Sofosbuvir + Ribavirin for 24 weeks or Sofosbuvir + Pegylated-interferon + Ribavirin for 12 Weeks in Genotype 1 or Genotype 6 HCV-infected Patients: Results from a Phase 3 Study in Vietnam

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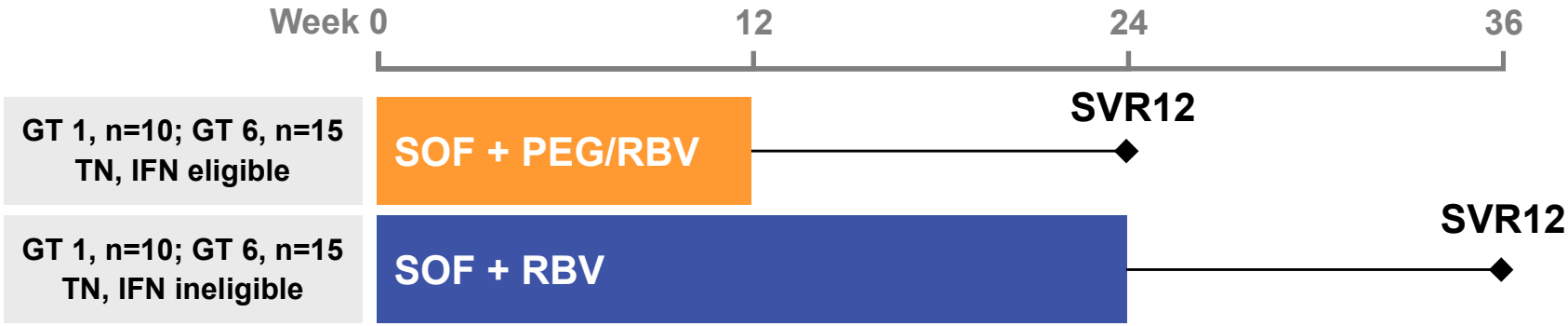
Disclosures

Background and Aim

- Estimates of HCV prevalence in Vietnam are 2.0–2.9% with genotypes (GTs) 1 and 6 most prevalent[1]
- Sofosbuvir is a pangenotypic, direct-acting antiviral NS5B inhibitor
- This study evaluated SOF + ribavirin (RBV) ± pegylated interferon (PEG) for treatment of patients with HCV GT 1 or 6 infection

1. Sievert W, et al. Liver Int 2011;31(Suppl 2):61-80.

Methods: Study Design



- Multicenter study, open-label study at 6 sites in Vietnam
- HCV GT 1 or 6 treatment-naïve (TN) patients ± cirrhosis
- Patients were assigned treatment based on IFN eligibility

Key eligibility criteria

- Creatinine clearance (CL_{cr}) ≥50 mL/min
- Platelets ≥50,000/μL
- For patients assigned to receive concomitant PEG:
  - Platelets ≥90,000/μL
  - White blood cell count ≥2500/μL
  - Absolute neutrophil count (ANC) ≥1500/μL

