Boehringer Ingelheim

# 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**.

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| **Name of company:** Boehringer Ingelheim | | **Tabulated Trial Report** | Boehringer Ingelheim |
| **Name of finished product:** Viramune®, Reyataz® | | **EudraCT No.:** 2005-004330-40 | |
| **Name of active ingredient:** Nevirapine, Atazanavir | | **Page:** **1 of 9** | **Synopsis No.:** |
| **Module:** | | **Volume:** | |
| **Report date:** 22 NOV 2011 | **Trial No. / U No.:** 1100.1470 / U11-2659-01 | **Dates of trial:** 03 NOV 2006 – 08 FEB 2011 | **Date of revision:** Not applicable |



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| **Title of trial:** | Open-label, randomised clinical trial to compare the virological efficacy and safety of **A**tazanavir/**R**itonavir on a background of **T**enofovir and **E**mtricitabine vs. **N**evirapine on same background, in HIV-1-infected patients who have received no previous antiretroviral treatment (ARTEN) |
| **Coordinating Investigator:** | [redacted] |
| **Trial sites:** | Multinational, multicentre trial in 68 sites in 10 countries, cf. Appendix 16.1.4 |
| **Publication (reference):** | 1. Soriano V, Rossi L de, Eur Infect Dis 2009;2(2):42-44 [P09-08976] (trial design overview);<br>2. Vicente Soriano1, Keikawus Arasteh, et al. Antiviral Therapy 2011; 16:339–348 [P11-03553] (results from 48 week interim analysis) |
| **Clinical phase:** | IIIb |
| **Objectives:** | The objective of this study was to determine the comparative efficacy and safety of two different nevirapine dosing regimens and atazanavir/ritonavir, all on an emtricitabine/tenofovir DF background |
| **Methodology:** | This was an open-label, randomised, multinational trial.<br>After successful screening, patients were randomised in a 1:1:1 allocation to nevirapine (NVP) 200 mg BID, or NVP 400 mg QD, or ritonavir-boosted atazanavir (ATZ/r), all in combination with emtricitabine (FTC) and tenofovir DF (TDF). All patients who were randomised to NVP, started on NVP 200 mg QD for 2 weeks, because it has been demonstrated that this escalating dosing regimen reduces the frequency of NVP-induced rash. At Week 2, patients increased the NVP dose to either 200 mg BID or to 400 mg QD. Patients who were randomised to ATZ/r were treated with ATZ 300 mg QD, boosted by 100 mg ritonavir (RTV) QD. Background antiretroviral therapy for all patients consisted of FTC 200 mg QD and TDF 300 mg QD in the fixed combination of Truvada®. Treatment duration was 48 weeks (primary endpoint) with an extension to 144 weeks. The randomisation at baseline was stratified by screening VL (VL) and CD4+ count. |

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| **No. of subjects:** | |
| **planned:** | entered: 561 |
| **actual:** | enrolled: 710<br>entered: 576<br>Treatment Nevirapine QD :<br>entered: 191 treated: 188 analysed (for primary endpoint): 188<br>Treatment Nevirapine BID:<br>entered: 192 treated: 188 analysed (for primary endpoint): 188<br>Treatment Atazanavir:<br>entered: 193 treated: 193 analysed (for primary endpoint): 193 |
| **Diagnosis and main criteria for inclusion:** | This study was conducted in antiretroviral treatment-naïve HIV-1-infected males and females.<br>Inclusion criteria:<br>1. Signed informed consent in accordance with GCP and local regulatory requirements prior to trial participation<br>2. HIV-1- infected males or females ≥ 18 years of age with positive serology (ELISA) confirmed by Western blot<br>3. No previous antiretroviral treatment (of more than 7 days)<br>4. Males with CD4+ counts < 400 cells/$mm^3$ and females with CD4+ counts < 250 cells/$mm^3$<br>5. NVP- and ATZ/r susceptibility based on HIV-1 genotypic resistance report<br>6. Adequate renal function was defined as a calculated creatinine clearance (CLCr) ≥ 50 mL/min according to the Cockcroft-Gault formula<br>7. Karnofsky score ≥ 70<br>8. Acceptable medical history, as assessed by the investigator |
| **Test product:** | Nevirapine |
| **dose:** | 200 mg QD for 2 weeks followed by 400 mg QD for the duration of the trial |
| **mode of admin.:** | Oral |
| **batch no.:** | See Appendix 16.1.6 |

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| **dose:** | 200 mg QD for 2 weeks followed by 200 mg BID for the duration of the trial |
| **mode of admin.:** | Oral |
| **batch no.:** | See Appendix 16.1.6 |
| **Reference therapy:** | Atazanavir |
| **dose:** | 300 mg QD boosted with ritonavir 100 mg QD |
| **mode of admin.:** | Oral |
| **batch no.:** | See Appendix 16.1.6 |
| **Duration of treatment:** | 48 weeks with an extension to 144 weeks |
| **Criteria for evaluation:** | |
| **Efficacy:** | The primary endpoint was the virologic response after 48 weeks of treatment. Treatment response was defined as a VL < 50 copies/mL measured at two consecutive visits prior to Week 48 and without subsequent rebound or change of ARV therapy prior to Week 48. |
| **Safety:** | Determination of safety:<br>1. Adverse events (treatment related and unrelated)<br>2. Serious adverse events<br>3. Occurrences of rashes and hepatic events<br>4. Laboratory test changes |
| **Statistical methods:** | The primary analysis was the test of the non-inferiority of the combined NVP groups compared to the ATZ/r group, as the first step of testing in the ordered system of null hypotheses, and if significant followed by testing of the individual NVP groups vs. ATZ/r. The primary endpoint was the proportion of evaluable patients with a treatment response at Week 48. The non-inferiority test was performed by calculating the two-sided 95% confidence interval (CI) for the difference in the proportions of responders between the two treatment groups, NVP and ATZ/r, adjusted for the stratification by screening VL and CD4+ cell count. Non-inferiority was established if -12% is excluded from the CI. |

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**SUMMARY – CONCLUSIONS:**

**Efficacy:**

The FAS consisted of 569 randomized and treated patients in total, 188 patients in the NVP BID group, 188 patients in the NVP QD group and 193 in the ATZ/r group. The mean age was 38.6 years, and patients were predominantly male (83.8%) and white (80.0%). The majority of patients were recruited in Western Europe (71.0%), followed by Latin America (21.3%) and Eastern Europe (7.7%). Overall, 393 (69.1%) of 569 patient were not prematurely discontinued prior to week 144: 125 (66.5%) patients were still receiving NVP QD at Week 144, 116 (61.7%) patients were still receiving NVP BID and 152 (78.8%) patients were still receiving ATZ/r. The most frequent reasons in the NVP arms for discontinuation were adverse events (15.4%), "other" reasons (10.6%), primarily lack of efficacy, and lost-to-follow up (5.6%). For ATZ/r, the most frequent reasons for discontinuation were refusal to continue medication (5.7%) and adverse events (5.2%).

In the primary analysis, the combined NVP treatment regimens were non-inferior to ATZ/r on the primary endpoint at Week 48 using the pre-defined 12% non-inferiority margin. 66.5% of patients in the combined NVP arms and 65.3% of patients in the ATZ/r arm had a treatment response according to the primary endpoint definition at Week 48 (95% CI for difference: -6.2% to 9.5%). This result at Week 48 was supported by the sensitivity analysis endpoint based on the TLOVR algorithm at week 48. In the combined NVP arms, 69.4% of patients had a treatment response according to the TLOVR algorithm compared to 73.6% in the ATZ/r arm (95% CI for difference: -11.2% to 3.7%).

At Weeks 96 and 144, the responder rates in the ATZ/r group were higher than in the NVP groups. This appears to be due to the very late response to treatment in a relatively large proportion of ATZ/r patients. 19.7% of ATR/r patients first became responders just up to or after the Week 48 visit compared to 5.6% of NVP patients (TLOVR endpoint). This difference is balanced to some extent by the larger proportion of NVP patients who were withdrawn early up to Week 48 due to lack of efficacy (8.2% on NVP vs. 1.6% on ATZ/r) and who were therefore not given the opportunity to respond later during treatment.

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Non-inferiority was also established in the key secondary analyses of the

comparison of each of the individual NVP groups with the ATZ/r group for the treatment response at week 48 as defined for the primary endpoint. However,

the same pattern of higher response rates at weeks 96 and 144 was seen for ATZ/r vs. the individual NVP groups.

