



VALEANT

Pharmaceuticals International

Viramidine Safety and Efficacy Versus Ribavirin

VISER1

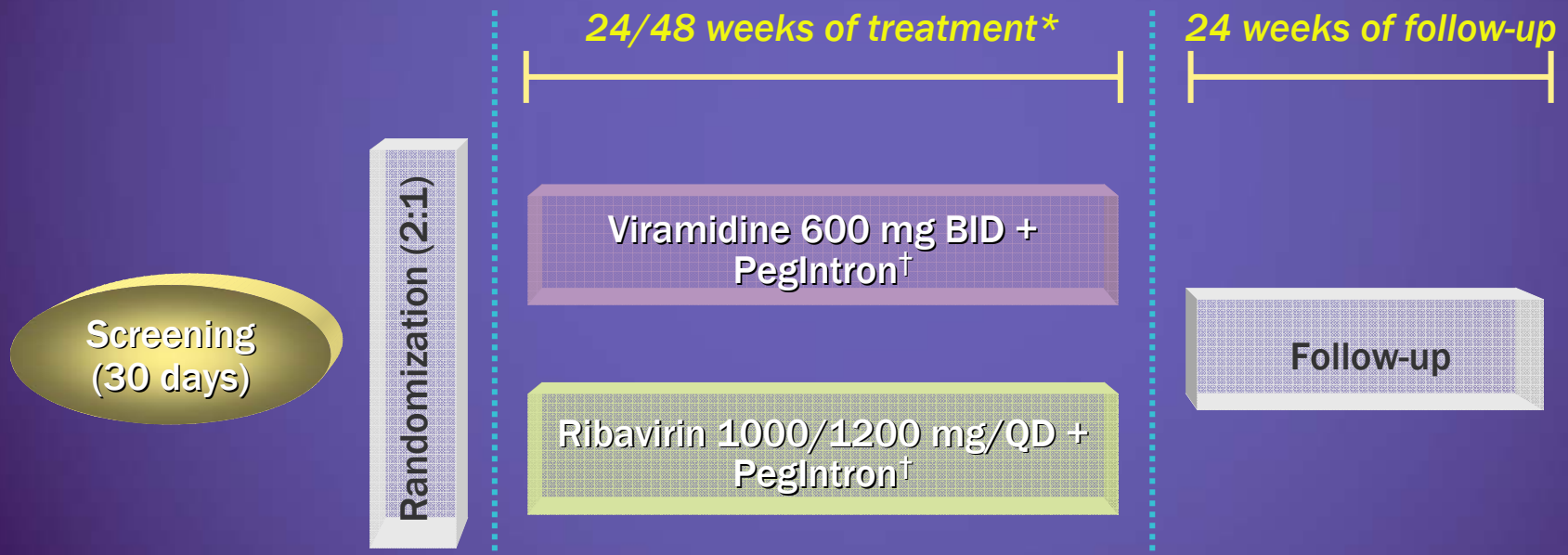
(first of two Phase 3 studies)

VISER1 Summary

- Confirms superior safety profile
- Clear dose response based on weight
- Higher concentrations of Viraamidine do not result in proportional increases in anemia
- Regional anomalies influenced results

Viramidine Phase 3 (VISER1) Study: Design

Randomized, Double-blind Multicenter, Parallel-group Study
in Treatment-naïve Subjects (N = 970)



