Enfuvirtide in Treatment-Experienced Pediatric Patients

PACTG P1005 Trial
## Enfuvirtide (T-20) in Treatment-Experienced Children
### PACTG P1005: Study Design

**Study Design: PACTG P1005**

### Background
Two-part, phase I/II open-label, dose-finding and chronic dosing study of enfuvirtide (ENF, T-20) in treatment-experienced children with HIV infection.

### Inclusion Criteria (n=26)
- Age 3 to 12 years old
- On stable ART regimen with 2NRTIs +/- NNRTI or PI ≥16 weeks
- HIV RNA >10,000 copies/mL
- Limited exposure to NNRTIs and PIs

### Treatment Arms
- **Part A**: Single injection of enfuvirtide 15 mg/m², 30 mg/m², or 60 mg/m² + background regimen
- **Part B**: enfuvirtide 30 mg/m² or 60 mg/m² + background regimen

### Study Design Details

**Part A** (dose-finding)
- 7 days

**Part B** (chronic dosing)
- 24 weeks

**Part A** (dose-finding) (n = 14)
- 7 days

**Part B** (chronic dosing) (n = 12)
- Background regimen changed at day 7 to include new agents

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- 7 days

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- Background regimen changed at day 7 to include new agents

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Enfuvirtide (T-20) in Treatment-Experienced Children
PACTG P1005: Result (Part A)

<table>
<thead>
<tr>
<th>Enfuvirtide Dosage (mg/m²)</th>
<th>Plasma Enfuvirtide Concentration (ng/mL)</th>
<th>No. of subjects ≥1000 ng/mL Plasma Enfuvirtide</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>322.6 +/- 323.1*</td>
<td>0</td>
</tr>
<tr>
<td>30</td>
<td>591.3 +/- 275.1</td>
<td>2</td>
</tr>
<tr>
<td>60</td>
<td>1809.8 +/- 391.7</td>
<td>4</td>
</tr>
</tbody>
</table>

*Mean +/- SD

### T-20 Trough Plasma Concentrations 12 h after 7 Days of BID SC Dosing

<table>
<thead>
<tr>
<th>T-20 Dosage (mg/m²)</th>
<th>No. of subjects</th>
<th>Concentration (ng/mL)</th>
<th>No. of subjects with T-20 &gt;1000 ng/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean +/- SD</td>
<td>Range</td>
</tr>
<tr>
<td>30</td>
<td>4</td>
<td>870 +/- 306</td>
<td>470-1323</td>
</tr>
<tr>
<td>60</td>
<td>6</td>
<td>2363 +/- 1597</td>
<td>268-4875</td>
</tr>
</tbody>
</table>

Enfuvirtide (T-20) in Treatment-Experienced Children
PACTG P1005: Result (Part B)

Week 96: Virologic Response (ITT Analysis)

## Number of Children with Local Injection Site Reactions

<table>
<thead>
<tr>
<th>Worst Grade</th>
<th>Erythema</th>
<th>Induration</th>
<th>Pain</th>
<th>Lymph Node Swelling</th>
<th>All Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>1</td>
<td>5</td>
<td>4</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Grade 2</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Grade 3</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>All grades</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>2</td>
<td>11</td>
</tr>
</tbody>
</table>

**Conclusions**: “These results indicate that a 24-week regimen of twice daily s.c. dosing of T-20 in HIV-1-infected children is safe and tolerable and that it is associated with suppression of HIV-1 replication during 24 weeks of administration.”
The National HIV Curriculum is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

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