Elvitegravir versus Raltegravir in Treatment Experienced

Study 0145

Elvitegravir versus Raltegravir in Treatment Experienced
Study 0145: Design

Study Design: 0145

- **Background**: Randomized, double-blind phase 3 study comparing the safety and efficacy of elvitegravir versus raltegravir with efavirenz, in combination with background regimen
- **Inclusion Criteria (n = 702)**
  - Treatment-experienced patients
  - Age ≥ 18
  - HIV RNA ≥ 1000 copies/mL
  - Stable regimen for at least 30 days
  - Resistance to at least 2 classes
  - No AIDS condition in prior 30 days
- **Treatment Arms**
  - Elvitegravir + TDF-FTC
  - Raltegravir + Background (RTV + PI + 3rd Drug)

Elvitegravir* (150 mg QD) **+**
Ritonavir + Protease Inhibitor +
3rd Antiretroviral Agent
(n = 351)

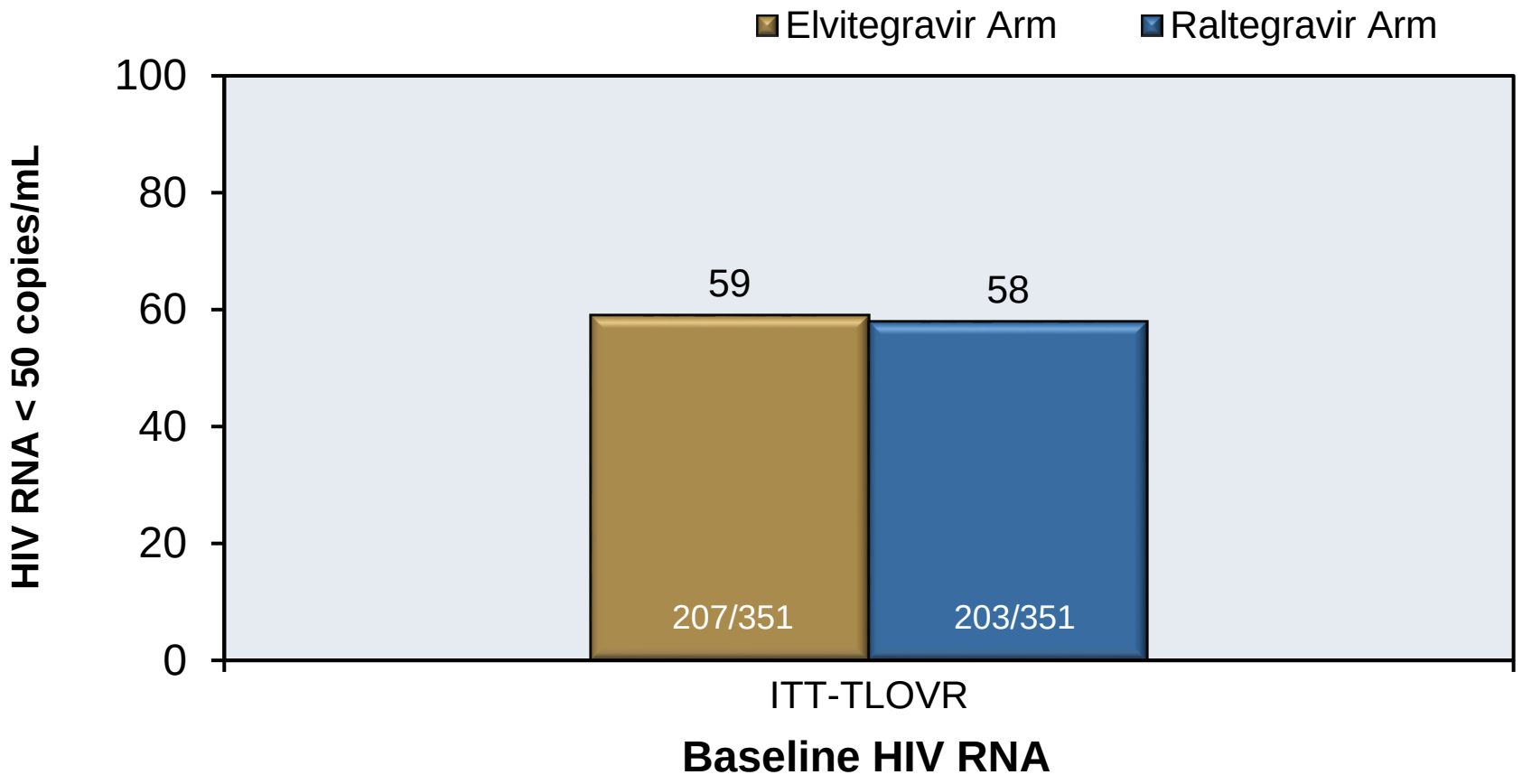
Raltegravir (400 mg BID)
Ritonavir + Protease Inhibitor +
3rd Antiretroviral Agent
(n = 351)

*Elvitegravir dose reduced to 85 mg QD with ritonavir-atazanavir and ritonavir-lopinavir

Source: Molina JM, et al. Lancet. 2012;12:27-35.

