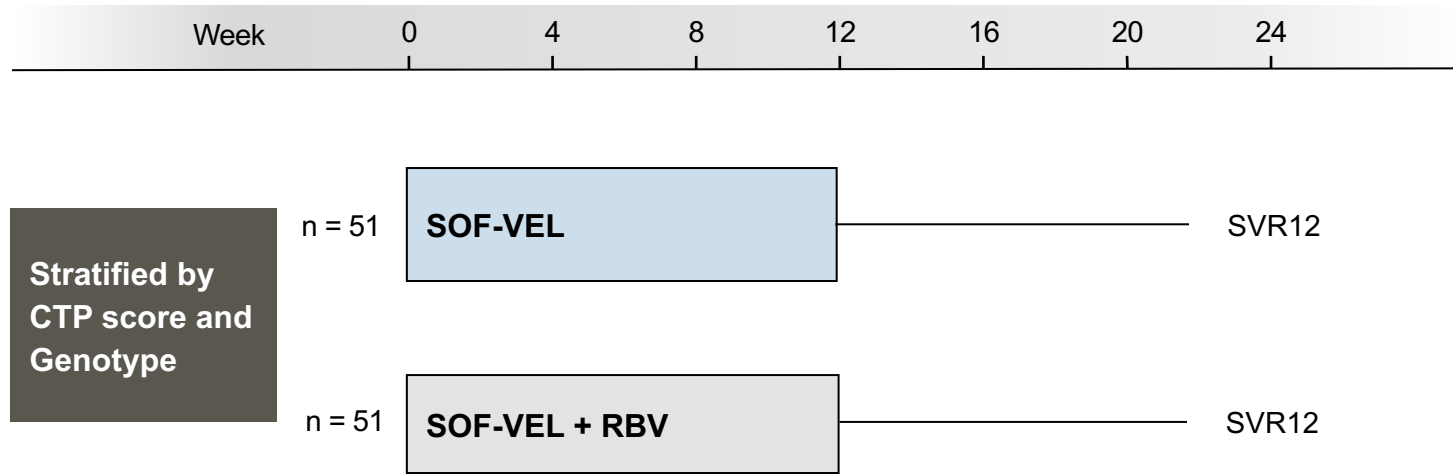


## Sofosbuvir-Velpatasvir with or without Ribavirin in Decompensated Cirrhosis (Japan)

# Sofosbuvir-Velpatasvir +/- Ribavirin for Decompensated Cirrhosis Study Features

- **Design:** Randomized, open-labeled, phase 3 trial to evaluate the safety and efficacy of the fixed-dose combination of sofosbuvir-velpatasvir for 12 weeks with or without ribavirin in treatment-naïve or treatment-experienced adults with chronic HCV infection and decompensated cirrhosis
- **Setting:** 13 sites in Japan
- **Key Eligibility Criteria**
  - Chronic HCV GT 1, 2, 3, 4, 5, or 6
  - Age  $\geq 20$  years
  - Decompensated cirrhosis (Child-Turcotte-Pugh score 7-12)
  - Hepatocellular carcinoma excluded in imaging within 4 months of baseline
  - Naïve or treated with peginterferon +/- ribavirin (PR) or PR +/- sofosbuvir
  - HIV, chronic hepatitis B coinfections excluded
- **Primary End Point:** SVR12

# Sofosbuvir-Velpatasvir +/- Ribavirin for Decompensated Cirrhosis Study Design



**Abbreviations:** CTP, Child-Turcotte-Pugh; SOF-VEL, Sofosbuvir-velpatasvir; RBV, Ribavirin

**Drug Dosing:** Sofosbuvir-velpatasvir (400/100 mg): fixed-dose combination; one pill once daily  
Ribavirin (weight-based and divided bid): 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

