

3D + RBV in Liver Transplant Recipients with Recurrent HCV GT1 CORAL-I

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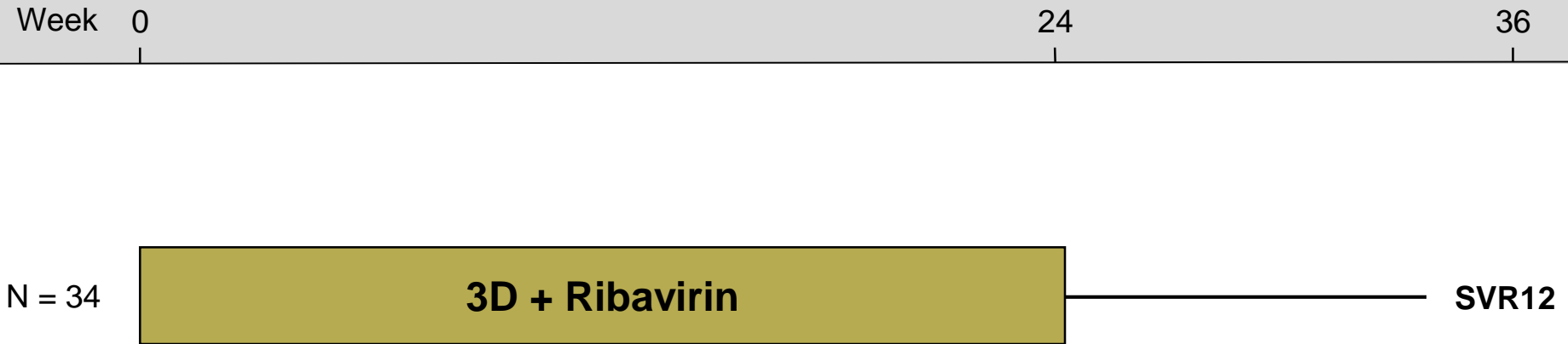
3D + RBV in Liver Transplant Recipients with Recurrent HCV GT1

CORAL-I Trial: Study Design

CORAL-I: Features

- **Design:** Phase 2, open-label, single-arm trial evaluating safety and efficacy of 3D (paritaprevir-ritonavir-ombitasvir + dasabuvir) + ribavirin x 24 weeks in liver transplant recipients with recurrent HCV GT 1
- **Setting:** International
- **Entry Criteria**
 - Chronic HCV infection with genotype 1
 - Liver transplantation due to HCV at least 12 months prior
 - Treatment-naïve after transplantation
 - Pre-transplant treatment with peginterferon + ribavirin allowed
 - Age 18-70
 - Metavir score \leq F2 confirmed by liver biopsy
- **Use of Immunosuppressants**
 - Receiving stable immunosuppressant regimen (tacrolimus or cyclosporin)
 - Tacrolimus or cyclosporin dose based on phase I pharmacokinetic study
 - Prednisone at dose \leq 5 mg/day permitted but not use of mTOR inhibitors
- **Primary End-Point:** SVR12

3D + RBV in Liver Transplant Recipients with Recurrent HCV GT1 CORAL-I Trial: Regimen