VL <50 copies/mL:
During the first 12 weeks of treatment, the proportion of patients who achieved undetectable VL was slightly higher for NVP patients compared to ATZ/r. At Week 12, 44.7% of patients receiving NVP and 39.9% of patients receiving ATZ/r had VL <50 copies/mL.
The percentages of patients with VL <50 copies/mL increased at Week 24 and Week 36 in all treatment groups. However, the number of patients with VL <50 copies/mL increased more in the ATZ/r arm compared to the NVP arms. Accordingly, the percentage of patients with VL <50 copies/mL at Week 48 and thereafter was significantly higher with ATZ/r compared to NVP when considering non-completers as failures. However, when considering non-completers as missing, NVP was generally better compared to ATZ/r.

Virologic failure:
The proportion of patients with virological failure was comparable between the treatment arms at Week 48 but there were slightly larger proportions of NVP patients with virologic failure at Weeks 96 and 144. Broken down by reason for virological failure, more patients on NVP were discontinued by the investigators due to an insufficient VL response. In contrast, substantially more patients in the ATZ/r group did not have confirmed VL <50 copies/mL at Week 48, qualifying these patients as virological failures.

Time to treatment response:
The time to treatment response (defined as first of two consecutive VL values <50 copies/mL) was significantly better for the combined NVP group than for the ATZ/r group (p= 0.0002; median time to response was 12 weeks in NVP

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patients and 24 weeks in ATZ/r patients). Patients withdrawing early were censored after their withdrawal and more patients withdrew early on NVP compared to on ATZ/r, so some bias can be introduced in this analysis. Therefore, additional analyses were performed on the subset of responders. Among those who responded, the time to response was still significantly better in the combined NVP group than in the ATZ/r group ($p<0.0001$). Further analyses were performed using a different censoring approach on all patients whereby patients who withdrew early were considered censored at Week 144. In this analysis, no significant difference was seen between the treatment groups.

CD4+ count:
Up to Week 48, the treatment groups were comparable in terms of the changes over time in CD4+ cell count. Some slight differences were seen between Week 48 and Week 96, and from Week 96 onwards, patients in the ATZ/r group showed a significantly greater mean increase in CD4+ cell count from Week 96 onwards compared to NVP patients. This difference was seen in both men and women.

AIDS-defining illnesses:
Overall, 33 (5.8%) out of 569 patients in this study developed new or worsening of AIDS-defining illnesses up to the Week 144. Of them, 26 (6.9%) patients were in the NVP arms and 7 (3.6%) in the ATZ/r arm. The most frequent events were pneumonia (1.6% NVP and 1.0% ATZ/r), Kaposi's sarcoma (1.3% NVP and 0.5% ATZ/r), and Hodgkin's disease (1.1% NVP and 0.0% ATZ/r).

In the Cox regression analysis, the time to AIDS progression or death differed significantly between the combined NVP group and the ATZ/r group (hazard ratio 0.46; $p= 0.040$), with a more rapid time-to-event seen in the NVP group.

Quality of life and cost effectiveness:
No significant differences were seen between the treatment groups with regard to quality of life measurements. Similarly, no clear differences in cost effectiveness were seen.

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**Safety results:**

The overall frequency of AEs in this study was comparable between the three treatment arms (NVP QD 89.9%, NVP BID 92.6%, ATZ/r 93.3%). Drug-related AEs as judged by the investigator were observed more frequently in patients on ATZ/r, mainly due to the known hyperbilirubinaemia associated with ATZ/r treatment. The most frequently reported AEs (preferred term) are given in the table below.

| | Frequency of adverse events (%) (over 10% in any treatment arm) | | |
|---|---|---|---|
| | NVP QD | NVP BID | ATZ/r |
| nasopharyngitis | 21.8 | 19.1 | 20.7 |
| diarrhoea | 15.4 | 17.6 | 24.4 |
| rash | 13.8 | 16.5 | 11.9 |
| headache | 14.9 | 12.8 | 18.7 |
| nausea | 11.7 | 11.2 | 10.9 |
| bronchitis | 14.9 | 10.1 | 9.8 |
| influenza | 11.2 | 9.6 | 8.3 |
| cough | 9.6 | 12.2 | 10.9 |
| blood bilirubin increased | 0.0 | 1.1 | 17.6 |
| jaundice | 0.0 | 0.0 | 20.7 |

The vast majority of adverse events were DAIDS Grade 1 and DAIDS Grade 2 events. The proportion of patients experiencing DAIDS Grade 3 or 4 AEs were 16.0% and 4.8% for NVP QD, 14.9% and 8.0% for NVP BID, and 20.2% and 4.7% for ATZ/r, respectively.

Although the overall frequency of AEs was well balanced between NVP and ATZ/r, substantially more patients in the NVP groups discontinued study medication due to an adverse event. 26 patients (13.8%) treated with NVP QD and 32 patients (17.0%) treated with NVP BID were prematurely discontinued due to an AE. In contrast, only 10 patients (5.2%) treated with ATZ/r discontinued treatment due to an AE.

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Hepatic adverse events occurred more frequently in patients receiving ATZ/r (47.7%) compared with NVP (NVP QD 13.8%, NVP BID 12.8%). This difference is mainly driven by jaundice and hyperbilirubinaemia. Increases in ALT/AST or hepatitis were rare events in the ATZ/r group. DAIDS Grade 3 jaundice was reported in the ATZ/r arm in 7/193 (3.6%) and Grade 3 hyperbilirubinaemia in 5/193 (2.6%) of patients. Hepatocellular damage, hepatitis NEC, hypertransaminasaemia and liver disorders were reported in 10/376 (2.7%) NVP patients compared to 2/193 (1.0%) on ATZ/r.

The overall incidence of rash was similar between NVP and ATZ/r. However, severity of rash, expressed by DAIDS Grading and percentage of concerned BSA, was somewhat higher in NVP patients. In addition, rash was the most frequent AE leading to study medication discontinuation. The majority of rashes leading to discontinuation occurred during the 200mg lead-in period. No DAIDS Grade 4 rash events have been observed.

The frequency and severity according to DAIDS Grading of SAEs was comparable between patients receiving NVP and ATZ/r. SAEs were experienced by 25/188 patients (13.3%) in the NVP QD arm, 31/188 patients (16.5%) in the NVP BID arm and 27/193 patients (14.0%) in the ATZ/r group.

The overall number of fatal cases was low considering the underlying disease, the number of patients and the treatment duration. In total, seven patients died during the study including the post-treatment period . Three patients were receiving NVP QD, three patients NVP BID and one patient ATZ/r. None of these cases was considered related to the study medication.

Regarding laboratory evaluation, ALT/AST elevations of DAIDS Grade 3 and 4 were seen more frequently with NVP compared with ATZ/r. The percentage of patients that experienced DAIDS Grade 3 and 4 ALT/AST elevations were within the predicted range of the expanded analysis of hepatic reaction in NVP clinical trials, showing the usefulness of the CD4+ cell count restrictions. In addition, there was no major difference between NVP BID and NVP QD nor was there an excess of liver enzyme elevations in the NVP QD as previously reported.

In this study, many ATZ/r patients showed increases in total bilirubin with 89.1% having a DAIDS Grade of ≥2. In addition, DAIDS Grade 3 and 4 elevations occurred at a higher rate in ARTEN than in the CASTLE study, but only one patient discontinued treatment due to jaundice.