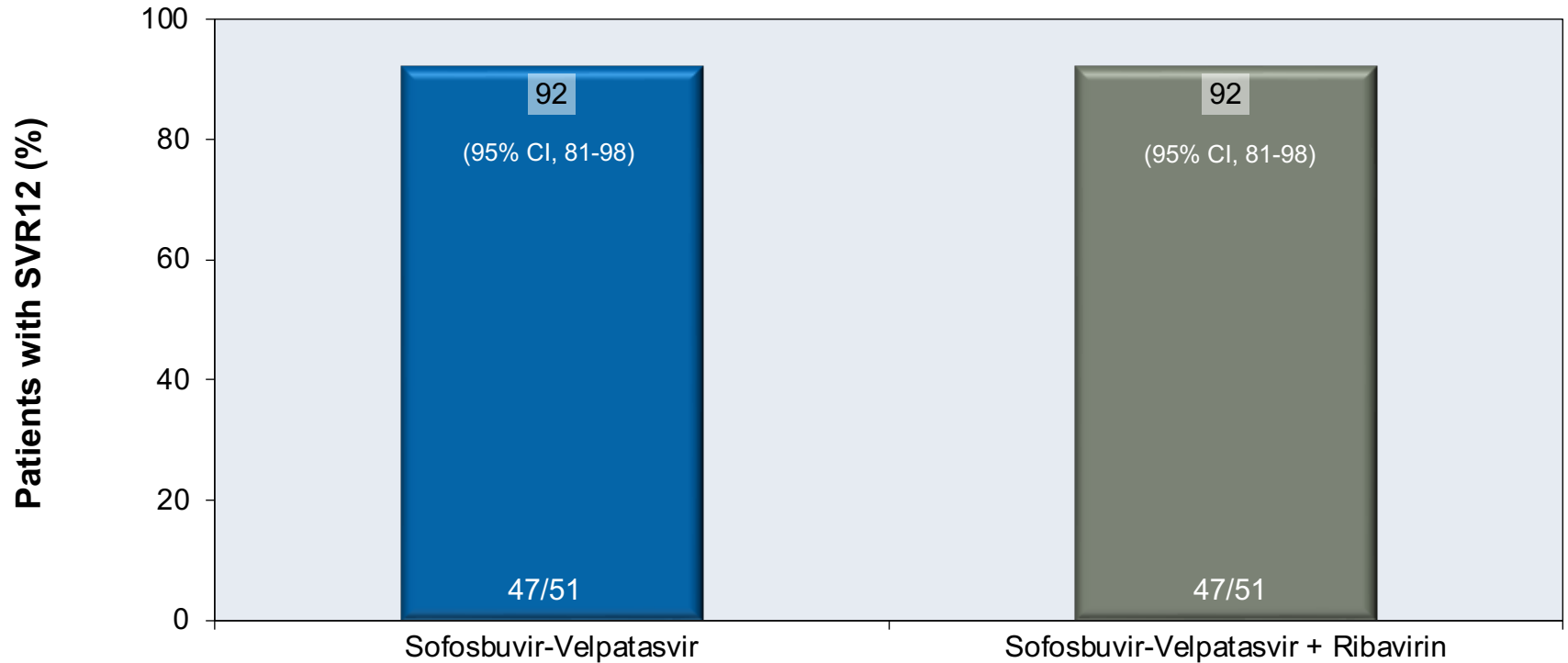
# Sofosbuvir-Velpatasvir +/- Ribavirin for Decompensated Cirrhosis Participants

Baseline Characteristics	SOF-VEL (n = 51)	SOF-VEL + RBV (n = 51)
Age, mean years (range)	66 (43-82)	66 (41-83)
Female, n (%)	33 (65)	29 (57)
Body mass index, mean kg/m <sup>2</sup> (range)	26.5 (20.4-43.0)	25.8 (18.3-58.6)
HCV RNA, mean log <sub>10</sub> IU/mL (range)	5.7 (3.7-7.1)	
IL28B CC genotype, n (%)	33 (65)	37 (73)
HCV genotype, n (%)		
1	41 (80)	39 (76)
1a / 1b	1 (2) / 40 (78)	0 / 39 (76)
2	9 (18)	11 (22)
3b	1 (2)	0
Treatment-naïve, n (%)	27 (53)	31 (61)