3D = Paritaprevir-Ritonavir-Ombitasvir + Dasabuvir

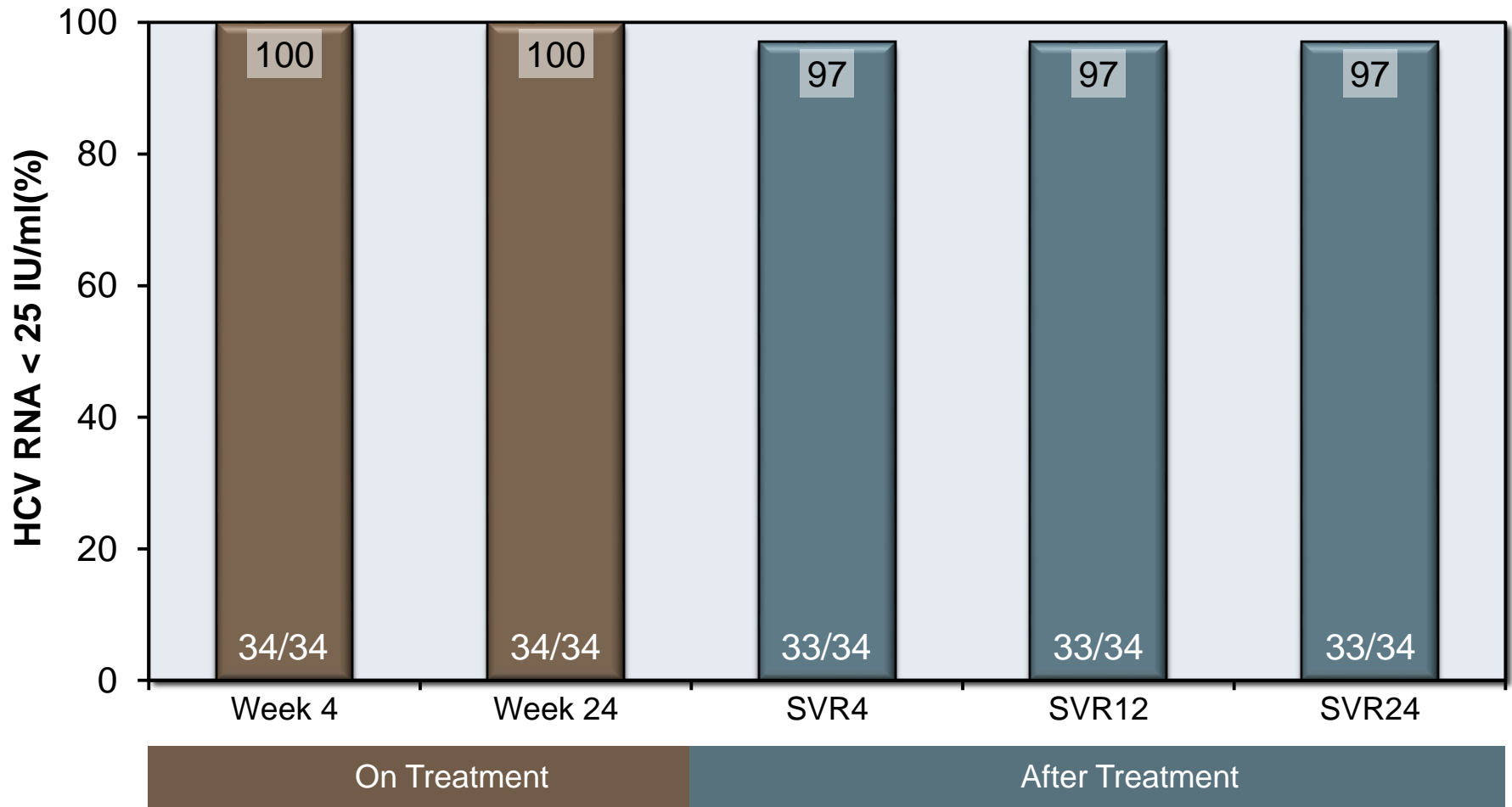
Drug Dosing

3D = Paritaprevir-Ritonavir-Ombitasvir (150/100/25 mg once daily) + Dasabuvir: 250 mg twice daily
Ribavirin (RBV): dosing managed per investigator discretion; most patients received 600-800 mg/day

3D + RBV in Liver Transplant Recipients with Recurrent HCV GT1 CORAL-I Trial: Baseline Characteristics

Baseline Characteristic	3D + Ribavirin (n=34)
Age (years), Mean	59.6
Male sex—no. (%)	27 (79)
Race—no. (%)	
White	29 (85)
Black	4 (12)
Multiple	1 (3)
Body Mass Index (kg/m ²) Mean	29.7
HCV genotype—no. (%)	
1a	29 (85)
1b	5 (15)
IL28B, non-CC genotype—no. (%)	26 (76)
HCV RNA, log ₁₀ IU/ml	6.6
Fibrosis stage (%)	
F0	6 (18)
F1	13 (38)
F2	15 (44)

3D + RBV in Liver Transplant Recipients with Recurrent HCV GT1 CORAL-I Trial: Results



3D + RBV in Liver Transplant Recipients with Recurrent HCV GT1 CORAL-I Trial: Adverse Events

Adverse Event Occurring in > 15% of the 34 Patients Receiving 3D + RBV	
Event	N (%)
Any adverse event	33 (97)
Fatigue	17 (50)
Headache	15 (44)
Cough	11 (32)
Anemia	10 (29)
Diarrhea	9 (26)
Insomnia	9 (26)
Asthenia	8 (24)
Nausea	8 (24)
Muscle spasms	7 (21)
Rash	7 (21)
Back pain	6 (18)
Dizziness	6 (18)
Peripheral edema	6 (18)
Rhinorrhea	6 (18)

3D + RBV in Liver Transplant Recipients with Recurrent HCV GT1 CORAL-I Trial: Conclusions

Conclusions: “Treatment with the multitargeted regimen of ombitasvir-ABT-450/r and dasabuvir with ribavirin was associated with a low rate of serious adverse events and a high rate of sustained virologic response among liver-transplant recipients with recurrent HCV genotype 1 infection, a historically difficult-to-treat population.”

Note: ABT-450/r = Paritaprevir-Ritonavir

This slide deck is from the University of Washington's *Hepatitis C Online* and *Hepatitis Web Study* projects.

Hepatitis C Online

www.hepatitisc.uw.edu

Hepatitis Web Study

<http://depts.washington.edu/hepstudy/>

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