Intensive Enfuvirtide-Containing Antiretroviral Therapy

APOLLO (ANRS 130)

Intensive Enfuvirtide-containing Antiretroviral Therapy
APOLLO (ANRS 130): Study Design

Study Design: APOLLO (ANRS 130)

- **Background**: Randomized, open label phase 3 study evaluating whether the addition of enfuvirtide to standard triple antiretroviral therapy improves immunological response in antiretroviral-naïve subjects with advanced HIV disease
- **Inclusion Criteria (n = 195)**
  - Antiretroviral-naïve patients
  - Asymptomatic with CD4 count <100 cells/mm^3 or stage B/C disease with CD4 count <200 cells/mm^3
  - Any HIV RNA level
- **Treatment Arms**
  - LPV-RTV 400/100 mg BID or EFV 600 mg QD, + TDF-FTC + Enfuvirtide 90 mg BID
  - LPV-RTV 400/100 mg BID or EFV 600 mg QD, + TDF-FTC

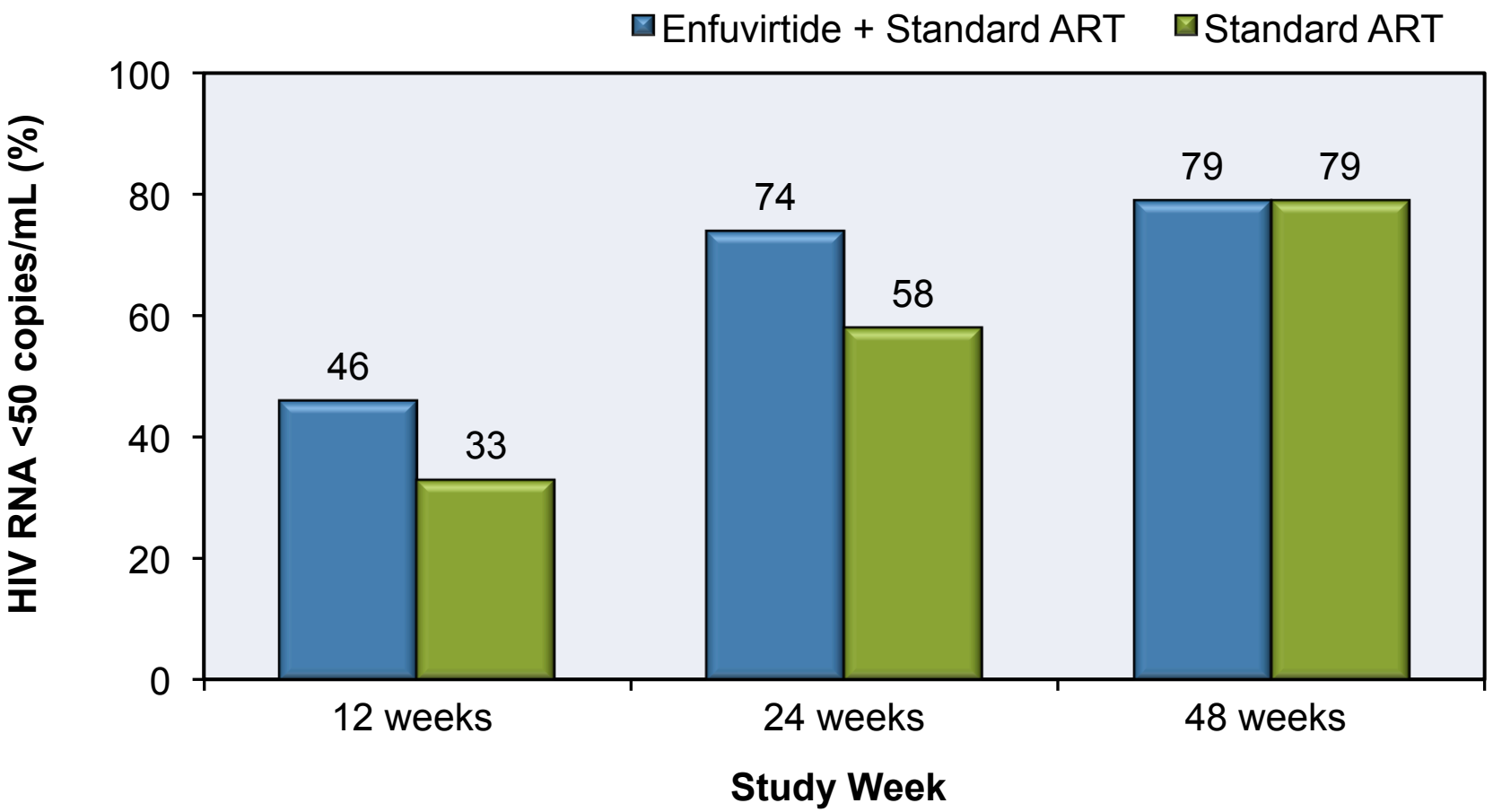
Enfuvirtide arm
LPV/r or EFV + TDF-FTC + Enfuvirtide
(n = 101)

Control arm
LPV/r or EFV + TDF-FTC
(n = 94)

Source: Joly V, et al. Antimicrob Agents Chemother. 2013;57:758-65.