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| | Regarding the changes in GFR during the course of treatment there were no clear differences between treatment arms. The mean changes from baseline to end of study were -3.3, -6.3 and -9.6 mL/min/1.73 $m^2$ in the NVP QD, NVP BID and ATZ/r groups respectively. |
| **Conclusions:** | In the primary analysis, NVP showed non-inferior efficacy at week 48 compared with ATZ/r, both combined with fixed-dose Tenofovir/Emtricitabine. At Weeks 96 and 144, the responder rates in the ATZ/r group were higher than in the NVP groups. This appeared to be due to the very late response to treatment in a relatively large proportion of ATZ/r patients. A greater proportion of NVP patients were withdrawn early due to lack of efficacy and were therefore not given the opportunity to respond later during treatment. When considering non-completers as missing, NVP was generally better compared to ATZ/r. Among patients on-study and on-treatment, the proportion with viral load < 50 copies/mL was significantly higher for NVP compared to ATZ/r at most of the visits up to Week 96 but not thereafter.<br><br>Despite similar rates of AEs, discontinuations were more frequent in NVP than in ATZ/r patients. Patients in the NVP groups discontinued mainly due to rash, which generally occurred during the 200 mg QD lead-in period. No unexpected safety issues were observed for NVP or ATZ/r. |

## Trial Synopsis - Appendix

The appended tables on the following pages supplements the trial results presented in the Trial Synopsis. They complement disposition results and results for primary and secondary endpoints of the trial. Note that not all secondary endpoints defined in the trial protocol are presented in this synopsis because their number was too large to allow meaningful presentation in this format.

| **Results for** | **presented in** |
|---|---|
| Treatment response at week 48 (Primary endpoint) | Table 15.2.1.1: 1 |
| Treatment response at each visit according to the TLOVR algorithm (Secondary endpoint) | Table 15.2.1.1: 4 |
| Virologic success at week 48, 96, 144 (Secondary endpoint) | Table 15.2.2.1.1.1: 1 |
| Proportion of patients with viral load <50 copies/mL at each visit (Secondary endpoint) | Table 15.2.2.1.1.2: 1 |
| Proportion of patients with viral load <400 copies/mL at each visit (Secondary endpoint) | Table 15.2.2.1.1.3: 1 |
| Proportion of patients with virologic rebound (VL ≥50 copies/mL) at week 24, 48, 96, 144 (Secondary endpoint) | Table 15.2.2.1.1.4: 1 |
| Proportion of patients with virologic rebound (VL ≥400 copies/mL) at week 24, 48, 96, 144 (Secondary endpoint) | Table 15.2.2.1.1.5: 1 |
| Proportion of patients with virologic failure at week 48, 96, 144 (Secondary endpoint) | Table 15.2.2.1.1.6: 1 |
| $Log_{10}$ of viral load at each visit and change from baseline (Secondary endpoint) | Table 15.2.2.1.1.7: 1 |
| Time to treatment response (Secondary endpoint) | Table 15.2.2.1.1.8: 1 |

Table 15.2.1.1: 1 Treatment response at week 48 (primary analysis endpoint) - comparison of NVP combined vs ATZ/r (FAS, ORGV-AS)

| | NVP200BID/400QD | ATZ/r |
|---|---|---|
| Number of patients in analysis population | 376 | 193 |
| Responder [N (%)] | 250 (66.49) | 126 (65.28) |
| Number of patients in analysis | 373 | 193 |
| Difference in proportions | 0.016 | |
| 95% CI upper bound | 0.095 | |
| 95% CI lower bound | -0.062 | |
| p-value* | 0.6842 | |

* p-value is based on Cochran-Mantel-Haenszel test stratified by screening viral load and CD4 cell count
Analysis controlling for screening viral load category and screening CD4+ count category
Since in one screening viral load/CD4+ strata combination (viral load <= 100000 and CD4 count < 50) there were no observations of responses or non-responses under the ATZ/r treatment the weighted differences in response rates for this strata was not defined. Thus the observations from patients in this strata under the alternative treatment did not contribute to the estimated treatment difference in the response rates, i.e. they were effectively excluded from the analysis.

Source data: Appendix 16.1.9.2, Statdoc 6.1.1.14 stat\tr48_ds.sas 23JUN2011

Table 15.2.1.1: 4 Treatment response at week 48, 96, 144 (sensitivity analysis endpoint based on TLOVR algorithm) comparison of NVP combined vs ATZ/r (FAS, ORGV-AS)

| | NVP200BID/400QD | ATZ/r |
|---|---|---|
| Number of patients in analysis population | 376 | 193 |
| Visit 10 | | |
| Responder [N (%)] | 261 (69.41) | 142 (73.58) |
| Number of patients in analysis | 373 | 193 |
| Difference in proportions | -0.038 | |
| 95% CI upper bound | 0.037 | |
| 95% CI lower bound | -0.112 | |
| p-value* | 0.3206 | |
| Visit 14 | | |
| Responder [N (%)] | 253 (67.29) | 149 (77.20) |
| Number of patients in analysis | 373 | 193 |
| Difference in proportions | -0.097 | |
| 95% CI upper bound | -0.022 | |
| 95% CI lower bound | -0.171 | |
| p-value* | 0.0109 | |
| End of Study Visit | | |
| Responder [N (%)] | 234 (62.23) | 143 (74.09) |
| Number of patients in analysis | 373 | 193 |
| Difference in proportions | -0.117 | |
| 95% CI upper bound | -0.040 | |
| 95% CI lower bound | -0.194 | |
| p-value* | 0.0031 | |

* p-value is based on Cochran-Mantel-Haenszel test stratified by screening viral load and CD4 cell count
Analysis controlling for screening viral load category and screening CD4+ count category
Since in one screening viral load/CD4+ strata combination (viral load <= 100000 and CD4 count < 50) there were no observations of responses or non-responses under the ATZ/r treatment the weighted differences in response rates for this strata was not defined. Thus the observations from patients in this strata under the alternative treatment did not contribute to the estimated treatment difference in the response rates, i.e. they were effectively excluded from the analysis.

Source data: Appendix 16.1.9.2, Statdoc 6.1.1.20 stat\tr48_ds.sas 23JUN2011

Table 15.2.2.1.1.1: 1 Virologic success defined as VL <50 copies m/L (FDA definition) at week 48, 96, 144 (i.e. Visits 10, 14, 18) (FAS,CAL-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD ATZ/r | |
|---|---|---|---|---|
| Number of patients | 188 | 188 | 376 | 193 |
| Virologic success at Visit 10 | | | | |
| Virologic success | 131 ( 69.68) | 124 ( 65.96) | 255 ( 67.82) | 155 ( 80.31) |
| Virologic failure | 12 ( 6.38) | 7 ( 3.72) | 19 ( 5.05) | 20 ( 10.36) |
| No virologic data in time window | 45 ( 23.94) | 57 ( 30.32) | 102 ( 27.13) | 18 ( 9.33) |
| Discontinued due to AE or death | 20 ( 10.64) | 27 ( 14.36) | 47 ( 12.50) | 5 ( 2.59) |
| Discontinued for other reasons | 24 ( 12.77) | 27 ( 14.36) | 51 ( 13.56) | 13 ( 6.74) |
| Missing data during window but on study | 1 ( 0.53) | 3 ( 1.60) | 4 ( 1.06) | 0 ( 0.00) |
| Virologic success at Visit 14 | | | | |
| Virologic success | 126 ( 67.02) | 118 ( 62.77) | 244 ( 64.89) | 146 ( 75.65) |
| Virologic failure | 3 ( 1.60) | 2 ( 1.06) | 5 ( 1.33) | 12 ( 6.22) |
| No virologic data in time window | 59 ( 31.38) | 68 ( 36.17) | 127 ( 33.78) | 35 ( 18.13) |
| Discontinued due to AE or death | 23 ( 12.23) | 30 ( 15.96) | 53 ( 14.10) | 7 ( 3.63) |
| Discontinued for other reasons | 32 ( 17.02) | 36 ( 19.15) | 68 ( 18.09) | 25 ( 12.95) |
| Missing data during window but on study | 4 ( 2.13) | 2 ( 1.06) | 6 ( 1.60) | 3 ( 1.55) |
| Virologic success at End of Study Visit | | | | |
| Virologic success | 114 ( 60.64) | 103 ( 54.79) | 217 ( 57.71) | 131 ( 67.88) |
| Virologic failure | 5 ( 2.66) | 6 ( 3.19) | 11 ( 2.93) | 10 ( 5.18) |
| No virologic data in time window | 69 ( 36.70) | 79 ( 42.02) | 148 ( 39.36) | 52 ( 26.94) |
| Discontinued due to AE or death | 26 ( 13.83) | 32 ( 17.02) | 58 ( 15.43) | 10 ( 5.18) |
| Discontinued for other reasons | 37 ( 19.68) | 40 ( 21.28) | 77 ( 20.48) | 31 ( 16.06) |
| Missing data during window but on study | 6 ( 3.19) | 7 ( 3.72) | 13 ( 3.46) | 11 ( 5.70) |

