HPTN 059:
Daily vs. Coitally
Dependent PMPA Gel

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For the HPTN 059 Team
HPTN 059: Phase II Expanded Safety and Acceptability Study of the Vaginal Microbicide 1% PMPA Gel

Primary objective –

- To assess the local and systemic safety of PMPA gel for vaginal use in HIV-uninfected women versus a placebo gel over 24 weeks of daily and coitally dependent use

Secondary objective –

- Acceptability and adherence to, two regimens of study gel use in women
Exploratory objectives –

- To measure vaginal flora characteristics, and to descriptively examine changes in these characteristics over the course of prolonged study gel use
- To assess the effects of study gel on cytokine and chemokine expression in cervical secretions
- To evaluate the association between cytokine and chemokine expression
- To correlate cytokine and chemokine expression with colposcopic evidence of inflammation and epithelial disruption
**HPTN 059: Phase II Expanded Safety and Acceptability Study of the Vaginal Microbicide 1% PMPA Gel**

- Study population: 200 sexually active HIV negative women with normal lower genital tract
- Women randomized to coitally dependent or daily use of placebo vs. 1% PMPA gel
- Product to be applied at least 2 hours before each act of intercourse in the coitally dependent group
- Maximum use of gel: twice daily
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- Status: currently enrolling in Pune India, and Birmingham, AL and Bronx Lebanon in NY
- Recruitment finalized in Pune India March 13, 2007

<table>
<thead>
<tr>
<th>Site</th>
<th>Date of First Enrollment</th>
<th>Total No. Screened</th>
<th>Total No. Enrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td>NARI</td>
<td>August 24, 2006</td>
<td>116</td>
<td>100</td>
</tr>
<tr>
<td>BLHC</td>
<td>August 11, 2006</td>
<td>92</td>
<td>42</td>
</tr>
<tr>
<td>UAB</td>
<td>August 9, 2006</td>
<td>67</td>
<td>39</td>
</tr>
<tr>
<td>Total</td>
<td>NA</td>
<td>275</td>
<td>181</td>
</tr>
</tbody>
</table>
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- Accrual of patients was 6½ months in Pune India which was very close to the target of six months.
- Recruitment had to be curtailed at both domestic sites due to a problem with gel availability and packaging which caused a slowdown in recruitment.
- Recruitment at domestic sites will be completed in April 2007.
Highlights of HPTN 059 Progress as of March 8, 2007

- Inappropriate enrollment: 0
- Completed visits per protocol
  - 4 week: 144/146 (97%)
  - 8 week: 117/119 (98%)
  - 12 week: 91/98 (93%)
  - 16 week: 67/72 (93%)
  - 20 week: 40/41 (98%)
  - 24 week: 11/11 (100%)
### Highlights of HPTN 059 Progress

#### Adherence to Gel Product

<table>
<thead>
<tr>
<th>Condom</th>
<th>N</th>
<th>Gel Used</th>
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</thead>
<tbody>
<tr>
<td>Used</td>
<td>312</td>
<td>Yes</td>
<td>296 (95%)</td>
<td>16 (5%)</td>
</tr>
<tr>
<td>Not Used</td>
<td>42</td>
<td>Gel Used</td>
<td>25 (60%)</td>
<td>17 (40%)</td>
</tr>
</tbody>
</table>

Karen Patterson of SCHARP says, “the data quality is outstanding”