HCV, NGI SuperQuant; sensitivity
to 100 copies/mL, 39 IU/mL

*Genotype 2, 3 = 24 weeks/1, 4, 5, 6 = 48 weeks

[†]PegIFN alfa-2b 1.5 µg/kg/week

Co-Primary Endpoints

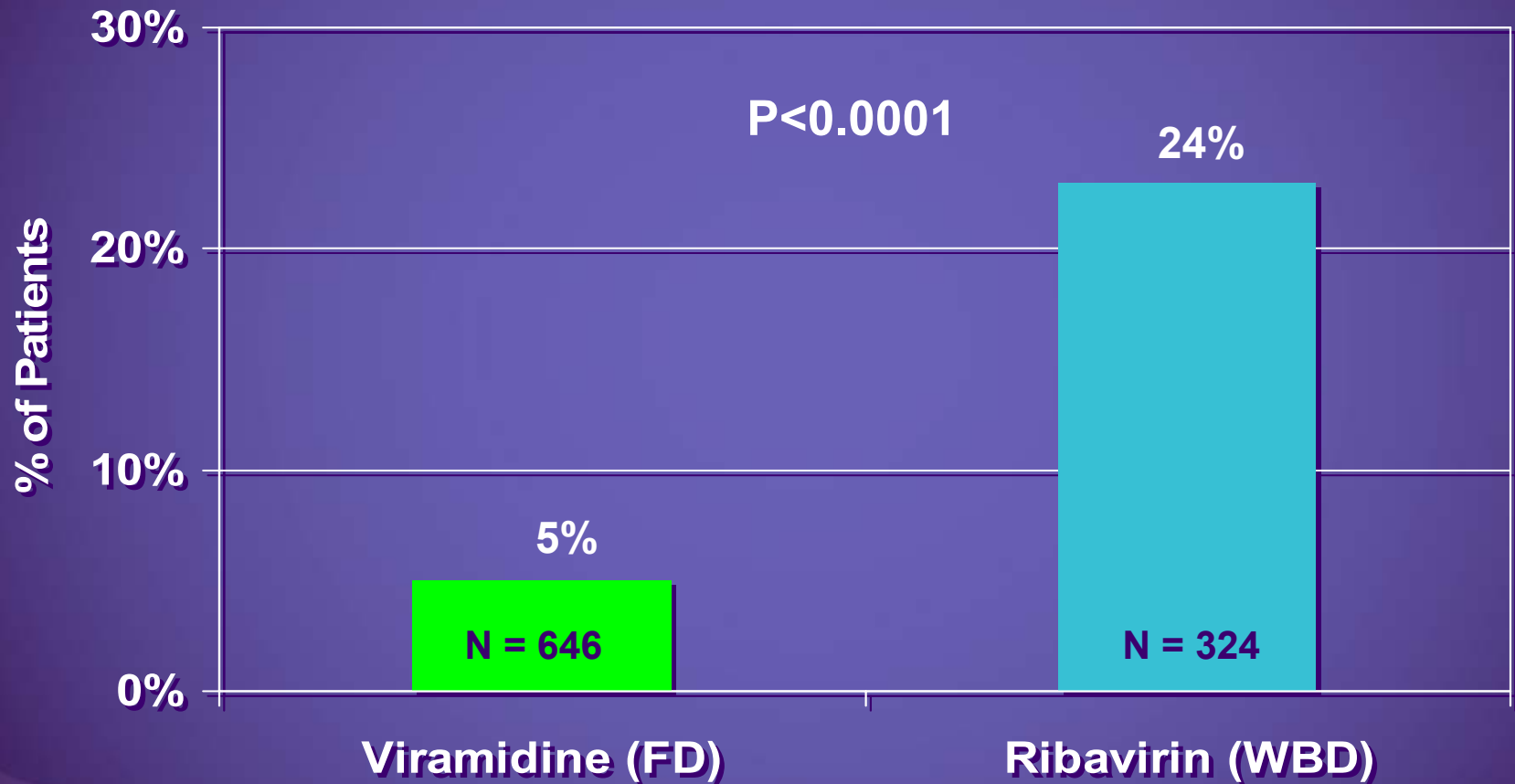
- **Primary safety endpoint:**
 - Hemoglobin < 10 g/dL or \geq 2.5 g/dL drop from baseline
 - *Superiority test vs. ribavirin*

- **Primary efficacy endpoint:**
 - Sustained Virologic Response - HCV RNA < 100 copies/mL at FW 24
 - *Non-inferiority test vs. ribavirin*

Superiority in Safety Confirmed

Safety: Anemia

Incidence Hgb <10 g/dL Anytime During Therapy
Overall Safety Population



Efficacy influenced by:

**Compliance (per protocol)
Regional anomalies
Weight-based dosing**

Efficacy influenced by:

Compliance (per protocol)