Table 15.2.2.1.1.2: 1 Proportion of patients with viral load < 50 copies/mL at each visit (FAS, CAL-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Number of patients in analysis population | 188 | 188 | 376 | 193 |
| Baseline | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 1 (0.53) | 0 (0.00) | 1 (0.27) | 0 (0.00) |
| Viral load >= 50 (copies/mL) [N(%)] | 187 (99.47) | 188 (100.00) | 375 (99.73) | 193 (100.00) |
| Missing [N (%)] | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) |
| Visit 4 | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 22 (11.70) | 15 (7.98) | 37 (9.84) | 16 (8.29) |
| Viral load >= 50 (copies/mL) [N(%)] | 156 (82.98) | 152 (80.85) | 308 (81.91) | 162 (83.94) |
| Missing [N (%)] | 10 (5.32) | 21 (11.17) | 31 (8.24) | 15 (7.77) |
| Visit 6 | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 58 (30.85) | 43 (22.87) | 101 (26.86) | 46 (23.83) |
| Viral load >= 50 (copies/mL) [N(%)] | 114 (60.64) | 117 (62.23) | 231 (61.44) | 138 (71.50) |
| Missing [N (%)] | 16 (8.51) | 28 (14.89) | 44 (11.70) | 9 (4.66) |
| Visit 7 | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 97 (51.60) | 71 (37.77) | 168 (44.68) | 77 (39.90) |
| Viral load >= 50 (copies/mL) [N(%)] | 73 (38.83) | 85 (45.21) | 158 (42.02) | 110 (56.99) |
| Missing [N (%)] | 18 (9.57) | 32 (17.02) | 50 (13.30) | 6 (3.11) |
| Visit 8 | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 131 (69.68) | 124 (65.96) | 255 (67.82) | 141 (73.06) |
| Viral load >= 50 (copies/mL) [N(%)] | 27 (14.36) | 21 (11.17) | 48 (12.77) | 40 (20.73) |
| Missing [N (%)] | 30 (15.96) | 43 (22.87) | 73 (19.41) | 12 (6.22) |
| Visit 9 | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 130 (69.15) | 124 (65.96) | 254 (67.55) | 146 (75.65) |
| Viral load >= 50 (copies/mL) [N(%)] | 17 (9.04) | 9 (4.79) | 26 (6.91) | 30 (15.54) |
| Missing [N (%)] | 41 (21.81) | 55 (29.26) | 96 (25.53) | 17 (8.81) |
| Visit 10 | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 131 (69.68) | 124 (65.96) | 255 (67.82) | 155 (80.31) |
| Viral load >= 50 (copies/mL) [N(%)] | 12 (6.38) | 7 (3.72) | 19 (5.05) | 20 (10.36) |
| Missing [N (%)] | 45 (23.94) | 57 (30.32) | 102 (27.13) | 18 (9.33) |
| Visit 11 | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 132 (70.21) | 123 (65.43) | 255 (67.82) | 155 (80.31) |
| Viral load >= 50 (copies/mL) [N(%)] | 5 (2.66) | 6 (3.19) | 11 (2.93) | 17 (8.81) |
| Missing [N (%)] | 51 (27.13) | 59 (31.38) | 110 (29.26) | 21 (10.88) |

Source data: Appendix 16.2.6, Listing 1.1.1 stat\vl50_ds.sas 25AUG2011

Table 15.2.2.1.1.2: 1 Proportion of patients with viral load < 50 copies/mL at each visit (FAS, CAL-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Visit 12 | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 131 (69.68) | 119 (63.30) | 250 (66.49) | 150 (77.72) |
| Viral load >= 50 (copies/mL) [N(%)] | 3 (1.60) | 6 (3.19) | 9 (2.39) | 14 (7.25) |
| Missing [N (%)] | 54 (28.72) | 63 (33.51) | 117 (31.12) | 29 (15.03) |
| Visit 13 | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 129 (68.62) | 118 (62.77) | 247 (65.69) | 146 (75.65) |
| Viral load >= 50 (copies/mL) [N(%)] | 2 (1.06) | 5 (2.66) | 7 (1.86) | 17 (8.81) |
| Missing [N (%)] | 57 (30.32) | 65 (34.57) | 122 (32.45) | 30 (15.54) |
| Visit 14 | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 126 (67.02) | 118 (62.77) | 244 (64.89) | 146 (75.65) |
| Viral load >= 50 (copies/mL) [N(%)] | 3 (1.60) | 2 (1.06) | 5 (1.33) | 12 (6.22) |
| Missing [N (%)] | 59 (31.38) | 68 (36.17) | 127 (33.78) | 35 (18.13) |
| Visit 15 | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 125 (66.49) | 115 (61.17) | 240 (63.83) | 151 (78.24) |
| Viral load >= 50 (copies/mL) [N(%)] | 5 (2.66) | 4 (2.13) | 9 (2.39) | 5 (2.59) |
| Missing [N (%)] | 58 (30.85) | 69 (36.70) | 127 (33.78) | 37 (19.17) |
| Visit 16 | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 123 (65.43) | 117 (62.23) | 240 (63.83) | 148 (76.68) |
| Viral load >= 50 (copies/mL) [N(%)] | 5 (2.66) | 1 (0.53) | 6 (1.60) | 7 (3.63) |
| Missing [N (%)] | 60 (31.91) | 70 (37.23) | 130 (34.57) | 38 (19.69) |
| Visit 17 | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 120 (63.83) | 114 (60.64) | 234 (62.23) | 142 (73.58) |
| Viral load >= 50 (copies/mL) [N(%)] | 6 (3.19) | 1 (0.53) | 7 (1.86) | 8 (4.15) |
| Missing [N (%)] | 62 (32.98) | 73 (38.83) | 135 (35.90) | 43 (22.28) |
| End of Study Visit | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 114 (60.64) | 103 (54.79) | 217 (57.71) | 131 (67.88) |
| Viral load >= 50 (copies/mL) [N(%)] | 5 (2.66) | 6 (3.19) | 11 (2.93) | 10 (5.18) |
| Missing [N (%)] | 69 (36.70) | 79 (42.02) | 148 (39.36) | 52 (26.94) |
| Post Trial Visit | | | | |
| Viral load < 50 (copies/mL) [N(%)] | 1 (4.76) | 1 (5.88) | 2 (5.26) | 1 (9.09) |
| Viral load >= 50 (copies/mL) [N(%)] | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) |
| Missing [N (%)] | 20 (95.24) | 16 (94.12) | 36 (94.74) | 10 (90.91) |

Table 15.2.2.1.1.3: 1 Proportion of patients with viral load < 400 copies/mL at each visit (FAS, CAL-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Number of patients in analysis population | 188 | 188 | 376 | 193 |
| Baseline | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 1 (0.53) | 0 (0.00) | 1 (0.27) | 0 (0.00) |
| Viral load >= 400 (copies/mL) [N(%)] | 187 (99.47) | 188 (100.00) | 375 (99.73) | 193 (100.00) |
| Missing [N (%)] | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) |
| Visit 4 | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 74 (39.36) | 52 (27.66) | 126 (33.51) | 51 (26.42) |
| Viral load >= 400 (copies/mL) [N(%)] | 104 (55.32) | 115 (61.17) | 219 (58.24) | 127 (65.80) |
| Missing [N (%)] | 10 (5.32) | 21 (11.17) | 31 (8.24) | 15 (7.77) |
| Visit 6 | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 126 (67.02) | 111 (59.04) | 237 (63.03) | 125 (64.77) |
| Viral load >= 400 (copies/mL) [N(%)] | 46 (24.47) | 49 (26.06) | 95 (25.27) | 59 (30.57) |
| Missing [N (%)] | 16 (8.51) | 28 (14.89) | 44 (11.70) | 9 (4.66) |
| Visit 7 | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 149 (79.26) | 130 (69.15) | 279 (74.20) | 156 (80.83) |
| Viral load >= 400 (copies/mL) [N(%)] | 21 (11.17) | 26 (13.83) | 47 (12.50) | 31 (16.06) |
| Missing [N (%)] | 18 (9.57) | 32 (17.02) | 50 (13.30) | 6 (3.11) |
| Visit 8 | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 148 (78.72) | 132 (70.21) | 280 (74.47) | 173 (89.64) |
| Viral load >= 400 (copies/mL) [N(%)] | 10 (5.32) | 13 (6.91) | 23 (6.12) | 8 (4.15) |
| Missing [N (%)] | 30 (15.96) | 43 (22.87) | 73 (19.41) | 12 (6.22) |
| Visit 9 | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 141 (75.00) | 130 (69.15) | 271 (72.07) | 170 (88.08) |
| Viral load >= 400 (copies/mL) [N(%)] | 6 (3.19) | 3 (1.60) | 9 (2.39) | 6 (3.11) |
| Missing [N (%)] | 41 (21.81) | 55 (29.26) | 96 (25.53) | 17 (8.81) |
| Visit 10 | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 140 (74.47) | 130 (69.15) | 270 (71.81) | 171 (88.60) |
| Viral load >= 400 (copies/mL) [N(%)] | 3 (1.60) | 1 (0.53) | 4 (1.06) | 4 (2.07) |
| Missing [N (%)] | 45 (23.94) | 57 (30.32) | 102 (27.13) | 18 (9.33) |
| Visit 11 | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 136 (72.34) | 128 (68.09) | 264 (70.21) | 170 (88.08) |
| Viral load >= 400 (copies/mL) [N(%)] | 1 (0.53) | 1 (0.53) | 2 (0.53) | 2 (1.04) |
| Missing [N (%)] | 51 (27.13) | 59 (31.38) | 110 (29.26) | 21 (10.88) |

