Author’s response to reviews

Title: Hepatic profile analyses of tipranavir in Phase II and III clinical trials

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Author’s response to reviews: see over
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Dear BioMed Central Editorial Team:

Thank you for the favorable response to our paper. The manuscript was changed according to the comments and suggestions received. We are enclosing our responses to each of the comments by the reviewers. We are looking forward to hearing from you soon.

Thank you

Kind Regards

Jaromir Mikl
Response to reviewers' comments:

- **Dr. Nicola Abrescia:**

  The following paragraph was added to the discussion section (paragraph 4) of the paper:

  Per protocol, any patient experiencing DAIDS 4 toxicity, according to the GCP and ICH guidelines, was to be discontinued from treatment. However, the patient population consisted of patients with advanced stage of HIV disease, presenting with opportunistic infections and the TPV/r was their last option for treatment. These compassionate trial designs were developed and approved by the regulatory authorities and key opinion leaders and continued treatment despite toxicity was a decision between the principal investigator and the patient on a case by case basis with very close patient monitoring.

- **Dr. Marina Nunez:**

  The following text was added to the conclusions section of the abstract:

  Among the 14 patients with hepatic SAE, 6 experienced hepatic failure (0.5%); these patients had profound immunosuppression and the rate appears higher among hepatitis co-infected patients. The overall probability of experiencing a hepatic SAE in this patient cohort was 1.4% through 96 weeks of treatment.