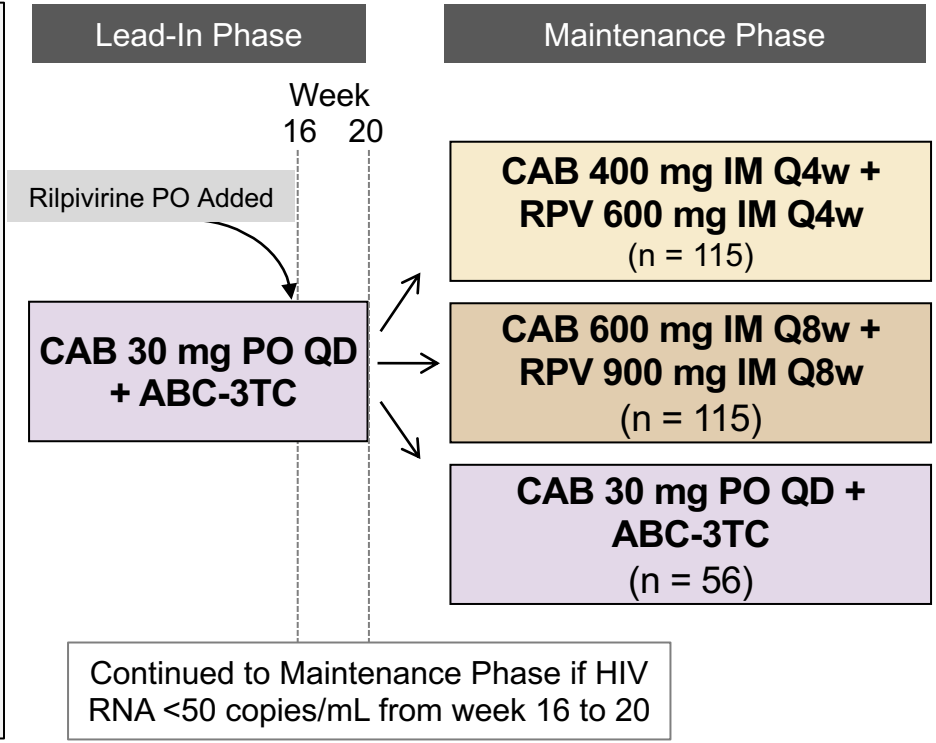
Cabotegravir IM + Rilpivirine IM Every One or Two Months versus Oral CAB + ABC-3TC

LATTE-2

IM Cabotegravir + IM Rilpivirine versus Cabotegravir + ABC-3TC
LATTE-2 Study: Design