Intensive Enfuvirtide-containing Antiretroviral Therapy
APOLLO (ANRS 130): Result

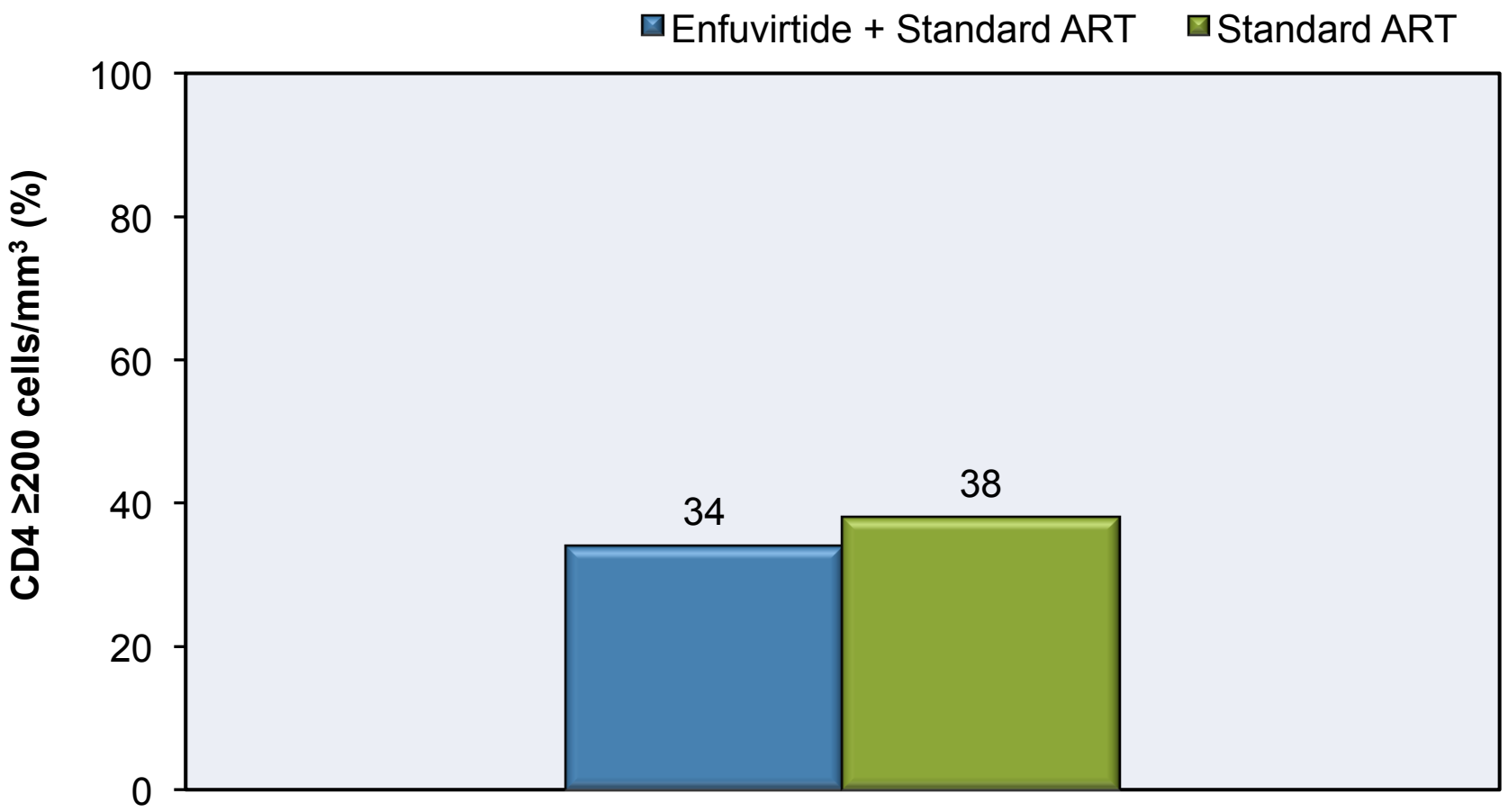
Weeks 12 through 48: Virologic Response



Source: Joly V, et al. Antimicrob Agents Chemother. 2013;57:758-65.