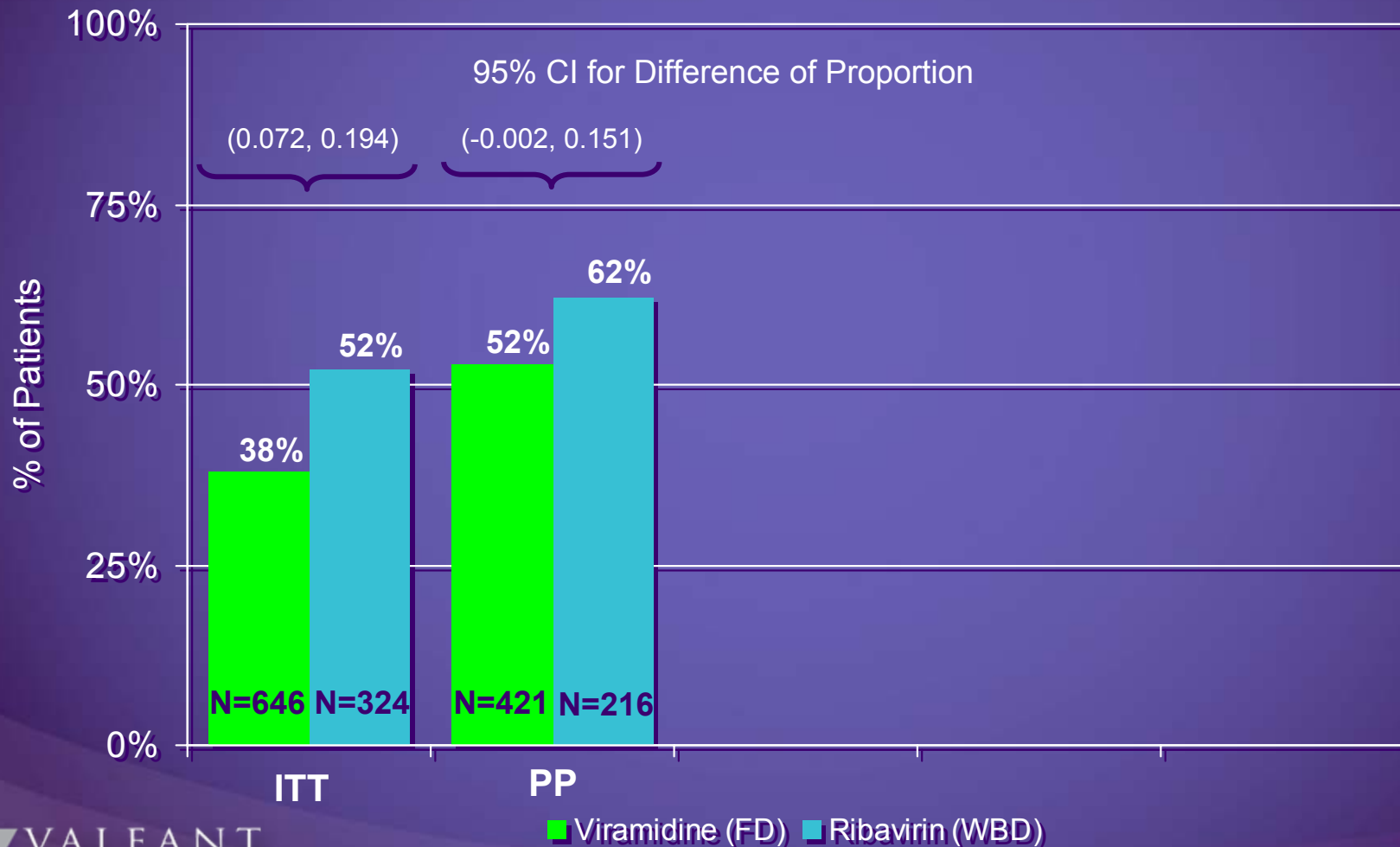
Regional anomalies

Weight-based dosing

Per Protocol Population (PP)

- Completed protocol specified treatment duration
 - ≥ 23 weeks for GT 2,3
 - ≥ 47 weeks for GT non 2,3
- Had overall study drug exposure of $\geq 90\%$ for both components of the combination therapy
- Did not have therapy interruption ≥ 15 days
- Did not receive any prohibited con-meds (e.g. growth factors)
- Did not receive additional HCV treatment prior to the follow up 24 week visit
- Did not receive any incorrect treatment inadvertently
- Were not stratified erroneously at the randomization