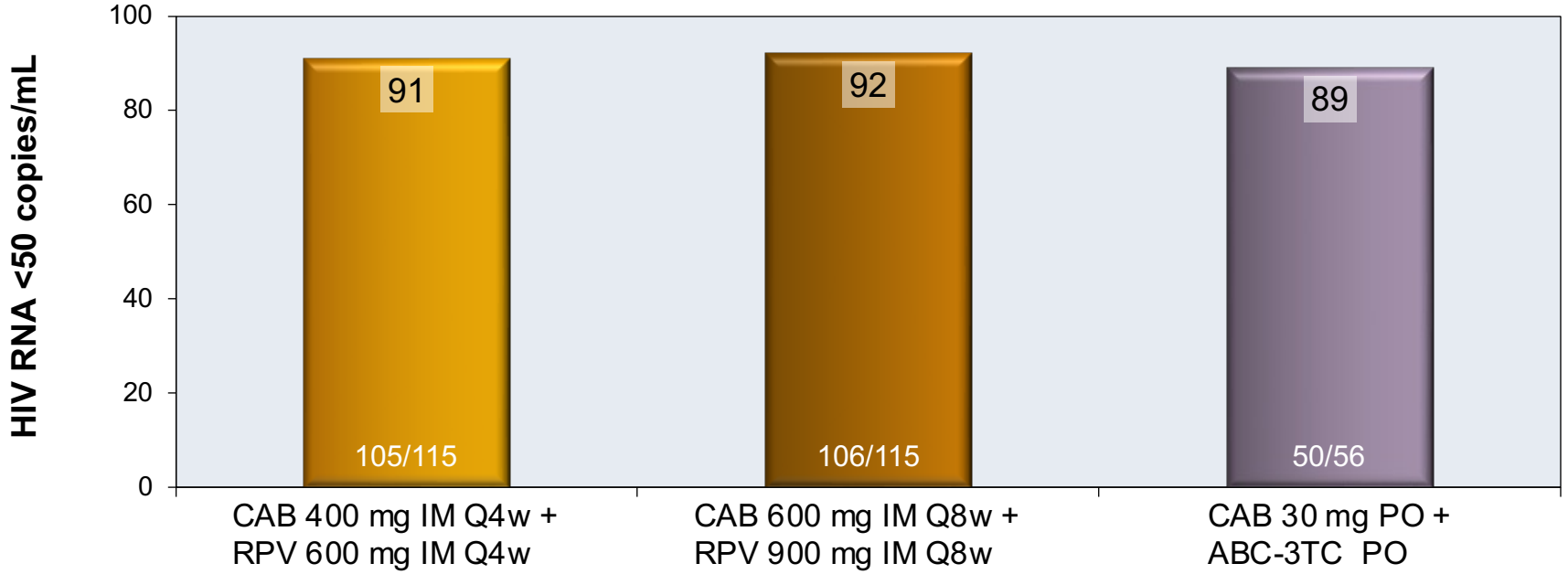
- **Background**
  - Phase 2b, randomized, open-label trial assessing dual therapy with long-acting, injectable agents for maintenance
- **Inclusion Criteria**
  - Age ≥18 years
  - Antiretroviral-naïve
  - HIV RNA >1,000 copies/mL
  - CD4 count >200 cells/mm^3
  - CrCl >50 mL/min
- **Exclusions**
  - Major resistance mutations
  - Pregnancy
  - Significant hepatic impairment
  - AIDS-defining condition



Source: Margolis DA, et al. Lancet 2017;390:1499-1510.

IM Cabotegravir + IM Rilpivirine versus Cabotegravir + ABC-3TC LATTE-2 Study: Results

Week 48 Virologic Results (by FDA Snapshot Algorithm)

