Association Between Week 60 HIV RNA Level and Virologic Outcomes

- For NFV-treated subjects, those with subsequent detectable HIV RNA >50 copies/mL (n=11) had significantly higher week 60 HIV RNA values compared to those (n=60) with sustained response (0.98 vs. 0.41 log_{10} copies/mL, p=0.001, Figure 5). The effect remained statistically significant (p=0.01) if a lone outlying value in the detectable HIV RNA group was excluded.

- In contrast, LPV/r-treated subjects with subsequent detectable HIV RNA >50 copies/mL (n=10) had similar mean week 60 HIV RNA values compared to those (n=58) with sustained response (0.53 vs. 0.50 log_{10} copies/mL, p=0.83).

**CONCLUSIONS**

- Among subjects with HIV RNA <50 copies/mL consistently for at least 36 weeks who had samples tested by SCA at week 60, a trend toward higher risk of subsequent virologic failure (confirmed rebound >400 copies/mL) was observed among NFV-treated subjects compared to LPV/r-treated subjects. This suggests that a LPV/r-based regimen continues to show superior long-term virologic efficacy compared to a NFV-based regimen even among patients achieving undetectable viral load (<50 copies/mL) for an extended duration of time.

- Week 60 SCA values were significantly associated with subsequent HIV RNA rebound >50 copies/mL for NFV-treated subjects, but not for LPV/r-treated subjects, suggesting that the clinical significance of very low viremia may be different for regimens containing different protease inhibitors.

**REFERENCES**

Outcomes After Week 60
- Sustained response: HIV RNA <50 copies/mL at all subsequent visits beyond week 60.
- Subsequent HIV RNA >50 copies/mL.
  - Virologic failure: confirmed HIV RNA rebound >400 copies/mL or a single HIV RNA rebound >400 copies/mL followed by discontinuation.
  - “Blips”: subsequent HIV RNA >50 copies/mL without meeting virologic failure criteria.

Analysis
- Among subjects with HIV RNA <50 copies/mL for weeks 24–60, the association between week 60 HIV RNA value by SCA and subsequent virologic outcomes was assessed by one-way analysis of variance.

RESULTS

Week 60 Results
- As shown previously, no difference between treatment groups in week 60 HIV RNA level by SCA was observed, with a mean value of 0.51 log_{10} copies/mL (p=0.9) in each treatment group.
- However, week 60 HIV RNA value was significantly associated with baseline HIV RNA level (p=0.001 for each group, Figure 2a).
- In an analysis based on combined treatment groups, a slow (slope of decline: –0.004 log_{10} copies/mL/week) in each treatment group.

Virologic Outcomes Beyond Week 60
- Median (range) total follow-up was 95 (60–114) weeks for the LPV/r group (n=71) and 95 (60–109) weeks for the NFV group (n=74).

Virologic outcomes beyond week 60 are summarized in Figure 3.
- 3 subjects in each group had no data available after week 60 and were excluded.
- 118 subjects (58 LPV/r, 60 NFV) maintained HIV RNA <50 copies/mL at all subsequent visits (median 32 additional weeks, range 9–54).
- 6 subjects (1 LPV/r, 5 NFV) met criteria for virologic failure (p=0.076 for the difference between groups).
- In an analysis based on combined treatment groups, a slow (slope of decline: –0.004 log_{10} copies/mL/week), but statistically significant (p=0.04) decline in persistent viremia was observed over the period from weeks 60–110 (Figure 2b).

145 with data at week 60
(71 LPV/r, 74 NFV)
118 with sustained response
(58 LPV/r, 60 NFV)
139 with data after week 60
(68 LPV/r, 71 NFV)
115 with sustained response
(68 LPV/r, 60 NFV)
21 with HIV RNA >50 copies/mL
(10 LPV/r, 11 NFV)
15 with “blips”
(9 LPV/r, 6 NFV)
6 with virologic failure
(1 LPV/r, 5 NFV)
6 with no data after week 60
(10 LPV/r, 11 NFV)