

Treatment-Naïve

Daclatasvir + Peg/RBV in Treatment-Naïve Genotype 1 or 4 COMMAND-1 Study

Hézode C, et. al. Gut. 2015;64:948-56.

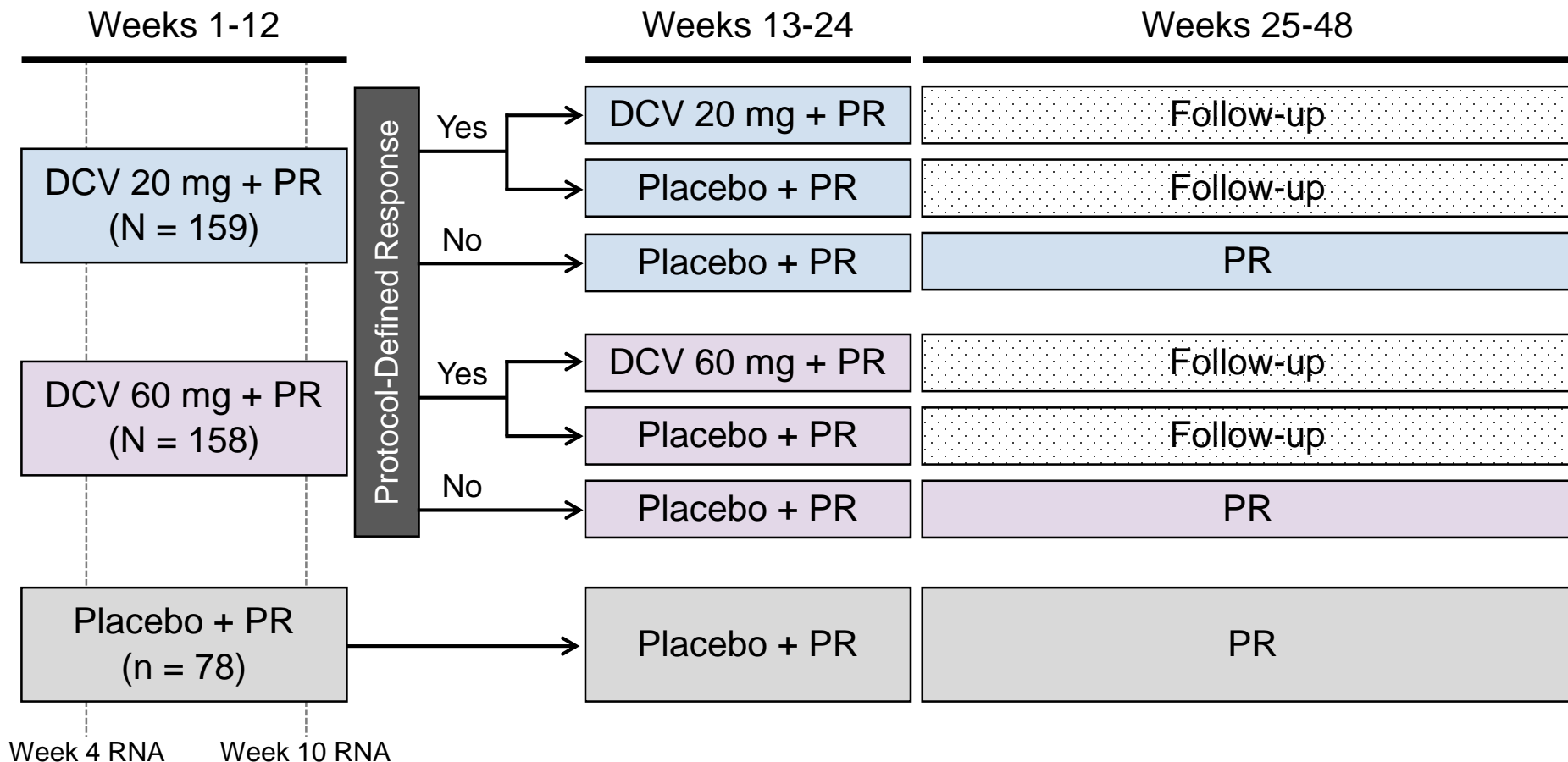
Daclatasvir + Peginterferon/RBV for HCV GT 1 or 4

COMMAND-1 Trial: Study Features

COMMAND-1 Trial: Features

- **Design:** Phase 2b randomized, double-blind placebo-controlled trial of daclatasvir (DCV) or placebo given with peginterferon alfa-2a and ribavirin in treatment-naïve patients with chronic HCV genotype 1 or 4
- **Setting:** United States and Europe
- **Entry Criteria**
 - Chronic HCV Genotype 1 or 4
 - Treatment-naïve
 - Adults 18-70
 - HCV RNA >100,000 IU/ml
 - ALT less than 5x upper limit of normal
 - Compensated cirrhosis allowed (maximum of 10% with each GT)
- **End-Points:** Primary = SVR12

