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## [PL2.5] SAQUINAVIR/r (SQV/r) BID VS LOPINAVIR/r (LPV/r) BID PLUS EMTRICITABINE/TENOFOVIR (FTC/TDF) QD IN ARV-NAÏVE HIV-1 INFECTED PATIENTS: GEMINI STUDY

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**PURPOSE OF THE STUDY:** This prospective, multi-national, open-label study assesses the efficacy and tolerability of SQV/r vs LPV/r plus FTC/TDF in 310 ARV-naïve patients.

**METHODS:** Subjects with HIV RNA  $>10,000$  c/mL and CD4  $\leq 350$  cells/mm<sup>3</sup> were randomized to SQV/r 1000/100 mg BID or LPV/r 400/100 mg BID plus FTC/TDF 200/300 mg QD for 48 wks. The efficacy analysis will assess non-inferiority of SQV/r to LPV/r. These results are from a predefined interim analysis of the first 150 randomized patients who completed Wk 24. As all patients have been randomized, the reporting of these results should have minimal impact on study recruitment or bias final outcome-assessments.

**SUMMARY OF RESULTS:** Mean baseline HIV RNA was  $5.1 \pm 0.63$  vs  $5.2 \pm 0.60$  log<sub>10</sub> c/mL and median CD4 (range) was 107 (2–378) vs 84 (2–362) cells/mm<sup>3</sup> for SQV/r ( $n=74$ ) vs LPV/r ( $n=76$ ) respectively. Fourteen patients discontinued SQV/r (3 AEs, 11 non-safety) vs 13 LPV/r (4 AEs, 9 non-safety). There were no significant differences in Wk 24 efficacy measures.

	% Patients <400 c/mL ITT/ OT	% Patients <50 c/mL ITT/ OT	Mean HIV RNA $\Delta \log_{10}$ c/mL	Mean CD4 $\Delta$ cells/mm <sup>3</sup>
SQV/r	80.6/92.1	69.4/79.4	-3.2	279
LPV/r	83.6/95.3	75.3/85.9	-3.5	294

Baseline fasting lipid parameters were balanced; at Wk 24 total cholesterol  $\geq 200$  mg/dL: SQV/r 7.9% vs LPV/r 25% (P<0.01); triglycerides  $\geq 400$  mg/dL: SQV/r 0% vs LPV/r 9.4% (P<0.05). Cumulative adherence  $\geq 80\%$  measured by 4-day recall at each visit was similar for SQV/r (83%) and LPV/r (85%).

**CONCLUSIONS:** At Wk 24, SQV/r appears comparable to LPV/r in terms of efficacy and tolerability. Non-inferiority of the regimen and lipid differences will be evaluated in the final 48-wk analysis.

### Plenary Session: Open Papers

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