Hepatic Safety & Efficacy of Raltegravir in Patients Co-infected with HIV and Hepatitis B (HBV) and/or C (HCV) Virus

Jürgen Rockstroh¹, Heidi Teppler¹, Jing Zhao¹, Peter Sklar¹, Charlotte Harvey¹, Randi Leavitt¹, and Bach-Yen Nguyen²

¹University of Bonn, Bonn-Venusberg, Germany; ²Merck Research Laboratories, West Point, PA, USA

Abstract

Background
• Raltegravir (RAL) is an HIV-1 integrase inhibitor, which is now
  approved for use in combination regimens for the treatment of HIV-
  infected adults. It has demonstrated efficacy and a favorable
  safety profile in clinical trials, including studies of patients co-
  infected with Hepatitis B and/or C virus.

Methods
• From 2007-2009, patients from 15 countries in Africa, Europe, Latin
  America, and Australia were treated with RAL as part of a Phase 3
  clinical program. In the STARTMRK (N=77) and BENCHMRK-1 & 2
  (N=266) studies, Hepatitis B/C - treated naive and -2, highly
treatment-experienced patients with multi-drug resistant virus failing
other therapies received RAL.

Results
• Overall efficacy through week 96
  - Proportion of patients with a CD4 cell count ≥ 500 cells/µL
  - Proportion of patients with an HIV RNA < 400 copies/mL
  - Proportion of patients with an ALT increase ≤ 3 x ULN

Conclusions
• RAL was efficacious in HIV-infected patients with and without Hepatitis B and/or Hepatitis C coinfections.

References

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Efficacy at Week 96 by Hepatitis Co-infection Status
Change from Baseline in CD4 Cell Count (cells/µL)