Long-Term Efficacy and Safety of Abacavir/Lamivudine (ABC/3TC) with Fosamprenavir + Ritonavir Versus LPV/r Over 144 Weeks

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Abstract

The KLEAN study was a long-term, open-label, non-inferiority study which randomized antiretroviral-naïve patients to receive FPV/r twice daily (BID) or LPV/r BID with ABC/3TC fixed dose combination (FDC) over 144 weeks. Methods: KLEAN was an open-label, non-inferiority study which randomized antiretroviral-naïve patients to receive FPV/r twice daily (BID) or LPV/r BID with ABC/3TC FDC over 144 weeks. Patients with a viral load ≥100,000 copies/mL at baseline, CD4+ cell counts ≥200 cells/µL were eligible. A total of 242 antiretroviral-naïve patients participated in the KLEAN study (84 BID and 158 QD). Patients were randomized to treatment in blocks of six. All patients who took part in the extension phase visit, and at wks 60, 72, 84, 96, 108, 120, 132 and 144 (or at early withdrawal).

Patients were evaluated for safety, tolerability and efficacy (HIV-1 RNA, CD4+ and CD8+ analyses) at the baseline extension phase visit, and at wks 60, 72, 84, 96, 108, 120, 132 and 144 (or at early withdrawal).

Results: 196 patients participated in the KLEAN study extension (84 BID and 158 QD) and 194 patients continued until Week 144, of whom 186 continued until Week 144 and 108 had discontinuations prior to Week 144. A total virological failure between Wk 84 and Wk 144.

The authors would like to thank all participating study subjects, site personnel and GSK study teams.

Conclusion

The KLEAN study extension (48-144 wks) supports durable viral suppression with FPV/r and LPV/r when used in combination with ABC/3TC over 144 weeks. Viral suppression was comparable between those patients who started with high baseline viral loads of greater than 100,000 copies/mL, and lower viral loads with both treatment arms. Only three patients experienced virological failure during the study extension (Week 48 to Week 144), and no protease-associated drug resistance was detected during this time when FPV/r and LPV/r were used in combination with ABC/3TC.

Both regimens were safe and generally well tolerated.

Acknowledgements

The authors would like to thank all participating study subjects, site personnel and GSK study teams.

References