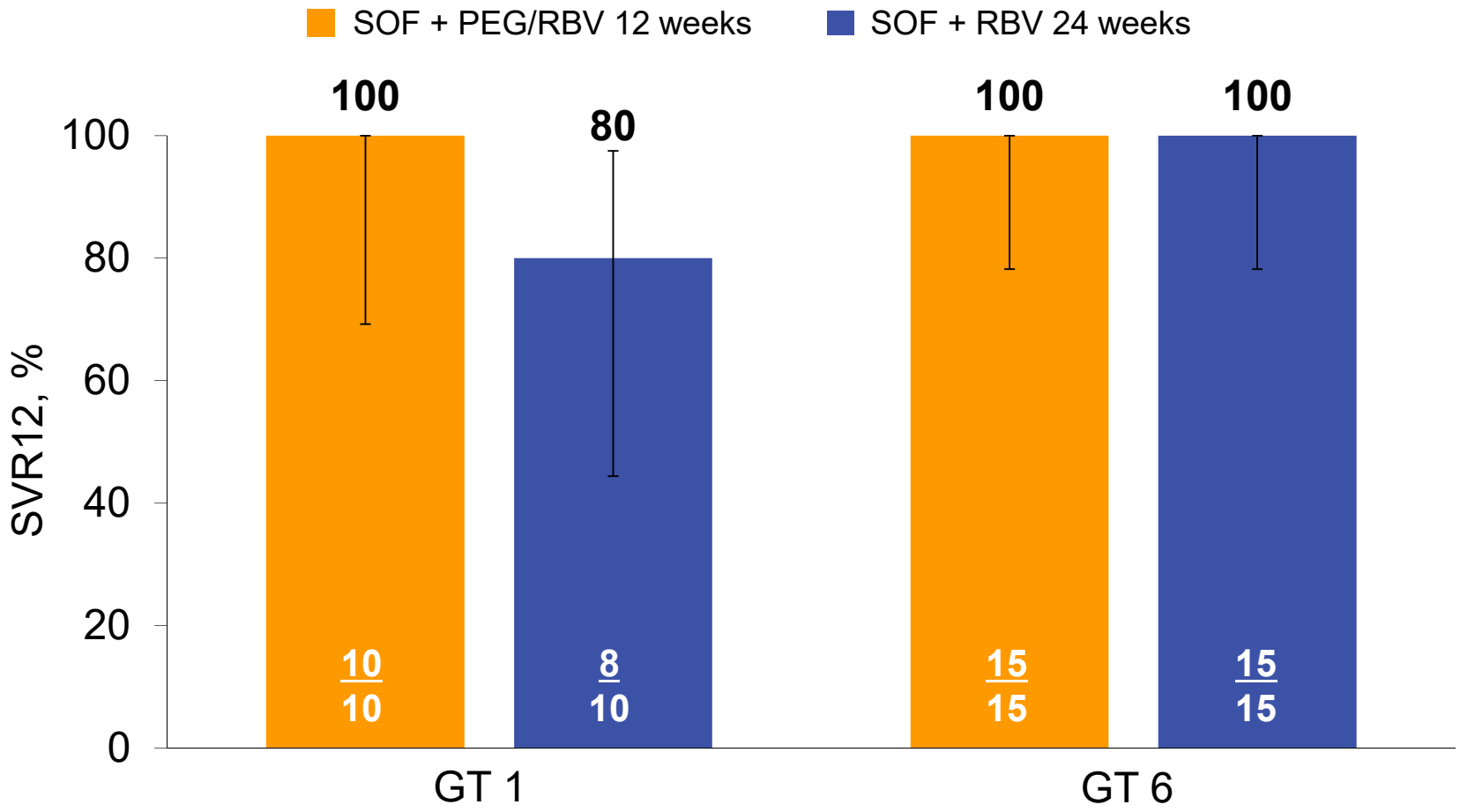
Methods: Study Endpoints

- Primary efficacy endpoint: SVR12
  - HCV RNA <LLOQ at post-treatment Week 12
    - Analyzed by Roche TaqMan® HCV Test v2.0 (LLOQ <25 IU/mL)
- Safety
  - Adverse events and discontinuations
  - Laboratory abnormalities