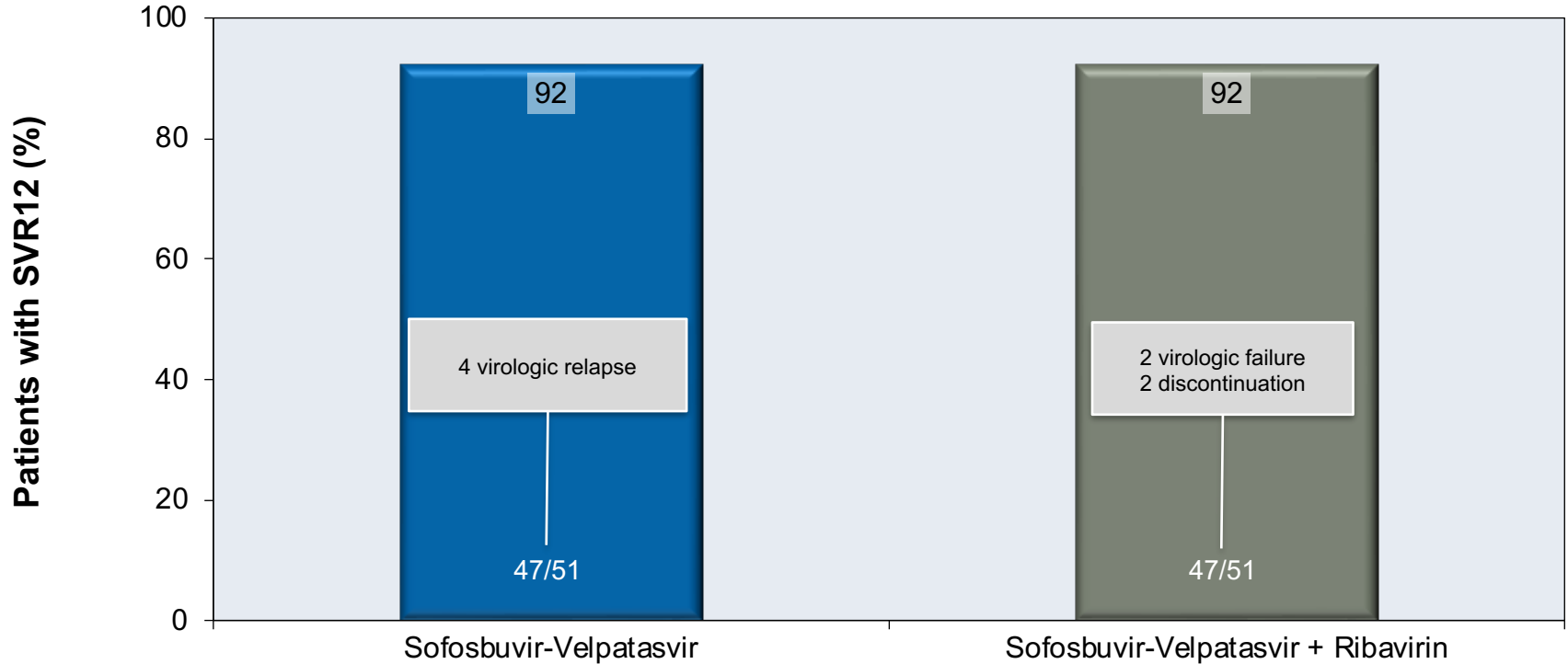
# Sofosbuvir-Velpatasvir +/- Ribavirin for Decompensated Cirrhosis Participants

Baseline Characteristics	SOF-VEL (n = 51)	SOF-VEL + RBV (n = 51)
Child-Turcotte-Pugh (class B) score 7-9 n (%)	40 (78)	39 (73)
MELD score ≥15	46 (90)	48 (76)
Ascites		
None	19 (37)	16 (31)
Mild/moderate	32 (63)	33 (65)
Severe	0	2 (4)
Encephalopathy		
None	23 (45)	22 (43)
Medication-controlled	28 (55)	29 (57)
Mean estimated GFR, mL/min (range)	93 (40-183)	89 (42-299)
<b>Abbreviations:</b> MELD, Model for End-Stage Liver Disease; GFR, glomerular filtration rate		