Viramidine Efficacy Analysis Sustained Virologic Response



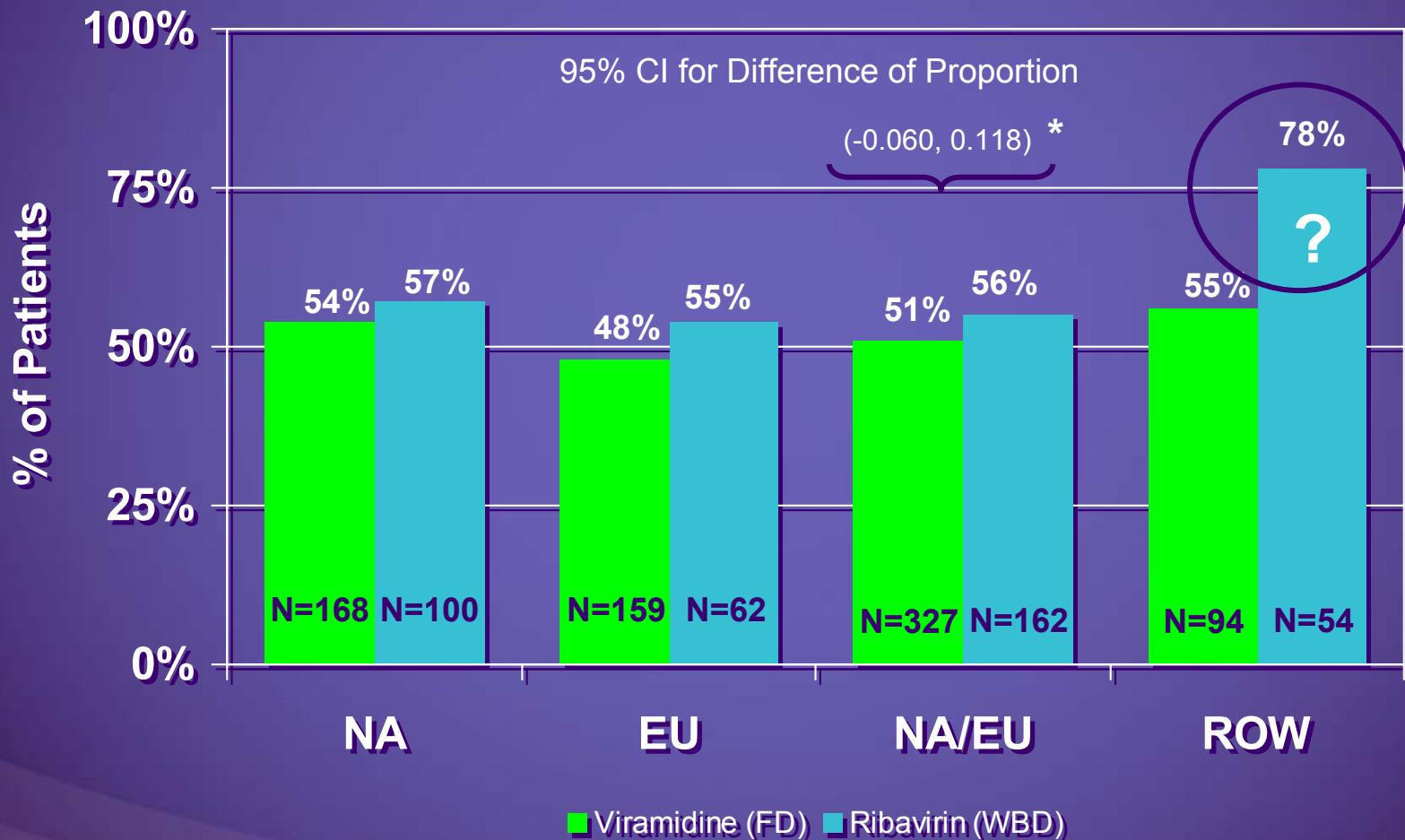
Efficacy influenced by:

Compliance (per protocol)