Source data: Appendix 16.2.6, Listing 1.1.1 stat\vl400_ds.sas 25AUG2011

Table 15.2.2.1.1.3: 1 Proportion of patients with viral load < 400 copies/mL at each visit (FAS, CAL-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Visit 12 | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 134 (71.28) | 124 (65.96) | 258 (68.62) | 162 (83.94) |
| Viral load >= 400 (copies/mL) [N(%)] | 0 (0.00) | 1 (0.53) | 1 (0.27) | 2 (1.04) |
| Missing [N (%)] | 54 (28.72) | 63 (33.51) | 117 (31.12) | 29 (15.03) |
| Visit 13 | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 130 (69.15) | 121 (64.36) | 251 (66.76) | 162 (83.94) |
| Viral load >= 400 (copies/mL) [N(%)] | 1 (0.53) | 2 (1.06) | 3 (0.80) | 1 (0.52) |
| Missing [N (%)] | 57 (30.32) | 65 (34.57) | 122 (32.45) | 30 (15.54) |
| Visit 14 | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 129 (68.62) | 120 (63.83) | 249 (66.22) | 156 (80.83) |
| Viral load >= 400 (copies/mL) [N(%)] | 0 (0.00) | 0 (0.00) | 0 (0.00) | 2 (1.04) |
| Missing [N (%)] | 59 (31.38) | 68 (36.17) | 127 (33.78) | 35 (18.13) |
| Visit 15 | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 130 (69.15) | 118 (62.77) | 248 (65.96) | 156 (80.83) |
| Viral load >= 400 (copies/mL) [N(%)] | 0 (0.00) | 1 (0.53) | 1 (0.27) | 0 (0.00) |
| Missing [N (%)] | 58 (30.85) | 69 (36.70) | 127 (33.78) | 37 (19.17) |
| Visit 16 | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 128 (68.09) | 118 (62.77) | 246 (65.43) | 154 (79.79) |
| Viral load >= 400 (copies/mL) [N(%)] | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.52) |
| Missing [N (%)] | 60 (31.91) | 70 (37.23) | 130 (34.57) | 38 (19.69) |
| Visit 17 | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 125 (66.49) | 115 (61.17) | 240 (63.83) | 149 (77.20) |
| Viral load >= 400 (copies/mL) [N(%)] | 1 (0.53) | 0 (0.00) | 1 (0.27) | 1 (0.52) |
| Missing [N (%)] | 62 (32.98) | 73 (38.83) | 135 (35.90) | 43 (22.28) |
| End of Study Visit | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 118 (62.77) | 108 (57.45) | 226 (60.11) | 139 (72.02) |
| Viral load >= 400 (copies/mL) [N(%)] | 1 (0.53) | 1 (0.53) | 2 (0.53) | 2 (1.04) |
| Missing [N (%)] | 69 (36.70) | 79 (42.02) | 148 (39.36) | 52 (26.94) |
| Post Trial Visit | | | | |
| Viral load < 400 (copies/mL) [N(%)] | 1 (4.76) | 1 (5.88) | 2 (5.26) | 1 (9.09) |
| Viral load >= 400 (copies/mL) [N(%)] | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) |
| Missing [N (%)] | 20 (95.24) | 16 (94.12) | 36 (94.74) | 10 (90.91) |

Table 15.2.2.1.1.4: 1 Proportion of patients with virologic rebound (i.e. VL >=50 copies/mL after CVR) at week 24, 48, 96, 144 (i.e. Visit 8, 10, 14, 18) - (FAS, ORGV-AS)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Number of patients | 188 | 188 | 376 | 193 |
| Visit 8 | | | | |
| Virologic rebound after CVR | 3 ( 1.60) | 2 ( 1.06) | 5 ( 1.33) | 5 ( 2.59) |
| No Virologic rebound | 140 ( 74.47) | 129 ( 68.62) | 269 ( 71.54) | 145 ( 75.13) |
| Missing | 45 ( 23.94) | 57 ( 30.32) | 102 ( 27.13) | 43 ( 22.28) |
| Visit 10 | | | | |
| Virologic rebound after CVR | 4 ( 2.13) | 5 ( 2.66) | 9 ( 2.39) | 12 ( 6.22) |
| No Virologic rebound | 149 ( 79.26) | 134 ( 71.28) | 283 ( 75.27) | 160 ( 82.90) |
| Missing | 35 ( 18.62) | 49 ( 26.06) | 84 ( 22.34) | 21 ( 10.88) |
| Visit 14 | | | | |
| Virologic rebound after CVR | 4 ( 2.13) | 6 ( 3.19) | 10 ( 2.66) | 10 ( 5.18) |
| No Virologic rebound | 150 ( 79.79) | 133 ( 70.74) | 283 ( 75.27) | 166 ( 86.01) |
| Missing | 34 ( 18.09) | 49 ( 26.06) | 83 ( 22.07) | 17 ( 8.81) |
| End of Study Visit | | | | |
| Virologic rebound after CVR | 8 ( 4.26) | 9 ( 4.79) | 17 ( 4.52) | 15 ( 7.77) |
| No Virologic rebound | 147 ( 78.19) | 135 ( 71.81) | 282 ( 75.00) | 164 ( 84.97) |
| Missing | 33 ( 17.55) | 44 ( 23.40) | 77 ( 20.48) | 14 ( 7.25) |

Table 15.2.2.1.1.5: 1 Proportion of patients with virologic rebound (i.e. VL >=400 copies/mL after CVR) at week 24, 48, 96, 144 (i.e. Visit 8, 10, 14, 18) - (FAS, ORGV-AS)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Number of patients | 188 | 188 | 376 | 193 |
| Visit 8 | | | | |
| Virologic rebound after CVR | 2 ( 1.06) | 2 ( 1.06) | 4 ( 1.06) | 2 ( 1.04) |
| No Virologic rebound | 141 ( 75.00) | 129 ( 68.62) | 270 ( 71.81) | 148 ( 76.68) |
| Missing | 45 ( 23.94) | 57 ( 30.32) | 102 ( 27.13) | 43 ( 22.28) |
| Visit 10 | | | | |
| Virologic rebound after CVR | 3 ( 1.60) | 3 ( 1.60) | 6 ( 1.60) | 2 ( 1.04) |
| No Virologic rebound | 150 ( 79.79) | 136 ( 72.34) | 286 ( 76.06) | 170 ( 88.08) |
| Missing | 35 ( 18.62) | 49 ( 26.06) | 84 ( 22.34) | 21 ( 10.88) |
| Visit 14 | | | | |
| Virologic rebound after CVR | 3 ( 1.60) | 6 ( 3.19) | 9 ( 2.39) | 2 ( 1.04) |
| No Virologic rebound | 151 ( 80.32) | 133 ( 70.74) | 284 ( 75.53) | 174 ( 90.16) |
| Missing | 34 ( 18.09) | 49 ( 26.06) | 83 ( 22.07) | 17 ( 8.81) |
| End of Study Visit | | | | |
| Virologic rebound after CVR | 4 ( 2.13) | 6 ( 3.19) | 10 ( 2.66) | 5 ( 2.59) |
| No Virologic rebound | 151 ( 80.32) | 138 ( 73.40) | 289 ( 76.86) | 174 ( 90.16) |
| Missing | 33 ( 17.55) | 44 ( 23.40) | 77 ( 20.48) | 14 ( 7.25) |

