cART + Enfuvirtide versus cART Alone in Virologic Failure

INTENSE Study
cART + Enfuvirtide versus cART Alone in Virologic Failure

INTENSE: Study Design

**Study Design: INTENSE**

- **Background**: Open-label, randomized, phase IIIb/IV study patients comparing the efficacy and safety of enfuvirtide in combination with a new antiretroviral regimen with at least 2 active agents (cART) with cART alone in antiretroviral-experienced patients with virologic failure.

- **Inclusion Criteria** (n = 47)
  - Age ≥ 18 years of age
  - HIV RNA ≥ 1000 copies/mL on current regimen

- **Treatment Arms**
  - cART* + ENF 90mg SC BID x 24 weeks, then 1:1 randomization to continue or discontinue ENF
  - cART alone

* cART= combination antirretroviral therapy

**cART regimen of 3 to 5 active agents was selected based on treatment history and resistance data.**

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INTENSE: Result

Week 24 & 48*: Virologic Response (Intent-to-Treat)

*48 week data based on original cART + enfuvirtide arm, regardless of second randomization at 24 weeks

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INTENSE: Result

Week 24 & 48*: Immunologic Response

*48 week data based on original cART + enfuvirtide arm, regardless of second randomization at 24 weeks

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INTENSE: Result

Time to Achievement of Viral Suppression

Conclusions: “Although limited by small participant numbers, these results suggest that treatment with enfuvirtide added to highly active antiretroviral therapy may be an option for many patients.”

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