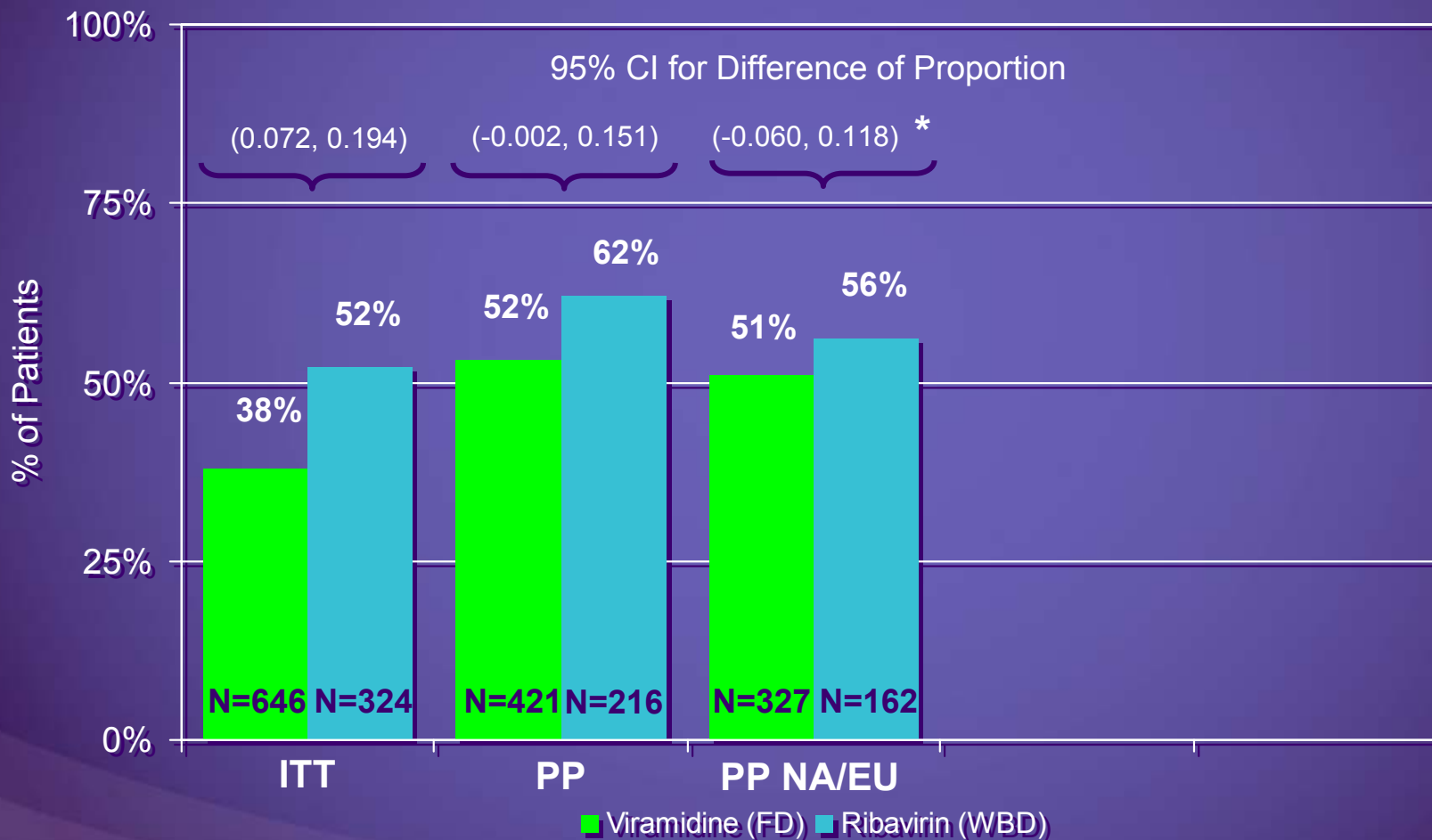
Regional anomalies

Weight-based dosing

Sustained Virologic Response Overall by Region (PP)



Viramidine Efficacy Analysis Sustained Virologic Response



Efficacy influenced by:

