

# 4th International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV



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## TWELVE WEEKS OF ATAZANAVIR TREATMENT REVERSES NELFINAVIR-ASSOCIATED HYPERLIPIDAEMIA: RESULTS FROM BMS AI424-044

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**BACKGROUND:** Atazanavir is a potent, safe and effective once-daily protease inhibitor (PI) in Phase III development. Unlike other PIs, atazanavir has not been associated with clinically relevant elevations in total cholesterol, fasting LDL or fasting triglycerides. Consistently, in BMS trial AI424-008, atazanavir demonstrated a lipid profile superior to nelfinavir in treatment-naïve subjects.

**OBJECTIVES:** To examine the lipid profiles of subjects switched from nelfinavir to atazanavir, as well as atazanavir safety and tolerability.

**METHODS:** Subjects completing AI424-008 were eligible for treatment with atazanavir/stavudine/lamivudine in AI424-044. Subjects on nelfinavir in AI424-008 switched to atazanavir 400 mg; subjects on atazanavir continued with atazanavir 400 or 600 mg. Total cholesterol, fasting LDL, HDL and fasting triglycerides were assessed upon entry into AI424-044 and at 12 weeks.

**RESULTS:** 346 subjects were treated after completing a median 72 weeks in AI424-008. Subjects who switched from nelfinavir to atazanavir showed a significant mean percent increase in HDL (+5%,  $P<0.05$ ) and significant mean percent decreases in total cholesterol (-16%), LDL (-21%) and triglycerides (-28%) ( $P<0.0001$ ) from entry into AI424-044 to week 12. At week 12, median total cholesterol, LDL and triglyceride levels of the switched subjects were 165, 94 and 86 mg/dl, respectively, which were comparable to the levels observed upon initiating treatment in AI424-008. Atazanavir was safe and well tolerated.

**CONCLUSIONS:** Substitution of atazanavir for nelfinavir as part of a three-drug treatment regimen with stavudine and lamivudine correlates with significant improvement in total cholesterol, fasting LDL, HDL and fasting triglycerides at week 12. In this study, the nelfinavir-associated elevations in total cholesterol, fasting LDL and fasting triglycerides were reversed by 12 weeks of atazanavir treatment to levels observed in treatment-naïve subjects.

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