Clinical Study Synopsis for Public Disclosure

This clinical study synopsis is provided in line with **Boehringer Ingelheim's *Policy on Transparency and Publication of Clinical Study Data***.

The synopsis - which is part of the clinical study report - had been prepared in accordance with best practice and applicable legal and regulatory requirements at the time of study completion.

The synopsis may include approved and non-approved uses, doses, formulations, treatment regimens and/or age groups; it has not necessarily been submitted to regulatory authorities.

A synopsis is not intended to provide a comprehensive analysis of all data currently available regarding a particular drug. More current information regarding a drug is available in the approved labeling information which may vary from country to country.

Additional information on this study and the drug concerned may be provided upon request based on **Boehringer Ingelheim's *Policy on Transparency and Publication of Clinical Study Data***.

Name of company: Boehringer Ingelheim		**Tabulated Study Report**		
Name of finished product: Tipranavir				
Name of active ingredient: Tipranavir		**Page:**	**Number:**	
Ref. to Documentation:	**Volume:**	**Page:**		**Addendum No.:**
Report date: 30 Oct 2006	**Number:** U06-3706-01	**Study period (dates):** 20 Feb 2006 – 12 Apr 2006		**Revision Date:** 06 July 2007

Title of study:	An open-label, single-site, one-sequence cross-over study to assess the Relative Bioavailability of TPV/r 500 mg/200 mg at steady state when TPV and RTV are administered as oral solutions vs. capsules in the fed and fasted state.
Investigator:	[redacted]
Study center:	[redacted], Canada [redacted]
Publication (reference):	Data of this study has not been published
Clinical phase:	1
Objectives:	To establish the relative bioavailability of the TPV oral solution formulation (500 mg coadministered with RTV oral solution 200 mg) to the TPV capsule formulation (500 mg coadministered with RTV capsules 200 mg), with both treatments at steady-state under fasted and fed conditions in healthy male and female volunteers.
Methodology:	Open label, one-sequence, non-randomised cross-over design
No. of subjects: **planned:** **actual:**	 Planned Entered: 30 Actual enrolled: 39 Actual entered: Actual treated: 35 Actual analysed (for primary endpoint): 32
Diagnosis and main criteria for inclusion:	Healthy male and female volunteers, age ≥18 and ≤65 years, BMI range: ≥18.5 and ≤35 kg/m^2
Test product: **dose:** **mode of admin.:** **batch no.:**	Tipranavir oral solution with ritonavir oral solution 500 mg q12h Oral, administration with food vs fasted TPV: PD-2567B RTV: PD-2757 & PD-2778
Duration of treatment:	3.5 days

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Reference therapy:	Tipranavir capsules with ritonavir capsules
dose:	500 mg q12h
mode of admin.:	Oral, administration with food vs fasted
batch no.:	TPV: PD-2534 RTV: PD-2756
Duration of treatment:	10.5 days
Criteria for evaluation:	
Efficacy:	Bioavailability/PK
Safety:	AEs and laboratory parameters
Statistical methods:	Pairwise comparisons of TPV (and RTV) after each mode of administration were summarized using geometric mean ratios and confidence intervals.

SUMMARY – CONCLUSIONS:

Efficacy results: Comparable Bioavailability of TPV oral solution to oral capsules in fed and fasted states was demonstrated

Safety results: No unexpected safety issues arose during conduct of the study

Conclusions: TPV/r oral solution formulation administered as a 500/200 mg dose twice-daily to steady state was slightly more bioavailable ($AUC_{0\text{-}12h}$ increased by 23%) than the marketed TPV/r capsule formulation at steady state, and Cmax was about 21% lower when TPV/r oral solutions are administered with food. These differences are not sufficient to change the dose regimen from the current recommended dose of TPV/r 500/200 mg bid.

Food did not affect tipranavir steady-state PK for capsule formulations. This supports administration of TPV and RTV capsules either with food, or without food