# Sofosbuvir-Velpatasvir +/- Ribavirin for Decompensated Cirrhosis Results

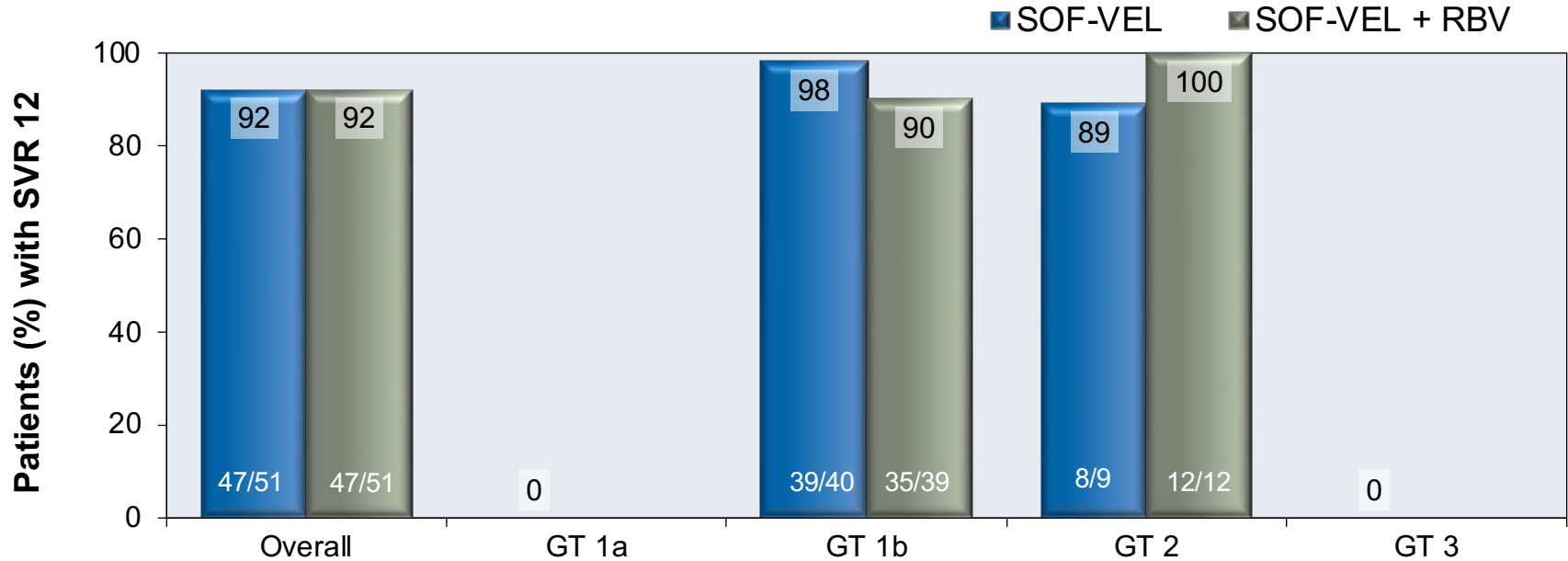


# Sofosbuvir-Velpatasvir +/- Ribavirin for Decompensated Cirrhosis Results



# Sofosbuvir-Velpatasvir +/- Ribavirin for Decompensated Cirrhosis Results

## SVR12, Overall and by Genotype

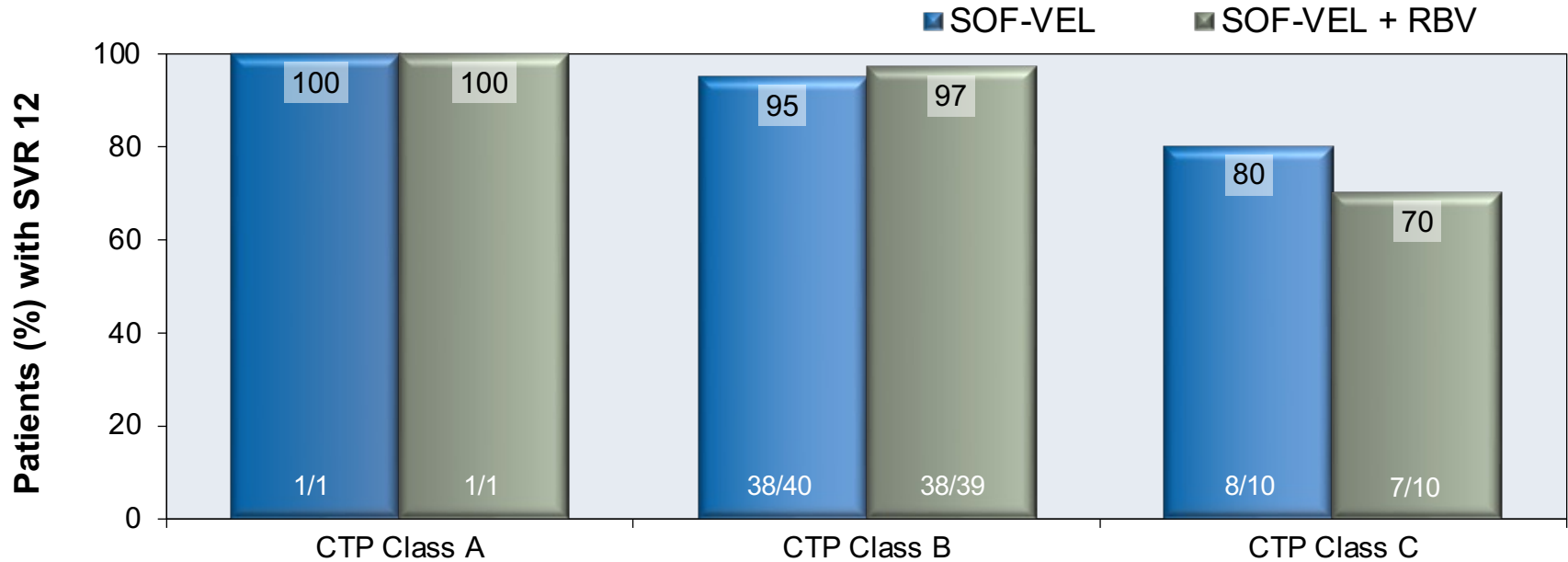


**Abbreviations:** SOF-VEL, sofosbuvir-velpatasvir; RBV, ribavirin



# Sofosbuvir-Velpatasvir +/- Ribavirin for Decompensated Cirrhosis Results

## SVR12 by Child-Turcotte-Pugh (CTP) Class



**Abbreviations:** SOF-VEL, sofosbuvir-velpatasvir; RBV, ribavirin

# Sofosbuvir-Velpatasvir +/- Ribavirin for Decompensated Cirrhosis

## Adverse Events

Adverse events (AEs), n (%)	SOF-VEL (n = 51)	SOF-VEL + RBV (n = 51)
Any AE	35 (69)	44 (86)
Grade ≥3 AE	2 (4)	5 (10)
Serious AE	4 (8)	7 (14)
AE leading to		
Discontinuation of SOF-VEL	0	2 (4)
Discontinuation of RBV	n/a	9 (18)
Interruption of RBV	n/a	18 (35)
Deaths	0	3 (6)
Common AE in ≥10% in either group		