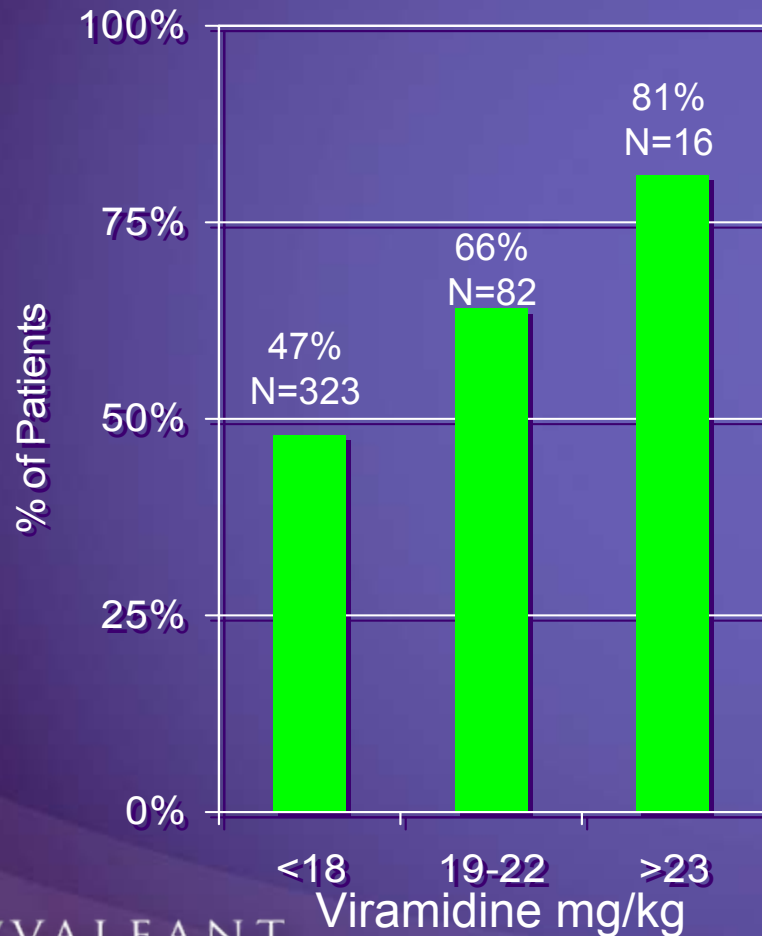
Compliance (per protocol)

Regional anomalies

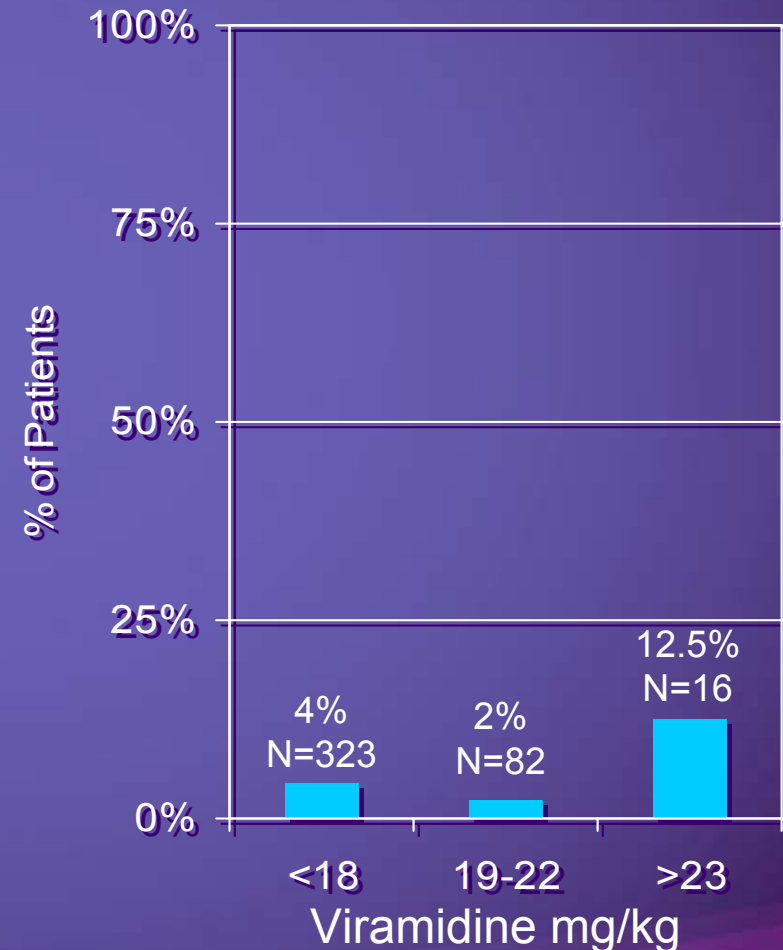
Weight-based dosing

Viramidine Weight Based Analysis Overall (PP)

