Non-Nuke TMC-278 Comparable to Sustiva

March 2, 2007 By Tim Horn

An international team of researchers presented the first results from a Phase II study of rilpivirine (TMC-278), Tibotec's experimental non-nucleoside reverse transcriptase inhibitor (NNRTI), on Wednesday at the 14th Conference on Retroviruses and Opportunistic Infections (CROI). The 48-week data indicate that, when combined with Truvada® (tenofovir plus emtricitabine) or Combivir® (zidovudine plus lamviduine), rilpivirine has comparable efficacy to leading NNRTI Sustiva® (efavirenz).

Bonus Coverage: AIDSmeds founder Peter Staley recently interviewed Dr. Calvin Cohen, research director of the Community Research Initiative of New England. Click here to hear more about TMC-278, Tibotec's new non-nuke. Study C204 is a 96-week study comparing three once-daily doses of rilpivirine to Sustiva, all in combination with Truvada or Combivir. Ninety-three patients have been randomized to the 25 mg rilpivirine group, 95 to the 75 mg group, 91 to the 150 mg, and 89 to Sustiva. All patients enrolled into the study were treatment-naïve, meaning that they had not taken any other HIV medications in the past.

Approximate 33% of the study participants are women. Combivir is being used by 76% of the study volunteers; Truvada by 24%.

At study entry, the average viral load was approximately 70,000 and the average CD4 count was 203.

After 48 weeks of treatment, average viral load reductions were 2.63 log in the 25 mg rilpivirine group, 2.65 in the 75 mg group, 2.63 in the 150 mg group, and 2.64 in the Sustiva group.

Viral loads below 50 copies – undetectable – were documented in 81% of those in the 25 mg group, 80% of those in the 75 mg group, and 77% in the 125 mg group. Statistically speaking, these data were comparable to the 81% undetectable rate in the Sustiva group.

CD4 count changes did not differ significantly between the groups; average increases of 125 to 145 cells after 48 weeks of treatment were reported.

In the rilpivirine groups, approximately 20% of patients experienced nausea, compared to 18% of those in the Sustiva group. Central nervous system effects – such as dizziness, somnolence, and

vertigo – were significantly more common in the Sustiva group (53%) compared to the rilpivirine groups (33%). Rash was also less likely to occur among those taking any dose of rilpivirine (8%) compared to those receiving Sustiva (19%).

Total cholesterol increased by 5 mg/dL and "bad" LDL cholesterol increased by 0 mg/dL in the rilpivirine groups. In the Sutiva group, total cholesterol increased by 31 mg/dL and LDL cholesterol increased by 16 mg/dL.

Based on these study findings, the 75mg rilpivirine dose has been selected for Phase III development in treatment-naive patients.

Source:

Pozniak A, Morales-Ramirez J, Mohapi L, et al. **48-week primary analysis of trial TMC278-C204: TMC278 demonstrates potent and sustained efficacy in ART-naïve patients** [Abstract 144LB]. 14th Conference on Retroviruses and Opportunistic Infections, Los Angeles, 2007.

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