

ONLINE EXPERT POSTER REVIEW AND DISCUSSION

Advances in Chronic Hepatitis C Management and Treatment

REPORTING FROM
THE 62ND AMERICAN ASSOCIATION FOR
THE STUDY OF LIVER DISEASES ANNUAL MEETING
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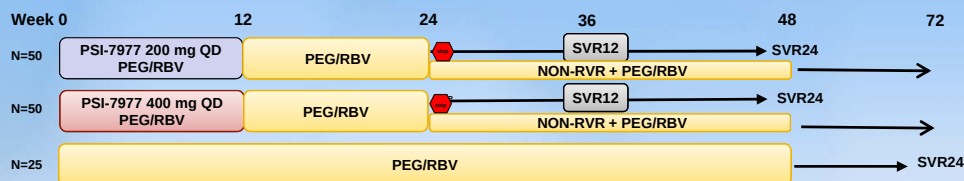
Once-Daily PSI-7977 Plus Peg/RBV in Treatment-naïve Patients with HCV GT1: Robust End of Treatment Response Rates are Sustained Post-treatment (PROTON)

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Abstract 225

Proton Study Design

HCV GT1



- 125 treatment-naïve patients with HCV GT1
- Dose finding study
- 12 Week Interim analysis*

HCV GT2/GT3

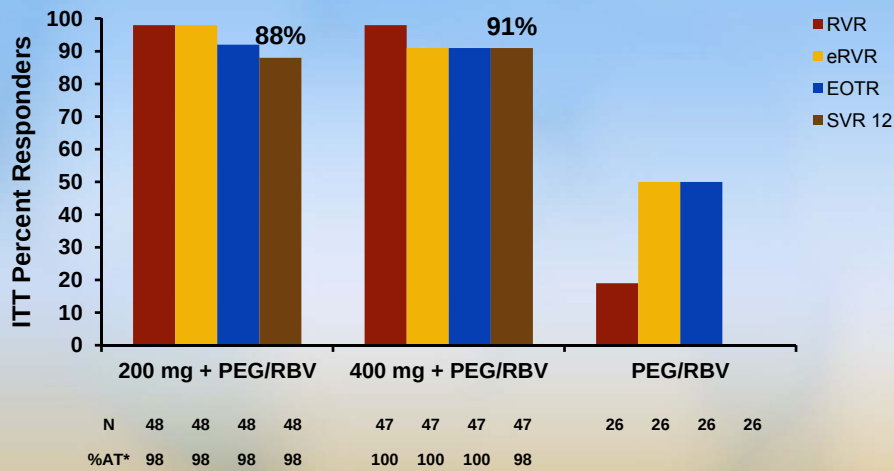


- 25 treatment-naïve patients with HCV GT2/3; one pt lost to F/U after Day 1
- 24/24 observed RVR, SVR 12 and SVR 24*

* Nelson, et al. EASL 2011 LB poster #1372

** Data reported at EASL 2011, Lalezari et al. Lawitz E, et al. 62nd AASLD; San Francisco, CA; November 04-08, 2011. Abst. 225.

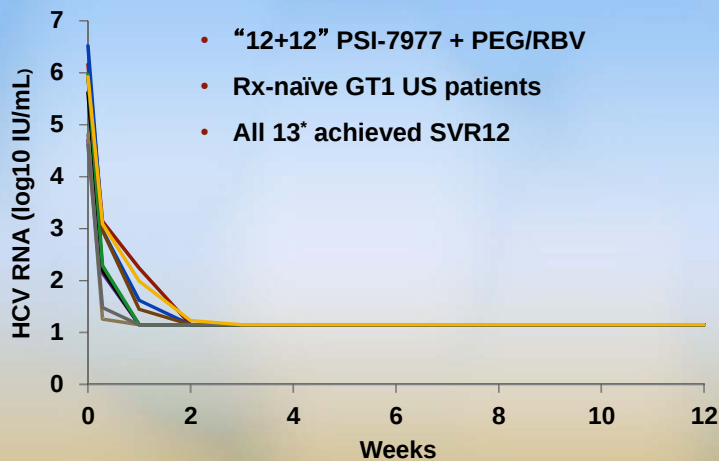
Results: 98% SVR in Subject Who Received at Least 8 Weeks of PSI-7977 400 mg QD + PEG/RBV



*As treated: Patients who received ≥ 8 wks PSI-7977

Lawitz E, et al. 62nd AASLD; San Francisco, CA; November 04-08, 2011. Abst. 225.

