Background
• Single agent therapy (SAT) with lopinavir/ritonavir (LPV/r) has demonstrated excellent control of viral replication in ARV naïve patients.3 In this study, we report the results of a 96-week, open label, randomized, phase 2/3, multicenter trial of LPV/r as single-agent therapy in patients with HIV RNA < 75 copies/mL on HAART.

Methods
ARV naïve patients aged 18 years or older with HIV-1 infection were randomized to 1:1:1 LPV/r (200 mg/50 mg), LPV/r + tenofovir disoproxil fumarate (TDF) (200 mg/300 mg), or LPV/r + emtricitabine (FTC) (200 mg/300 mg) regimens for 24 weeks. Patients were then randomized to receive LPV/r or LPV/r + TDF/FTC for 72 weeks. The primary endpoint was the proportion of patients achieving HIV RNA < 75 copies/mL at week 96. Patients were monitored for virologic and resistance-related clinical events through week 144.

Major Inclusion Criteria (day 0)
• CD4+≥200 cells/mm3
• HIV RNA < 75 copies/mL on HAART
• ≥1 year off all ARV medication
• ≥1 year off all HIV medications

Major Exclusion Criteria (day zero)
• *CD4+≥400 cells/mm3 allowed only with documented understanding of DHHS guidelines and desire for treatment.
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Baseline Characteristics
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>LPV/r</th>
<th>LPV/r + TDF</th>
<th>LPV/r + FTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>43.2</td>
<td>43.8</td>
<td>43.5</td>
</tr>
<tr>
<td>Gender (%)</td>
<td>Male 60</td>
<td>Male 62</td>
<td>Male 61</td>
</tr>
<tr>
<td>Race (%)</td>
<td>Hispanic 20</td>
<td>Hispanic 21</td>
<td>Hispanic 20</td>
</tr>
<tr>
<td>Ethnicity (%)</td>
<td>Asian 5</td>
<td>Asian 6</td>
<td>Asian 5</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26.5</td>
<td>26.2</td>
<td>26.6</td>
</tr>
<tr>
<td>Baseline CD4+</td>
<td>Median 545</td>
<td>Median 520</td>
<td>Median 527</td>
</tr>
<tr>
<td>Viral load</td>
<td>Median 4.48 (3.62 - &gt;5.70) log copies/ml</td>
<td>Median 4.48 (3.62 - &gt;5.70) log copies/ml</td>
<td>Median 4.48 (3.62 - &gt;5.70) log copies/ml</td>
</tr>
</tbody>
</table>

Results
Figure 1: Subject disposition through week 48
Figure 2: Subject Disposition 48 – 96 weeks
Figure 3: Viral suppression (ITT M=F)
Figure 4: Change in CD4+ from baseline through 96 weeks (median)
Figure 5: Point prevalence of virologic response

Discussion
• In this study, the strategy of LPV/r SAT in ARV naïve patients demonstrated excellent viral suppression capability and was as effective as LPV/r + TDF/FTC in ARV experienced patients.3
• LPV/r treated patients achieved >90% virologic suppression at week 40. Suppression was sustained throughout the study, with 74% achieving <75 copies/mL and 79% <400 copies/mL at week 96. ITT: M=F
• In the first 48 weeks, 4 out of 6 rebounding patients re-suppressed upon adherence counseling and/or treatment intensification (10/30 (33%) reported diarrhea onset while receiving soft-gel capsules. 7/39 (18%) reported new onset or exacerbation of diarrhea while receiving tablets. No subjects withdrew due to adverse events.
• In the second 48 weeks and beyond, no patients withdrew due to intolerance or adverse events.
• A 1.3% overall virological failure rate was observed in LPV/r treated patients. 1 patient (3%) who was non-compliant had CD4<200 and non-suppressed viral load at week 40. Suppressed to VL < 75 c/mL at week 44 and 48. Dose intensified at week 48.
• Rebounded and resuppressed throughout study. Week 40 = VL 120,000 c/mL. Week 96 = VL 1100 c/mL.
• The strategy of LPV/r SAT in ARV naïve patients, demonstrated durable virologic response and resistance sequele except in 1 subject who selected the I54V, but upon further investigation was not ARV naive.
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Table 1: All grade adverse events potentially related to study drug week 48-96
Table 2: All grade adverse events potentially related to study drug week 48-96
Table 3: All grade adverse events potentially related to study drug week 48-96
Table 4: All grade adverse events potentially related to study drug week 48-96

Table 5: Viral suppression through 96 weeks
Table 6: Viral suppression through 96 weeks
Table 7: Viral suppression through 96 weeks
Table 8: Viral suppression through 96 weeks

Table 9: Subjects who qualified for resistance testing weeks 48 to 96
Table 10: Subjects who qualified for resistance testing weeks 48 to 96
Table 11: Subjects who qualified for resistance testing weeks 48 to 96
Table 12: Subjects who qualified for resistance testing weeks 48 to 96

References