Elvitegravir versus Raltegravir in Treatment Experienced
Study 0145: Results

Week 48: Virologic Response (ITT-TLOVR*)

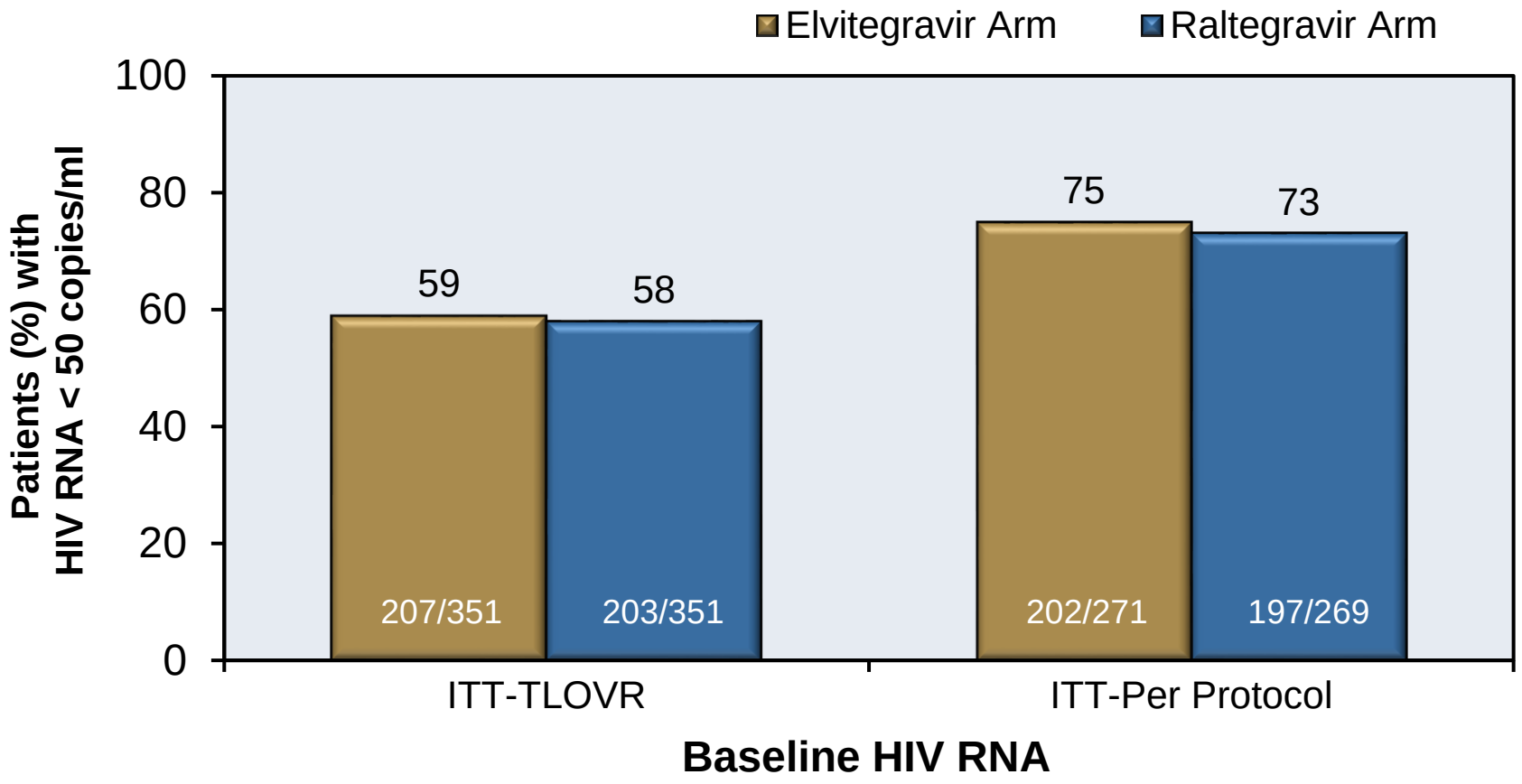


*ITT-TLOVR = Intention to Treat-Time to Loss of Virologic Response

Source: Molina JM, et al. Lancet. 2012;12:27-35.

Elvitegravir versus Raltegravir in Treatment Experienced
Study 0145: Results

Week 48: Virologic Response (ITT-TLOVR and Per Protocol*)



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Source: Molina JM, et al. Lancet. 2012;12:27-35.