Table 15.2.2.1.1.6: 1 Proportion of patients with virologic failure at week 48, 96, 144 (i.e. Visits 10, 14, 18) (FAS, ORGV-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD ATZ/r | |
|---|---|---|---|---|
| Number of patients | 188 | 188 | 376 | 193 |
| Patients with virologic failure | | | | |
| Visit 10 | 20 ( 10.64) | 25 ( 13.30) | 45 ( 11.97) | 25 ( 12.95) |
| Visit 14 | 15 ( 7.98) | 25 ( 13.30) | 40 ( 10.64) | 13 ( 6.74) |
| End of Study Visit | 19 ( 10.11) | 28 ( 14.89) | 47 ( 12.50) | 17 ( 8.81) |

Table 15.2.2.1.1.7: 1 Log10 of Viral load at each visit and change from baseline to each visit (FAS, CAL-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Baseline (Visit 2) | | | | |
| N | 188 | 188 | 376 | 193 |
| Mean | 5.08 | 5.08 | 5.08 | 5.08 |
| SD | 0.696 | 0.600 | 0.649 | 0.660 |
| Geo-Mean | 5.02 | 5.05 | 5.04 | 5.03 |
| Geo-SD | 1.168 | 1.132 | 1.151 | 1.149 |
| Min | 1.73 | 3.34 | 1.73 | 2.82 |
| Q1 | 4.69 | 4.75 | 4.70 | 4.68 |
| Median | 5.20 | 5.17 | 5.19 | 5.18 |
| Q3 | 5.56 | 5.53 | 5.54 | 5.58 |
| Max | 6.76 | 6.25 | 6.76 | 6.55 |
| Visit 4 | | | | |
| N | 178 | 167 | 345 | 178 |
| Mean | 2.75 | 2.80 | 2.78 | 2.88 |
| SD | 0.802 | 0.718 | 0.762 | 0.676 |
| Geo-Mean | 2.64 | 2.72 | 2.68 | 2.80 |
| Geo-SD | 1.323 | 1.281 | 1.304 | 1.276 |
| Min | 1.69 | 1.69 | 1.69 | 1.69 |
| Q1 | 2.25 | 2.40 | 2.31 | 2.56 |
| Median | 2.70 | 2.78 | 2.75 | 2.92 |
| Q3 | 3.13 | 3.13 | 3.13 | 3.25 |
| Max | 5.88 | 5.59 | 5.88 | 5.48 |
| Visit 6 | | | | |
| N | 172 | 160 | 332 | 184 |
| Mean | 2.33 | 2.39 | 2.36 | 2.35 |
| SD | 0.839 | 0.870 | 0.853 | 0.634 |
| Geo-Mean | 2.21 | 2.28 | 2.24 | 2.27 |
| Geo-SD | 1.350 | 1.351 | 1.351 | 1.289 |
| Min | 1.69 | 1.69 | 1.69 | 1.69 |
| Q1 | 1.69 | 1.69 | 1.69 | 1.71 |
| Median | 1.99 | 2.14 | 2.06 | 2.23 |
| Q3 | 2.65 | 2.72 | 2.67 | 2.79 |
| Max | 5.46 | 5.81 | 5.81 | 5.30 |

Table 15.2.2.1.1.7: 1 Log10 of Viral load at each visit and change from baseline to each visit (FAS, CAL-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Visit 7 | | | | |
| N | 170 | 156 | 326 | 187 |
| Mean | 2.10 | 2.20 | 2.15 | 2.12 |
| SD | 0.884 | 0.946 | 0.914 | 0.566 |
| Geo-Mean | 1.98 | 2.07 | 2.03 | 2.06 |
| Geo-SD | 1.347 | 1.375 | 1.362 | 1.257 |
| Min | 1.69 | 1.69 | 1.69 | 1.69 |
| Q1 | 1.69 | 1.69 | 1.69 | 1.69 |
| Median | 1.69 | 1.74 | 1.69 | 1.90 |
| Q3 | 2.09 | 2.26 | 2.15 | 2.44 |
| Max | 5.64 | 5.85 | 5.85 | 5.26 |
| Visit 8 | | | | |
| N | 158 | 145 | 303 | 181 |
| Mean | 1.88 | 1.96 | 1.92 | 1.84 |
| SD | 0.659 | 0.827 | 0.744 | 0.419 |
| Geo-Mean | 1.82 | 1.86 | 1.84 | 1.81 |
| Geo-SD | 1.258 | 1.323 | 1.290 | 1.184 |
| Min | 1.69 | 1.69 | 1.69 | 1.69 |
| Q1 | 1.69 | 1.69 | 1.69 | 1.69 |
| Median | 1.69 | 1.69 | 1.69 | 1.69 |
| Q3 | 1.69 | 1.69 | 1.69 | 1.69 |
| Max | 5.10 | 5.77 | 5.77 | 4.88 |
| Visit 9 | | | | |
| N | 147 | 133 | 280 | 176 |
| Mean | 1.81 | 1.76 | 1.79 | 1.78 |
| SD | 0.544 | 0.422 | 0.490 | 0.357 |
| Geo-Mean | 1.77 | 1.74 | 1.75 | 1.76 |
| Geo-SD | 1.207 | 1.159 | 1.186 | 1.146 |
| Min | 1.69 | 1.69 | 1.69 | 1.69 |
| Q1 | 1.69 | 1.69 | 1.69 | 1.69 |
| Median | 1.69 | 1.69 | 1.69 | 1.69 |
| Q3 | 1.69 | 1.69 | 1.69 | 1.69 |
| Max | 5.59 | 4.69 | 5.59 | 5.18 |

Table 15.2.2.1.1.7: 1 Log10 of Viral load at each visit and change from baseline to each visit (FAS, CAL-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Visit 13 | | | | |
| N | 131 | 123 | 254 | 163 |
| Mean | 1.70 | 1.73 | 1.71 | 1.73 |
| SD | 0.096 | 0.289 | 0.213 | 0.156 |
| Geo-Mean | 1.70 | 1.72 | 1.71 | 1.73 |
| Geo-SD | 1.045 | 1.113 | 1.085 | 1.078 |
| Min | 1.69 | 1.69 | 1.69 | 1.69 |
| Q1 | 1.69 | 1.69 | 1.69 | 1.69 |
| Median | 1.69 | 1.69 | 1.69 | 1.69 |
| Q3 | 1.69 | 1.69 | 1.69 | 1.69 |
| Max | 2.78 | 4.43 | 4.43 | 3.01 |
| Visit 14 | | | | |
| N | 129 | 120 | 249 | 158 |
| Mean | 1.70 | 1.70 | 1.70 | 1.72 |
| SD | 0.051 | 0.054 | 0.053 | 0.174 |
| Geo-Mean | 1.70 | 1.69 | 1.70 | 1.72 |
| Geo-SD | 1.027 | 1.028 | 1.028 | 1.080 |
| Min | 1.69 | 1.69 | 1.69 | 1.69 |
| Q1 | 1.69 | 1.69 | 1.69 | 1.69 |
| Median | 1.69 | 1.69 | 1.69 | 1.69 |
| Q3 | 1.69 | 1.69 | 1.69 | 1.69 |
| Max | 2.16 | 2.29 | 2.29 | 3.35 |
| Visit 15 | | | | |
| N | 130 | 119 | 249 | 156 |
| Mean | 1.70 | 1.71 | 1.70 | 1.69 |
| SD | 0.035 | 0.142 | 0.101 | 0.025 |
| Geo-Mean | 1.70 | 1.70 | 1.70 | 1.69 |
| Geo-SD | 1.019 | 1.061 | 1.045 | 1.014 |
| Min | 1.69 | 1.69 | 1.69 | 1.69 |
| Q1 | 1.69 | 1.69 | 1.69 | 1.69 |
| Median | 1.69 | 1.69 | 1.69 | 1.69 |
| Q3 | 1.69 | 1.69 | 1.69 | 1.69 |
| Max | 2.04 | 3.23 | 3.23 | 1.94 |