Daclatasvir + Peginterferon/RBV for HCV GT 1 or 4 COMMAND-1 Trial: Design



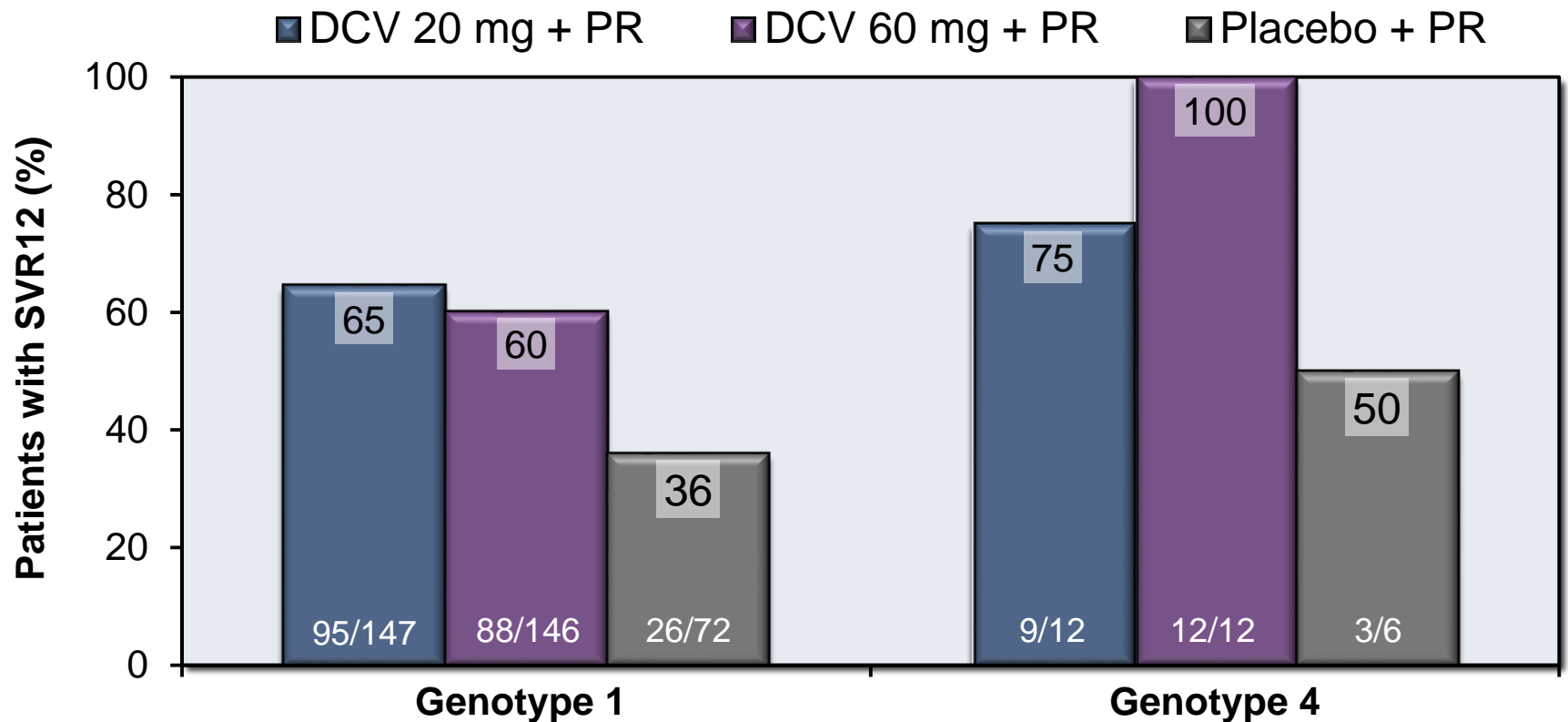
PDR = Protocol-Defined Response (HCV RNA <lower limit of quantitation at week 4 & undetectable at week 10)
DCV = daclatasvir; PEG = peginterferon; RBV = ribavirin

Daclatasvir + Peginterferon/RBV for HCV GT 1 or 4 COMMAND-1 Trial: Patient Characteristics

Characteristic	DCV 20 mg + PR (n=159)	DCV 60 mg + PR (n=82)	Placebo + PR (n=42)
Age, median years, years	51 (22-70)	50 (18-67)	51 (25-66)
Male %	67.3	65.2	70.5
Race, n (%)			
White	132 (83.0)	127 (80.4)	60 (76.9)
Black	15 (9.4)	21 (13.3)	9 (11.5)
Other	12 (7.5)	10 (6.3)	9 (11.5)
BMI ≥30 kg/m ² , n (%)	31 (19.5)	42 (26.6)	23 (29.5)
HCV RNA, mean log ₁₀ IU/ml	6.5	6.5	6.4
HCV RNA ≥800,000 IU/ml, (%)	133 (83.6)	123 (77.8)	61 (78.2)
Cirrhosis present, n (%)	13 (8.2)	8 (5.1)	8 (10.3)
<i>IL28B</i> CC genotype, n (%)	53 (33.3)	44 (27.8)	23 (29.5)

Daclatasvir + Peginterferon/RBV for HCV GT 1 or 4 COMMAND-1 Trial: Results

SVR12, by Genotype



DCV=daclatasvir; PR=peginterferon plus ribavirin

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Daclatasvir + Peginterferon/RBV for HCV GT 1 or 4 COMMAND-1: Conclusions

Conclusions: “The combination of daclatasvir/peginterferon-alfa/ribavirin was generally well tolerated and achieved higher SVR24 rates compared with placebo/peginterferon-alfa/ribavirin among patients infected with HCV genotype 1 or 4.”

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www.hepatitisc.uw.edu

Hepatitis Web Study

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

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