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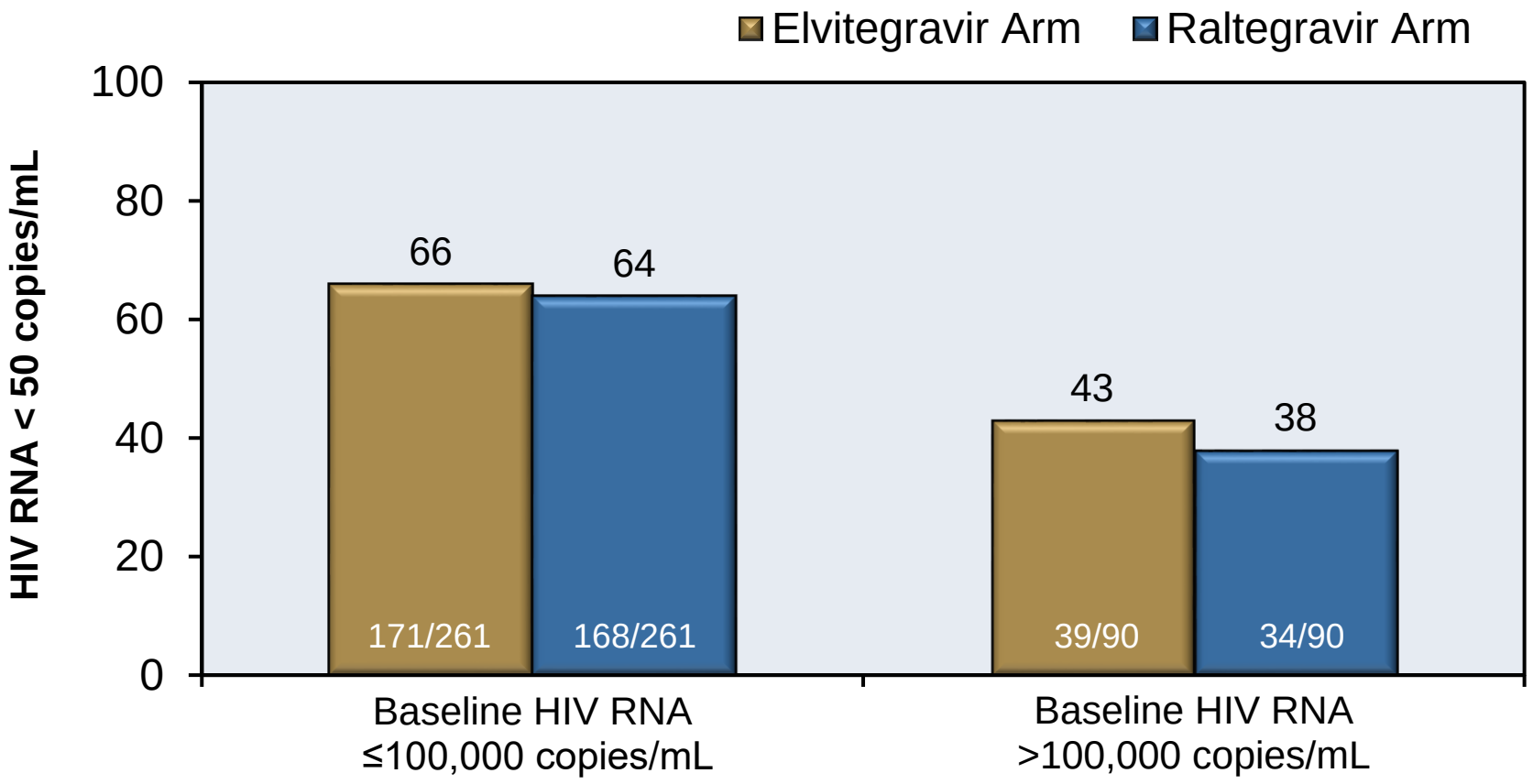
Study 0145: Results

Week 48: Virologic Response (mITT)



*ITT-TLOVR = Intention to Treat-Time to Loss of Virologic Response

Source: Molina JM, et al. Lancet. 2012;12:27-35.

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Study 0145: Results

Resistance Development by Week 48		
Subjects with Virologic Failure	**Elvitegravir** (n = 61)	**Raltegravir** (n= 75)
Any NRTI-Resistance	7 of 59 (12%)	10 of 75 (13%)
Any PI-Resistance	4 of 59 (7%)	3 of 75 (4%)
Any Integrase-Resistance	16 of 60 (27%)	15 of 72 (21%)
T66I/A	7 (12%)	0%
E92Q	5 (8%)	1 (1)%
T97A	3 (5%)	3 (4)%
Y143R/H/C	0%	1 (1)%
S147G	3 (5%)	0%
Q148R/H	3 (5%)	4 (6)%
N155H	3 (5%)	9 (13)%

Source: Molina JM, et al. Lancet. 2012;12:27-35.

Elvitegravir versus Raltegravir in Treatment Experienced
Study 0145: Conclusions

Interpretation: “Elvitegravir used in combination with a ritonavir-boosted protease inhibitor in treatment-experienced patients has similar efficacy and safety to raltegravir. Since elvitegravir can be given once a day compared with twice a day for raltegravir, elvitegravir might improve patients' adherence.”

Source: Molina JM, et al. Lancet. 2012;12:27-35.

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.

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AETC AIDS Education & Training Center Program
National Coordinating Resource Center