Table 15.2.2.1.1.7: 1 Log10 of Viral load at each visit and change from baseline to each visit (FAS, CAL-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Visit 10 | | | | |
| N | 143 | 131 | 274 | 175 |
| Mean | 1.74 | 1.72 | 1.73 | 1.75 |
| SD | 0.224 | 0.279 | 0.251 | 0.299 |
| Geo-Mean | 1.73 | 1.71 | 1.72 | 1.74 |
| Geo-SD | 1.099 | 1.098 | 1.099 | 1.124 |
| Min | 1.69 | 1.69 | 1.69 | 1.69 |
| Q1 | 1.69 | 1.69 | 1.69 | 1.69 |
| Median | 1.69 | 1.69 | 1.69 | 1.69 |
| Q3 | 1.69 | 1.69 | 1.69 | 1.69 |
| Max | 3.81 | 4.87 | 4.87 | 4.69 |
| Visit 11 | | | | |
| N | 137 | 129 | 266 | 172 |
| Mean | 1.73 | 1.73 | 1.73 | 1.75 |
| SD | 0.329 | 0.283 | 0.307 | 0.227 |
| Geo-Mean | 1.71 | 1.72 | 1.71 | 1.74 |
| Geo-SD | 1.109 | 1.103 | 1.106 | 1.106 |
| Min | 1.69 | 1.69 | 1.69 | 1.69 |
| Q1 | 1.69 | 1.69 | 1.69 | 1.69 |
| Median | 1.69 | 1.69 | 1.69 | 1.69 |
| Q3 | 1.69 | 1.69 | 1.69 | 1.69 |
| Max | 5.51 | 4.81 | 5.51 | 3.64 |
| Visit 12 | | | | |
| N | 134 | 125 | 259 | 164 |
| Mean | 1.69 | 1.72 | 1.70 | 1.73 |
| SD | 0.034 | 0.129 | 0.093 | 0.160 |
| Geo-Mean | 1.69 | 1.71 | 1.70 | 1.72 |
| Geo-SD | 1.019 | 1.065 | 1.047 | 1.079 |
| Min | 1.69 | 1.69 | 1.69 | 1.69 |
| Q1 | 1.69 | 1.69 | 1.69 | 1.69 |
| Median | 1.69 | 1.69 | 1.69 | 1.69 |
| Q3 | 1.69 | 1.69 | 1.69 | 1.69 |
| Max | 2.03 | 2.66 | 2.66 | 2.97 |

Table 15.2.2.1.1.7: 1 Log10 of Viral load at each visit and change from baseline to each visit (FAS, CAL-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Visit 16 | | | | |
| N | 128 | 118 | 246 | 155 |
| Mean | 1.70 | 1.68 | 1.69 | 1.70 |
| SD | 0.115 | 0.066 | 0.095 | 0.251 |
| Geo-Mean | 1.70 | 1.68 | 1.69 | 1.69 |
| Geo-SD | 1.064 | 1.045 | 1.056 | 1.101 |
| Min | 1.28 | 1.28 | 1.28 | 1.28 |
| Q1 | 1.69 | 1.69 | 1.69 | 1.69 |
| Median | 1.69 | 1.69 | 1.69 | 1.69 |
| Q3 | 1.69 | 1.69 | 1.69 | 1.69 |
| Max | 2.47 | 1.77 | 2.47 | 4.65 |
| Visit 17 | | | | |
| N | 126 | 115 | 241 | 150 |
| Mean | 1.70 | 1.65 | 1.68 | 1.69 |
| SD | 0.152 | 0.122 | 0.140 | 0.240 |
| Geo-Mean | 1.69 | 1.65 | 1.67 | 1.68 |
| Geo-SD | 1.081 | 1.086 | 1.085 | 1.119 |
| Min | 1.28 | 1.28 | 1.28 | 1.28 |
| Q1 | 1.69 | 1.69 | 1.69 | 1.69 |
| Median | 1.69 | 1.69 | 1.69 | 1.69 |
| Q3 | 1.69 | 1.69 | 1.69 | 1.69 |
| Max | 3.03 | 1.72 | 3.03 | 4.06 |
| End of Study Visit | | | | |
| N | 119 | 109 | 228 | 141 |
| Mean | 1.68 | 1.65 | 1.67 | 1.67 |
| SD | 0.259 | 0.183 | 0.226 | 0.253 |
| Geo-Mean | 1.67 | 1.63 | 1.65 | 1.66 |
| Geo-SD | 1.125 | 1.119 | 1.123 | 1.143 |
| Min | 1.28 | 1.28 | 1.28 | 1.28 |
| Q1 | 1.69 | 1.69 | 1.69 | 1.69 |
| Median | 1.69 | 1.69 | 1.69 | 1.69 |
| Q3 | 1.69 | 1.69 | 1.69 | 1.69 |
| Max | 4.09 | 2.70 | 4.09 | 3.31 |

Table 15.2.2.1.1.7: 1 Log10 of Viral load at each visit and change from baseline to each visit (FAS, CAL-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Post Trial Visit | | | | |
| N | 1 | 1 | 2 | 1 |
| Mean | 1.69 | 1.69 | 1.69 | 1.69 |
| SD | | | 0.000 | |
| Geo-Mean | 1.69 | 1.69 | 1.69 | 1.69 |
| Geo-SD | 1.000 | 1.000 | 1.000 | 1.000 |
| Min | 1.69 | 1.69 | 1.69 | 1.69 |
| Q1 | 1.69 | 1.69 | 1.69 | 1.69 |
| Median | 1.69 | 1.69 | 1.69 | 1.69 |
| Q3 | 1.69 | 1.69 | 1.69 | 1.69 |
| Max | 1.69 | 1.69 | 1.69 | 1.69 |

Table 15.2.2.1.1.7: 1 Log10 of Viral load at each visit and change from baseline to each visit (FAS, CAL-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Change from baseline to Visit 4 | | | | |
| N | 178 | 167 | 345 | 178 |
| Mean | -2.34 | -2.29 | -2.32 | -2.17 |
| SD | 0.640 | 0.513 | 0.582 | 0.520 |
| Min | -3.65 | -3.68 | -3.68 | -3.64 |
| Q1 | -2.72 | -2.60 | -2.66 | -2.44 |
| Median | -2.46 | -2.31 | -2.39 | -2.17 |
| Q3 | -2.02 | -2.03 | -2.03 | -1.83 |
| Max | 0.25 | -0.11 | 0.25 | -0.17 |
| Change from baseline to Visit 6 | | | | |
| N | 172 | 160 | 332 | 184 |
| Mean | -2.76 | -2.70 | -2.73 | -2.71 |
| SD | 0.760 | 0.749 | 0.755 | 0.576 |
| Min | -4.57 | -3.97 | -4.57 | -4.29 |
| Q1 | -3.27 | -3.21 | -3.22 | -3.06 |
| Median | -2.86 | -2.78 | -2.82 | -2.70 |
| Q3 | -2.42 | -2.40 | -2.42 | -2.38 |
| Max | -0.04 | 0.13 | 0.13 | -0.79 |
| Change from baseline to Visit 7 | | | | |
| N | 170 | 156 | 326 | 187 |
| Mean | -3.00 | -2.88 | -2.95 | -2.94 |
| SD | 0.834 | 0.911 | 0.872 | 0.644 |
| Min | -4.57 | -4.23 | -4.57 | -4.29 |
| Q1 | -3.54 | -3.47 | -3.50 | -3.36 |
| Median | -3.17 | -3.10 | -3.12 | -2.98 |
| Q3 | -2.73 | -2.68 | -2.71 | -2.62 |
| Max | 0.03 | 1.10 | 1.10 | -0.14 |