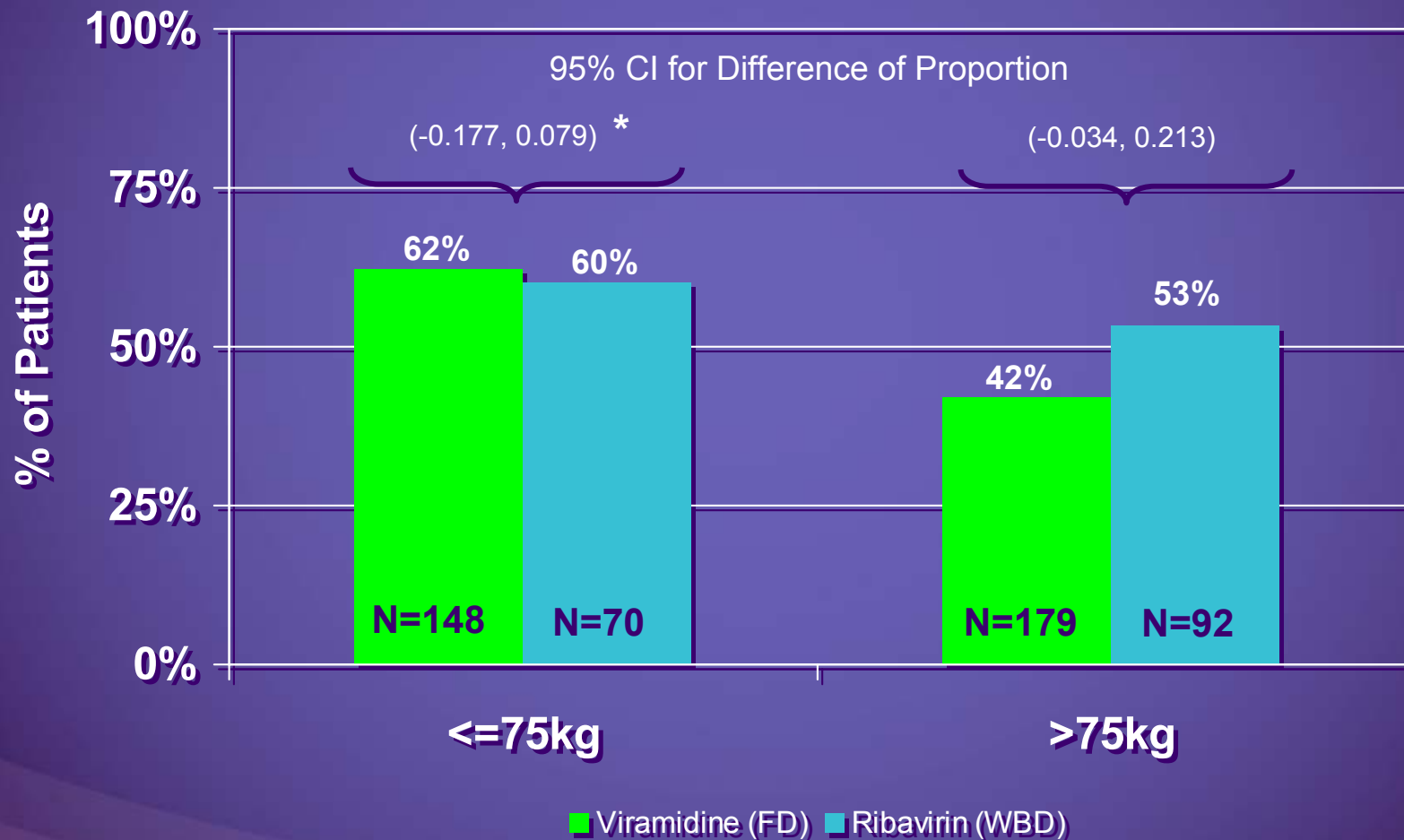
Sustained Virologic Response



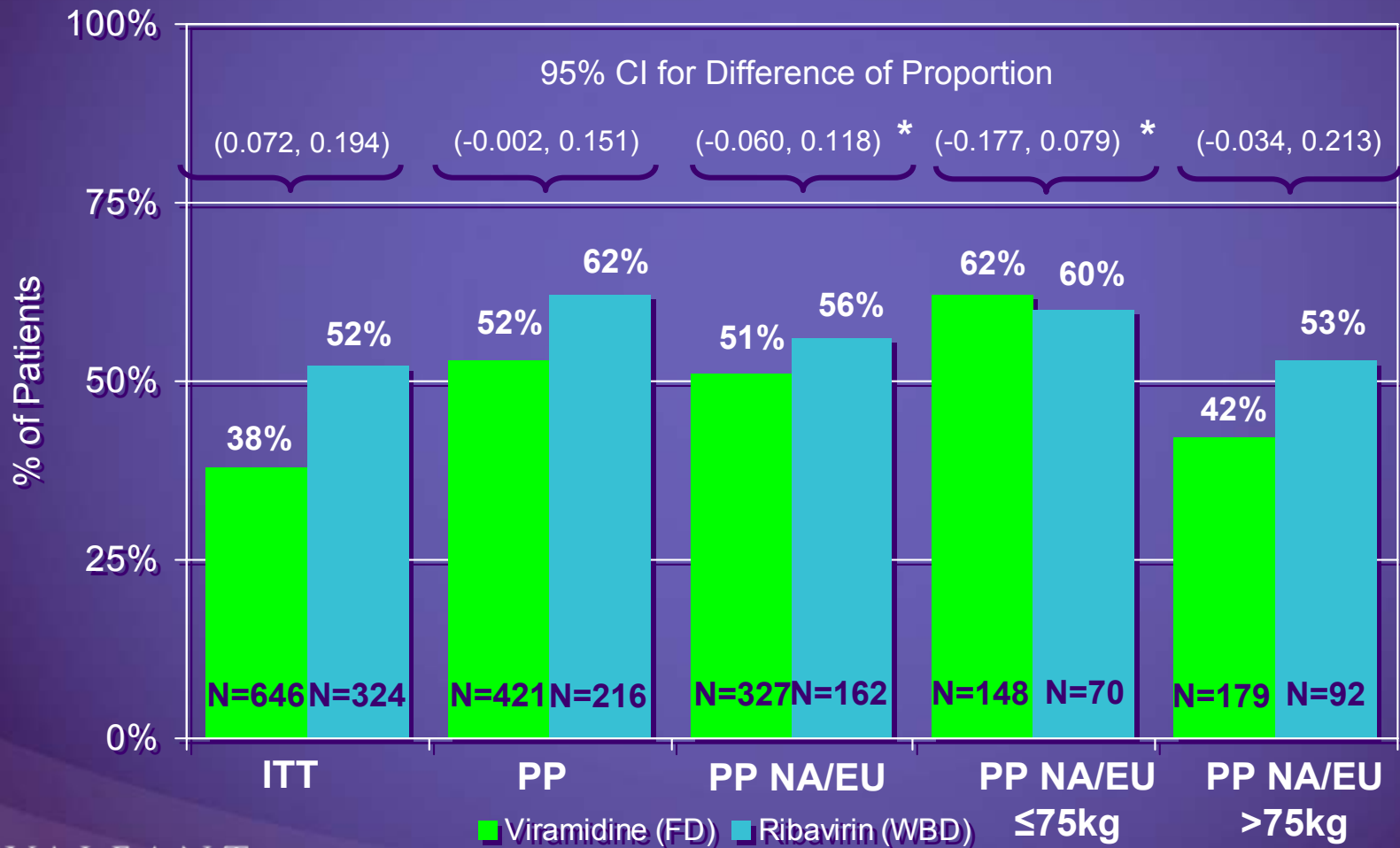
Anemia: <10 g/dL



Sustained Virologic Response Overall Weight Strata NA & EU (PP)



Viramidine Efficacy Analysis Sustained Virologic Response



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Viramidine Path to Market

- **VISER1 Presentation at Scientific Meeting – 1H06**
- **VISER2 Follow-up Completed – End of June 2006**
- **VISER2 Analyses Completed – 2H06**
- **VISER2 Presentation at Scientific Meeting – 4Q06;
1Q07**
- **Market Availability – Before End of 2007**



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