Anemia	0	20 (39)
Nasopharyngitis	7 (14)	3 (6)
Diarrhea	0	7 (14)
<b>Abbreviations:</b> SOF-VEL, sofosbuvir-velpatasvir; RBV, ribavirin		

# Sofosbuvir-Velpatasvir +/- Ribavirin for Decompensated Cirrhosis

## Laboratory Abnormalities

Lab abnormalities*, n (%)	SOF-VEL (n = 51)	SOF-VEL + RBV (n = 51)
Hemoglobin <10 g/dl	2 (4)	7 (14)
Lymphocytes <500 cells/mm <sup>3</sup>	0	5 (10)
Platelets 25,000 to 50,000 cells/mm <sup>3</sup>	1 (2)	6 (12)
Hyperglycemia >250-500 mg/dL	5 (10)	9 (18)
Total bilirubin >2.5 x ULN	6 (12)	12 (24)
*Occurring ≥10% in either group. ULN, upper limit of normal		

# Sofosbuvir-Velpatasvir +/- Ribavirin for Decompensated Cirrhosis

## Conclusion

**Conclusion:** “Sofosbuvir-velpatasvir for 12 weeks provides a highly effective and well-tolerated therapy for Japanese patients with HCV and decompensated cirrhosis. Ribavirin did not improve efficacy but increased toxicity.”

# Acknowledgments

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