterosexual intercourse as the mode of HIV-1 acquisition.

The highest virological response to both regimens was observed in Uganda and the lowest rate of response was reported in the U.S. due to lower study drug adherence and a higher rate of discontinuation attributed to lost to follow up. Women in Russia achieved a statistically higher response rate to Stribild due to adverse events, which prompted early discontinuation in the ritonavir-boosted atazanavir plus Truvada arm. Women receiving ritonavir-boosted atazanavir plus Truvada were at increased risk for rash, jaundice and liver-related adverse reactions that led to study drug discontinuation.

"Women account for half of the global HIV epidemic and the number of new infections continues to rise," said Dr. Hodder. Although regulatory guidelines specify that gender-based assessment of drug efficacy, toxicity and tolerability profiles should be incorporated into clinical trials, women are routinely underrepresented in HIV clinical trials.

"As a consequence, current HIV treatment guidelines are based on data obtained primarily from men, but subsequently generalized and applied to both men and women," said Dr. Hodder. This may promote gender bias and inaccuracies in the paradigm of evidence-based medicine.

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