Results: Consistent Antiviral Response in Subjects with Genetic Predictors of Non-Response to IFN (*IL28B* T/T)

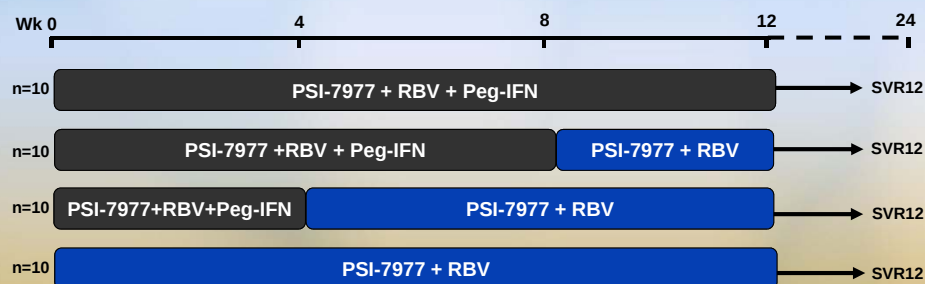


* 10 subjects with *IL28B* T/T allele randomized to the 400 mg group and 3 randomized to the 200 mg group

Lawitz E, et al. 62nd AASLD; San Francisco, CA; November 04-08, 2011. Abst. 225.

PSI-7977 ELECTRON Study Design for HCV GT2/3

- Treatment-naïve, non-cirrhotic, age ≥18 years
- HCV RNA >50,000 IU/mL
- Allowed concurrent methadone use
- Stratified by HCV genotype and IL28B genotype
- Randomized 1:1:1:1 into IFN-sparing or IFN-free



Gane EJ, et al. 62nd AASLD; San Francisco, CA; November 04-08, 2011. Abst. 34.

PSI-7977 ELECTRON 100% Concordance of SVR12 with SVR24

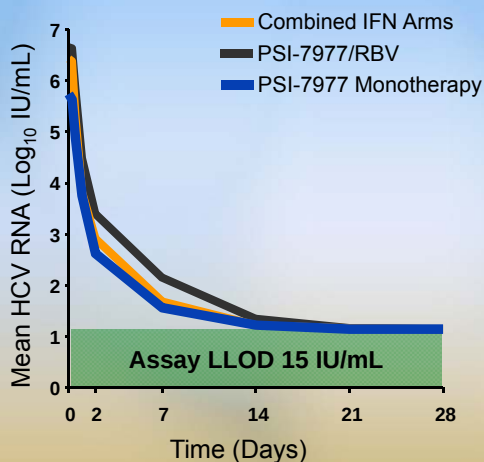
Time Wk	PSI-7977 RBV 12 weeks PEG		PSI-7977 RBV 8 weeks PEG		PSI-7977 RBV 4 weeks PEG		PSI-7977 RBV NO PEG	
	n	%<LOD	n	%<LOD	n	%<LOD	n	%<LOD
2	9/11	82	7/8	88	8/9	89	8/10	80
4	11/11	100	10/10	100	9/9	100	10/10	100
8	11/11	100	10/10	100	9/9	100	10/10	100
12	11/11	100	10/10	100	9/9	100	10/10	100
SVR4	11/11	100	10/10	100	9/9	100	10/10	100
SVR8	11/11	100	10/10	100	9/9	100	10/10	100
SVR12	11/11	100	10/10	100	9/9	100	10/10	100
SVR24	6/6	100	5/5	100	5/5	100	4/4	100

Gane EJ, et al. 62nd AASLD; San Francisco, CA; November 04-08, 2011. Abst. 34.

PSI-7977 ELECTRON

What is the Role of Ribavirin?

- PSI-7977 monotherapy arm (n=10) was added

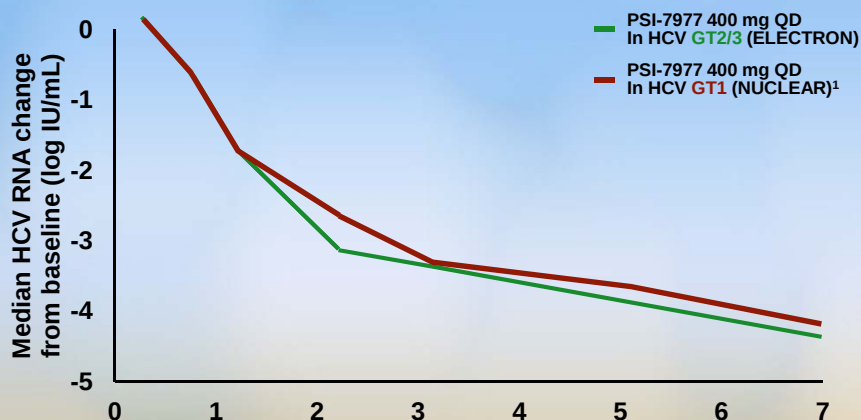


- No on-treatment viral breakthroughs or resistance
- 6/10 subjects achieved SVR4 Further studies of PSI-7977 monotherapy in progress
- PSI-7977/RBV for 12 weeks being advanced in IFN-free Phase 3 program

Gane EJ, et al. 62nd AASLD; San Francisco, CA; November 04-08, 2011. Abst. 34.

PSI-7977 ELECTRON

Rapid Viral Suppression Across HCV Genotypes



Confirms *in vitro* potency of PSI-7977 across HCV genotypes

1 Lawitz E, et al. J Hepatol 2011; 54: S543

Gane EJ, et al. 62nd AASLD; San Francisco, CA; November 04-08, 2011. Abst. 34.