Table 15.2.2.1.1.7: 1 Log10 of Viral load at each visit and change from baseline to each visit (FAS, CAL-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Change from baseline to Visit 8 | | | | |
| N | 158 | 145 | 303 | 181 |
| Mean | -3.19 | -3.10 | -3.15 | -3.22 |
| SD | 0.797 | 0.893 | 0.844 | 0.720 |
| Min | -4.98 | -4.41 | -4.98 | -4.51 |
| Q1 | -3.74 | -3.70 | -3.72 | -3.71 |
| Median | -3.36 | -3.30 | -3.32 | -3.36 |
| Q3 | -2.79 | -2.80 | -2.79 | -2.84 |
| Max | -0.04 | -0.17 | -0.04 | -0.15 |
| Change from baseline to Visit 9 | | | | |
| N | 147 | 133 | 280 | 176 |
| Mean | -3.22 | -3.27 | -3.24 | -3.28 |
| SD | 0.805 | 0.659 | 0.738 | 0.674 |
| Min | -4.96 | -4.41 | -4.96 | -4.51 |
| Q1 | -3.74 | -3.78 | -3.74 | -3.73 |
| Median | -3.39 | -3.35 | -3.36 | -3.41 |
| Q3 | -2.84 | -2.92 | -2.87 | -2.84 |
| Max | -0.04 | -0.93 | -0.04 | -0.97 |
| Change from baseline to Visit 10 | | | | |
| N | 143 | 131 | 274 | 175 |
| Mean | -3.29 | -3.32 | -3.30 | -3.29 |
| SD | 0.674 | 0.629 | 0.652 | 0.672 |
| Min | -5.07 | -4.41 | -5.07 | -4.51 |
| Q1 | -3.74 | -3.81 | -3.75 | -3.75 |
| Median | -3.42 | -3.37 | -3.39 | -3.39 |
| Q3 | -2.89 | -2.96 | -2.92 | -2.84 |
| Max | -0.04 | -0.97 | -0.04 | -1.13 |
| Change from baseline to Visit 11 | | | | |
| N | 137 | 129 | 266 | 172 |
| Mean | -3.30 | -3.30 | -3.30 | -3.29 |
| SD | 0.705 | 0.618 | 0.663 | 0.663 |
| Min | -5.07 | -4.41 | -5.07 | -4.51 |
| Q1 | -3.74 | -3.72 | -3.74 | -3.71 |
| Median | -3.42 | -3.36 | -3.39 | -3.40 |
| Q3 | -2.91 | -2.96 | -2.95 | -2.86 |
| Max | -0.04 | -1.03 | -0.04 | -0.64 |

Source data: Appendix 16.2.6, Listing 1.1.1 stat\vl_ds.sas 25AUG2011

Table 15.2.2.1.1.7: 1 Log10 of Viral load at each visit and change from baseline to each visit (FAS, CAL-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Change from baseline to Visit 12 | | | | |
| N | 134 | 125 | 259 | 164 |
| Mean | -3.33 | -3.31 | -3.32 | -3.31 |
| SD | 0.667 | 0.601 | 0.635 | 0.643 |
| Min | -5.07 | -4.41 | -5.07 | -4.34 |
| Q1 | -3.74 | -3.79 | -3.78 | -3.77 |
| Median | -3.42 | -3.37 | -3.40 | -3.45 |
| Q3 | -2.95 | -2.94 | -2.94 | -2.86 |
| Max | -0.04 | -1.65 | -0.04 | -1.13 |
| Change from baseline to Visit 13 | | | | |
| N | 131 | 123 | 254 | 163 |
| Mean | -3.34 | -3.30 | -3.32 | -3.30 |
| SD | 0.610 | 0.641 | 0.625 | 0.676 |
| Min | -5.07 | -4.41 | -5.07 | -4.51 |
| Q1 | -3.75 | -3.79 | -3.78 | -3.75 |
| Median | -3.43 | -3.37 | -3.41 | -3.43 |
| Q3 | -2.91 | -2.94 | -2.94 | -2.87 |
| Max | -1.65 | -1.27 | -1.27 | -1.03 |
| Change from baseline to Visit 14 | | | | |
| N | 129 | 120 | 249 | 158 |
| Mean | -3.32 | -3.31 | -3.31 | -3.32 |
| SD | 0.654 | 0.597 | 0.626 | 0.667 |
| Min | -5.07 | -4.41 | -5.07 | -4.51 |
| Q1 | -3.74 | -3.76 | -3.74 | -3.75 |
| Median | -3.41 | -3.37 | -3.39 | -3.41 |
| Q3 | -2.95 | -2.94 | -2.95 | -2.88 |
| Max | -0.04 | -1.65 | -0.04 | -1.13 |
| Change from baseline to Visit 15 | | | | |
| N | 130 | 119 | 249 | 156 |
| Mean | -3.31 | -3.31 | -3.31 | -3.33 |
| SD | 0.665 | 0.609 | 0.638 | 0.662 |
| Min | -5.07 | -4.27 | -5.07 | -4.51 |
| Q1 | -3.74 | -3.79 | -3.74 | -3.81 |
| Median | -3.40 | -3.40 | -3.40 | -3.43 |
| Q3 | -2.91 | -2.95 | -2.95 | -2.86 |
| Max | -0.04 | -1.65 | -0.04 | -1.13 |

Source data: Appendix 16.2.6, Listing 1.1.1 stat\vl_ds.sas 25AUG2011

Table 15.2.2.1.1.7: 1 Log10 of Viral load at each visit and change from baseline to each visit (FAS, CAL-OT)

| | NVP400QD | NVP200BID | NVP200BID/400QD | ATZ/r |
|---|---|---|---|---|
| Change from baseline to Visit 16 | | | | |
| N | 128 | 118 | 246 | 155 |
| Mean | -3.31 | -3.34 | -3.33 | -3.33 |
| SD | 0.665 | 0.605 | 0.636 | 0.748 |
| Min | -5.07 | -4.64 | -5.07 | -4.51 |
| Q1 | -3.73 | -3.81 | -3.75 | -3.86 |
| Median | -3.40 | -3.43 | -3.42 | -3.49 |
| Q3 | -2.93 | -2.97 | -2.96 | -2.87 |
| Max | -0.04 | -1.65 | -0.04 | 1.08 |
| Change from baseline to Visit 17 | | | | |
| N | 126 | 115 | 241 | 150 |
| Mean | -3.30 | -3.35 | -3.33 | -3.34 |
| SD | 0.670 | 0.594 | 0.634 | 0.752 |
| Min | -5.07 | -4.64 | -5.07 | -4.69 |
| Q1 | -3.74 | -3.79 | -3.75 | -3.87 |
| Median | -3.38 | -3.43 | -3.42 | -3.49 |
| Q3 | -2.89 | -2.97 | -2.95 | -2.88 |
| Max | -0.04 | -1.65 | -0.04 | 0.49 |
| Change from baseline to End of Study Visit | | | | |
| N | 119 | 109 | 228 | 141 |
| Mean | -3.32 | -3.38 | -3.35 | -3.38 |
| SD | 0.728 | 0.601 | 0.669 | 0.716 |
| Min | -5.07 | -4.69 | -5.07 | -4.72 |
| Q1 | -3.79 | -3.81 | -3.79 | -3.87 |
| Median | -3.43 | -3.43 | -3.43 | -3.51 |
| Q3 | -2.98 | -3.01 | -2.99 | -2.95 |
| Max | -0.01 | -1.65 | -0.01 | -0.26 |
| Change from baseline to Post Trial Visit | | | | |
| N | 1 | 1 | 2 | 1 |
| Mean | -0.04 | -3.98 | -2.01 | -3.59 |
| SD | | | 2.786 | |
| Min | -0.04 | -3.98 | -3.98 | -3.59 |
| Q1 | -0.04 | -3.98 | -3.98 | -3.59 |
| Median | -0.04 | -3.98 | -2.01 | -3.59 |
| Q3 | -0.04 | -3.98 | -0.04 | -3.59 |
| Max | -0.04 | -3.98 | -0.04 | -3.59 |

Source data: Appendix 16.2.6, Listing 1.1.1 stat\vl_ds.sas 25AUG2011

Table 15.2.2.1.1.8: 1 Time to treatment response (first confirmed VL < 50 copies/mL) comparison of NVP combined vs ATZ/r - Cox regression (FAS, ORGV-AS)

| | NVP200BID/400QD | ATZ/r |
|---|---|---|
| Number of patients in analysis population | 376 | 193 |
| Time to treatment response | | |
| Number of patients in analysis | 376 | 193 |
| Hazard ratio | 0.692 | |
| 95% CI upper bound | 0.839 | |
| 95% CI lower bound | 0.570 | |
| p-value | 0.0002 | |

Patients without treatment response are censored at their last observation

Source data: Appendix 16.1.9.2, Statdoc 6.2.1.1.5.6 stat\time_tr_cox.sas 23JUN2011