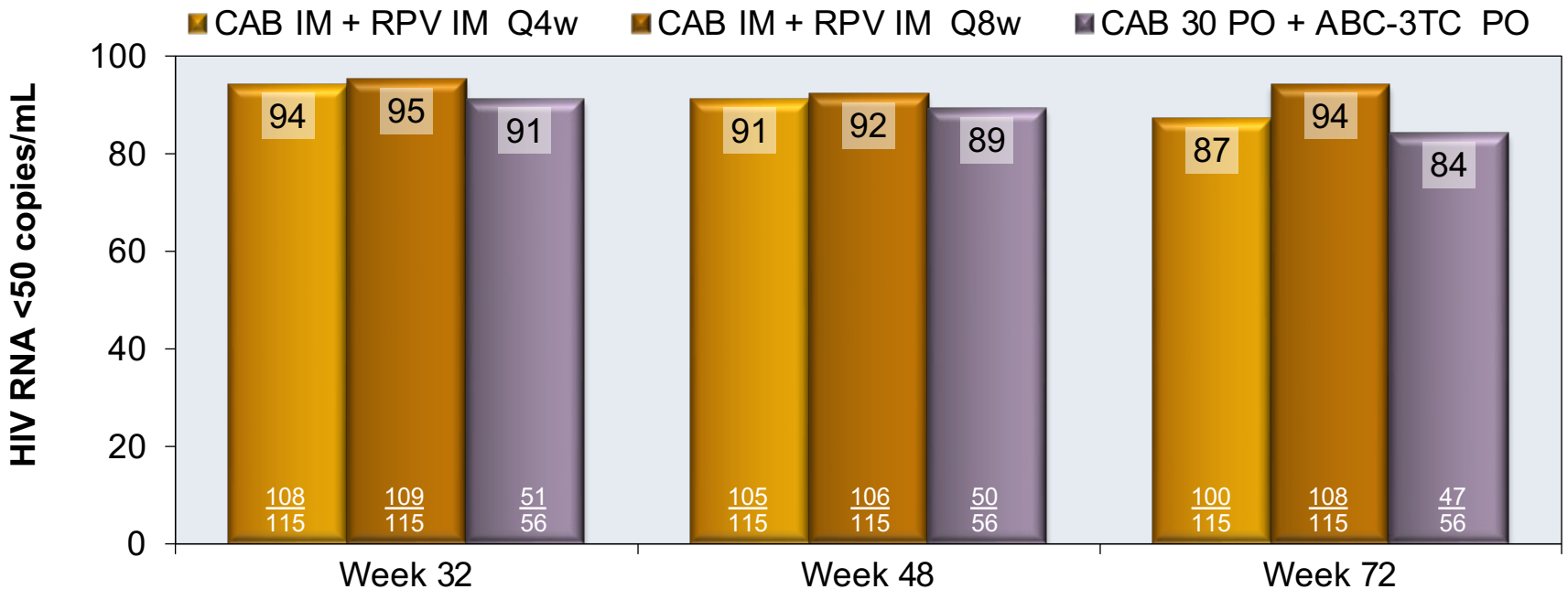


Abbreviations: CAB = cabotegravir; RPV = rilpivirine; ABC-3TC = abacavir-lamivudine

Source: Margolis DA, et al. Lancet 2017;390:1499-1510.

IM Cabotegravir + IM Rilpivirine versus Cabotegravir + ABC-3TC LATTE-2 Study: Results

Week 96 virologic results by FDA snapshot analysis



Abbreviations: CAB = cabotegravir; RPV = rilpivirine; ABC-3TC = abacavir-lamivudine

Source: Margolis DA, et al. Lancet 2017;390:1499-1510.

IM Cabotegravir + IM Rilpivirine versus Oral Cabotegravir + ABC-3TC LATTE-2 Study: Adverse Events

Treatment-related adverse events at 96 weeks (excluding injection site reactions)

	Q4 Weeks CAB IM + RPV IM (n = 115)	Q8 Weeks CAB IM + RPV IM (n = 115)	Oral CAB PO + ABC-3TC (n=56)
Pyrexia	7 (6%)	5 (4%)	0 (0%)
Nausea	12 (10%)	8 (7%)	5 (9%)
Headache	7 (6%)	6 (5%)	4 (7%)
Dyspepsia	6 (5%)	1 (<1%)	1 (2%)
Asthenia	3 (3%)	2 (2%)	3 (5%)

*All of the above treatment-related adverse reactions were grade 1-2.

Abbreviations: Q = every; IM = intramuscular; CAB = Cabotegravir; RPV = rilpivirine; ABC-3TC = abacavir-lamivudine

Source: Margolis DA, et al. Lancet 2017;390:1499-1510.

IM Cabotegravir + IM Rilpivirine versus Cabotegravir + ABC-3TC LATTE-2 Study: Adverse Events

Treatment-Related Injection Site Reactions

	Q4 Weeks IM CAB + IM RPV (n = 115)		Q8 Weeks IM CAB + IM RPV (n = 115)	
	Any	Grade 3-4	Any	Grade 3-4
Pain	112 (97%)	6 (5%)	109 (95%)	8 (7%)
Nodule	35 (30%)	1 (<1%)	29 (25%)	1 (<1%)
Swelling	34 (30%)	0	29 (25%)	1 (<1%)
Pruritis	33 (29%)	0	24 (21%)	0
Induration	25 (22%)	0	28 (24%)	1 (<1%)
Warmth	21 (18%)	0	22 (19%)	1 (<1%)
Bruising	14 (12%)	0	19 (17%)	0
Erythema	19 (17%)	0	12 (10%)	1 (<1%)
Discoloration	6 (5%)	0	3 (3%)	0

Abbreviations: Q = every; IM = intramuscular; CAB = Cabotegravir; RPV = Rilpivirine

Source: Margolis DA, et al. Lancet 2017;390:1499-1510.

IM Cabotegravir + IM Rilpivirine versus Oral Cabotegravir + ABC-3TC LATTE-2 Study: Conclusions

Conclusions: “The two-drug combination of all-injectable, long-acting cabotegravir plus rilpivirine every 4 weeks or every 8 weeks was as effective as daily three-drug oral therapy at maintaining HIV-1 viral suppression through 96 weeks and was well accepted and tolerated.”

Source: Margolis DA, et al. Lancet 2017;390:1499-1510.

Acknowledgments

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National HIV Curriculum

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