Intensive Enfuvirtide-containing Antiretroviral Therapy
APOLLO (ANRS 130): Result

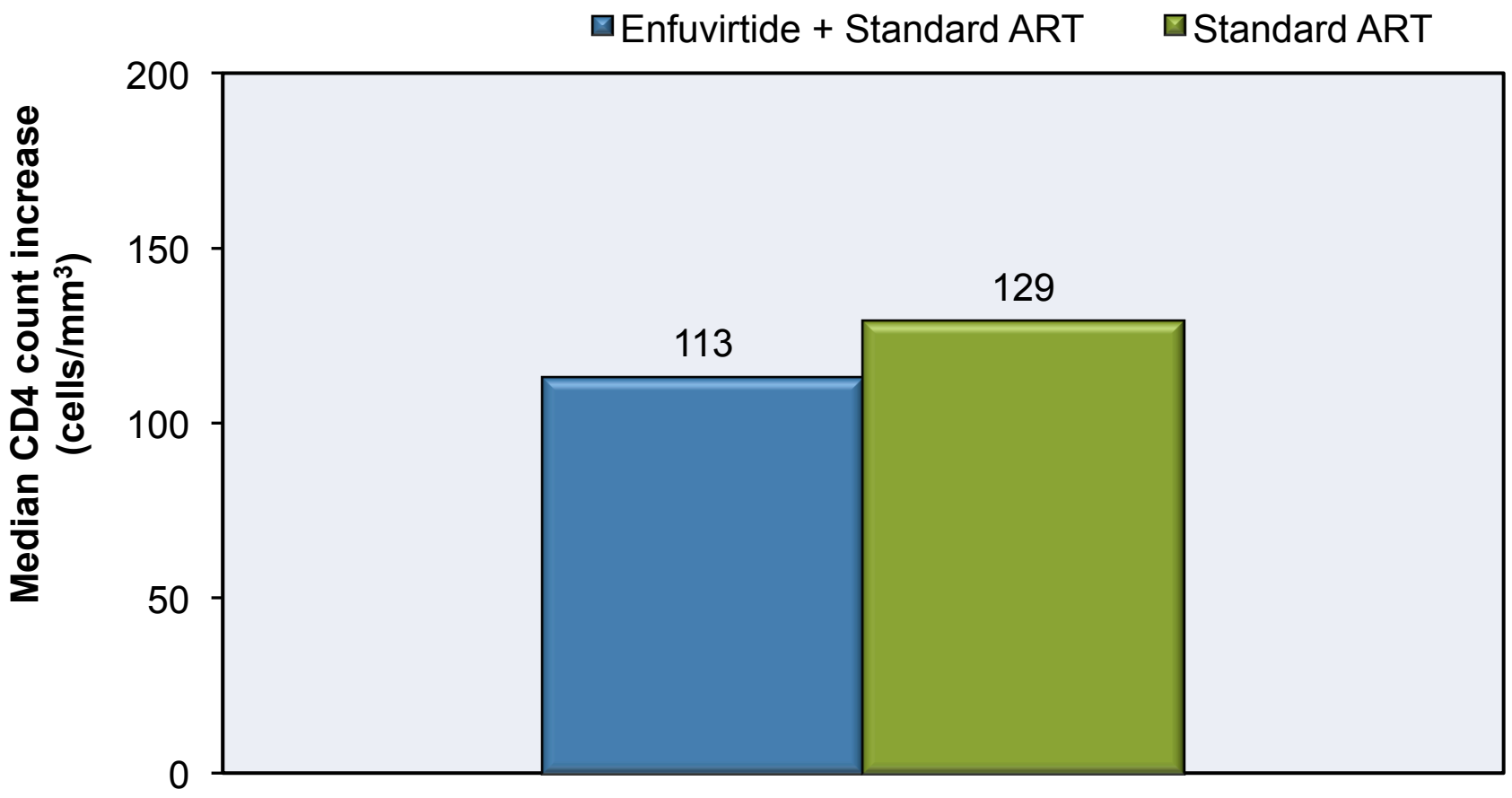
Week 24: Immunologic Response



Source: Joly V, et al. Antimicrob Agents Chemother. 2013;57:758-65.

Intensive Enfuvirtide-containing Antiretroviral Therapy
APOLLO (ANRS 130): Result

Week 24: Immunologic Response



Source: Joly V, et al. Antimicrob Agents Chemother. 2013;57:758-65.

Intensive Enfuvirtide-containing Antiretroviral Therapy
APOLLO (ANRS 130): Result

Clinical adverse events in Either Arm		
	Enfuvirtide + Standard ART arm (n = 100)	**Standard ART** (n= 94)
Clinical adverse events		
Any grade	92%	90%
Any grade and treatment related	61%	55%
Grades 3 and 4	23%	30%
Grades 3 and 4 and treatment related	7%	9%
Serious	28%	29%
Serious and study treatment related	9%	14%
AIDS events	20%	13%
IRIS	15%	21%
Deaths	2%	2%

Source: Joly V, et al. Antimicrob Agents Chemother. 2013;57:758-65.

Intensive Enfuvirtide-containing Antiretroviral Therapy
APOLLO (ANRS 130): Conclusions

Conclusions: “Although inducing a more rapid virological response, addition of enfuvirtide to a standard cART does not improve the immunological outcome in naive HIV-infected patients with severe immunosuppression.”

Source: Joly V, et al. Antimicrob Agents Chemother. 2013;57(2):758-65.

Acknowledgment

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The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.

National HIV Curriculum

AETC AIDS Education & Training Center Program
National Coordinating Resource Center