MK-0518 Appears Lipid Friendly

September 27, 2006 By Tim Horn

New data suggest that MK-0518 does not cause increased cholesterol or triglyceride as a side effect of treatment. The “late breaker” report, highlighting preliminary results from a study comparing Merck’s experimental integrase inhibitor MK-0518 to Bristol-Myers Squibb’s non-nucleoside reverse transcriptase inhibitor (NNRTI) Sustiva® (efavirenz), was presented on Wednesday at the 46th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in San Francisco.

Emerging clinical trial results indicate that MK-0518, when combined with other HIV medications, will likely be a potent addition to the current therapeutic armamentarium. Twenty-four week study data presented at the XVI International AIDS Conference, held in Toronto in August (and to be reported again at ICAAC), suggest that MK-0518 holds a great deal of promise for people with drug-resistant HIV in need of new treatment choices. It has also been suggested that this integrase inhibitor may be a useful regimen component for patients with drug-sensitive virus beginning therapy for the first time.

Beyond its effectiveness, HIV-positive people and their healthcare providers have been eager to learn more of MK-0518’s side effect profile. Encouragingly, the new data presented at ICAAC indicates that one of the most frequently noted side effects of NNRTIs and most protease inhibitors (PIs) – elevated lipid levels associated with an increased risk of cardiovascular problems – may not be a problem with this compound.

The preliminary 24-week results are from an ongoing 48-week study involving 198 HIV-positive people starting therapy for the first time. The patients were randomized to take either one of four doses of MK-0518 (100mg, 200mg, 400mg, or 600mg twice daily) or Sustiva (600mg once daily). All patients also took Viread® (tenofovir) and Epivir® (lamivudine).

Upon entering the study, the patients in the MK-0518 groups had average total cholesterol levels of 161 to 168 mg/dL. After 24 weeks, total cholesterol decreased by 2 mg/dL to 7 mg/dL in these groups. Among those in the Sustiva group, the average total cholesterol level at study entry was 170 mg/dL. After 24 weeks, their total cholesterol levels increased, on average, by 19 mg/dL. The differences between the MK-0518 groups and the Sustiva group with respect to total cholesterol changes was statistically significant, meaning that the differences weren’t due to chance.

As for triglycerides, patients taking MK-0518 had average levels of 110 mg/dL to 155 mg/dL upon entering the study. Twenty-four weeks later, there was a 2 mg/dL increase in the 100mg group and a decrease of 43 mg/dL in the 600mg group. Patients taking Sustiva had an average pre-treatment triglyceride level of 129 mg/dL, which increased 47 mg/dL after 24 weeks of treatment. These differences were also statistically significant.

The complete 48-week study results, including differences between MK-0518 and Sustiva with respect to viral load and CD4 (T4 cell) count changes, will likely be presented early next year.

“This study provides important preliminary data on this investigational compound in regard to lipid parameters in patients with HIV disease,” said Hedy Teppler, M.D., director of Infectious Diseases and Clinical Research at Merck. “Longer term follow-up of these patients is planned to confirm these findings.”

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