Results: Baseline Demographics

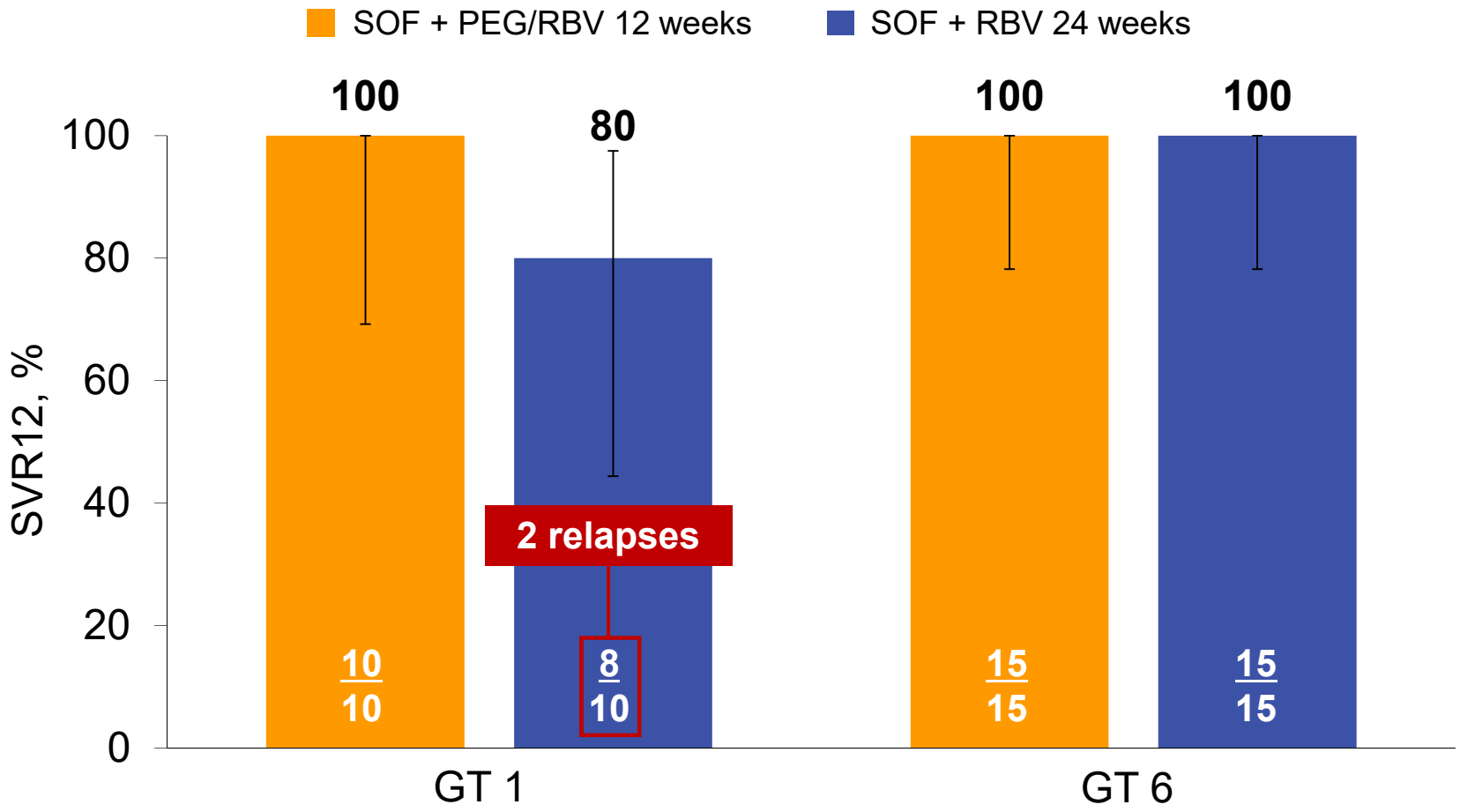
		GT 1		GT 6	
		SOF + PEG/RBV 12 wk n=10	SOF + RBV 24 wk n=10	SOF+ PEG/RBV 12 wk n=15	SOF + RBV 24 wk n=15
Mean age, y (range)		48 (36–63)	44 (26–65)	44 (31–55)	48 (25–67)
Male, n (%)		5 (50)	2 (20)	13 (87)	9 (60)
Mean BMI, kg/m^2 (range)		22 (20–26)	23 (20–26)	23 (19–29)	26 (19–34)
IL28B CC, n (%)		9 (90)	8 (80)	12 (80)	11 (73)
HCV GT, n (%)	GT 1a	4 (40)	3 (30)	n/a	n/a
	GT 1b	6 (60)	7 (70)	n/a	n/a
Mean baseline HCV RNA, $\log_{10}$ IU/mL (range)		6.5 (4.1–7.6)	6.4 (5.8–7)	6.6 (4.5–7.4)	6.4 (4.8–7.6)
TE, n (%)		0	0	0	0
Cirrhosis, n (%)		1 (10)	1 (10)	0	1 (7)

Results: SVR12



AO1

Results: SVR12



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AO1 Only 3 cirhotics, would consider adding footnote if all acheived SVR

Anu Osinusi, 2/7/2017

Results: Safety Summary

	Patients, n (%)	SOF + PEG/RBV 12 weeks n=25	SOF + RBV 24 weeks n=25
Overall Safety	AE	23 (92)	17 (68)
	Grade 3–4 AE	0	0
	Serious AE	0	0
	Treatment D/C due to AE	0	0
	Death	0	0
Laboratory Abnormalities	Grade 3–4	12 (48)*	1 (4)†
	Hb <10 g/dL	6 (24)	2 (8)
	Hb <8.5 g/dL	0	0

*Grade 3 Hb (n=5); Grade 3 lymphocytes (n=3); Grade 3 neutrophils (n=3); Grade 4 hyperkalemia (n=1).
†Grade 3 asymptomatic lipase elevation at post-treatment follow-up 4.

Results: Adverse Events (≥15% of Patients)

Patients, %	SOF + PEG/RBV 16 weeks n=25	SOF + RBV 24 weeks N=25
Pyrexia	8 (32)	1 (4)
Fatigue	6 (24)	5 (20)
Pain	6 (24)	2 (8)
Headache	5 (20)	2 (8)
Anemia	4 (16)	4 (16)
Cough	4 (16)	2 (8)
Decreased hemoglobin	4 (16)	1 (4)
Neutropenia	4 (16)	0
Abdominal pain	0	4 (16)

Conclusions

- SOF + PEG/RBV for 12 weeks resulted in 100% SVR12 rate in both treatment-naïve HCV GT 1 and GT 6 patients
- SOF + RBV for 24 weeks resulted in:
  - 80% SVR12 rate in GT 1
  - 100% SVR12 rate in GT 6
- SOF + RBV for 24 weeks and SOF + PEG/RBV for 12 weeks were well tolerated, with no treatment discontinuations due to adverse events
- SOF-based regimens provide an important treatment option for patients in Vietnam

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