Supplementary Online Content

Sulkowski MS, Naggie S, Lalezari J, et al. Sofosbuvir and ribavirin for hepatitis C in patients with HIV-1 coinfection. *JAMA*. DOI:10.1001/jama.2014.7734

This supplementary material has been provided by the authors to give readers additional information about their work.

Study Assessments

Plasma samples for viral sequence analysis were collected at Baseline/Day 1 and at each visit. Virologic failure was defined as: HCV RNA ≥LLOQ after having previously had HCV RNA <LLOQ while on treatment (ie, breakthrough); >1 $\log_{10}$ IU/mL increase in HCV RNA from nadir while on treatment (ie, rebound); HCV RNA persistently ≥LLOQ through 8 weeks of treatment (ie, nonresponse); HCV RNA ≥LLOQ during the posttreatment period having achieved HCV RNA <LLOQ at end of treatment (ie, relapse). At any unscheduled visit initiated for the purpose of confirming virologic breakthrough, a plasma sample for viral sequence analysis was collected. NS5B population sequencing was performed for all patients at Baseline/Day 1. For patients with virologic failure, samples from baseline and time of virologic failure were deep sequenced for NS5B mutants with an assay cut-off at 1%. DDL Diagnostics Laboratory (Rijswijk, The Netherlands, EU) performed NS5B amplification and population sequencing. Deep sequencing of amplified NS5B PCR products was conducted at Wuxi Apptec (Shanghai, China). Specific evaluations for sofosbuvir treatment emergent mutations S282T, L159F, and V321A were performed. The S282T variant has been shown in vitro to reduce susceptibility to sofosbuvir.

In addition to standard laboratory and clinical tests, screening assessments included serum HCV RNA levels and IL28B genotyping. Serum HCV RNA was measured with the COBAS® TaqMan® HCV Test, version 2.0 for Use with the High Pure System (Roche Molecular Systems, West Sussex, United Kingdom) with a lower limit of quantification (LLOQ) of 25 IU/mL. HCV genotype and subtype were determined using the Siemens VERSANT HCV Genotype INNO-LiPA 2.0 assay. IL28B genotype was determined by PCR amplification and sequencing of the rs12979860 single-nucleotide polymorphism. Screening assessments also included serum HIV-1

RNA quantification using the AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0 with a lower limit of quantification (LLOQ) of 20 copies/mL. HIV virologic breakthrough was defined as a subject with HIV-1 RNA >50 copies/mL on consecutive evaluations at least 2 weeks apart among patients with HIV-1 RNA <50 copies/mL at baseline.

On-treatment assessments included standard laboratory testing, serum HCV RNA, serum HIV-1 RNA, CD4 T-cell count and percentage, vital signs, electrocardiography, and symptom-directed physical examinations. All adverse events were recorded and graded for all patients receiving at least 1 dose of the study drug and through 30 days after the last dose. The severity of adverse events was graded according to a standardized scale adapted from the Division of AIDS Table 1 for Grading the Severity of Adult and Pediatric Adverse Events, version 1.0 (Supplemental appendix).

Plasma samples for viral sequence analysis were collected at Baseline/Day 1 and at each visit.

At any unscheduled visit initiated for the purpose of confirming virologic breakthrough, a plasma sample for viral sequence analysis was collected. NS5B population sequencing was performed for all patients Baseline/Day 1. For patients with virologic failure, NS5B was deep sequenced at baseline and virologic failure time point with an assay cut-off at 1%. DDL Diagnostics Laboratory (Rijswijk, The Netherlands, EU) performed NS5B amplification and population sequencing. Deep sequencing of amplified NS5B PCR products was conducted at Wuxi Apptec (Shanghai, China). Specific evaluations for sofosbuvir treatment emergent mutations S282T, L159F, and V321A were performed. S282T has been shown *in vitro* to reduce susceptibility to sofosbuvir.

eTable 1. Subgroup analysis of SVR12 for genotype 1 patients

Factor		Treatment Naïve (N=114)	
		SVR12	**% (95% CI)**
Overall		87/114	76% (67-84%)
Subgroup	1a	74/90	82% (73-89.5%)
	1b	13/24	54% (33-74%)
Age	<50	48/63	76% (64-86%)
	≥50	39/51	76% (62.5-87%)
Sex	Male	69/93	74% (64-83%)
	Female	18/21	886% (64-97%)
Race	Black	24/37	65% (47.5-80%)
	Non-Black	63/77	82% (71-90%)
Ethnicity	Hispanic/Latino	17/25	68% (46.5-85%)
	Non-Hispanic/Latino	70/89	79% (69-87%)
Cirrhosis	No	84/109	77% (68-85%)
	Yes	3/5	60% (15-95%)
HCV RNA	<6 $\log_{10}$ IU/mL	17/22	77% (55-92%)
	≥6 $\log_{10}$ IU/mL	70/92	76% (66-84%)
Body Mass Index	<30 kg/m^2	67/88	76% (66-85%)
	≥30 kg/m^2	20/26	77% (56-91%)
Baseline ALT	≤1.5 × ULN	47/64	73% (61-84%)
	>1.5 × ULN	40/50	80% (66-90%)
IL28B	CC	24/30	80% (61-92%)
	Non-CC	62/83	75% (64-84%)
Study Drug Completion	Completed	84/103	82% (73-88.5%)
	Not Completed	3/11	27% (6-61%)
ARV Type	NNRTI	32/49	65% (50-78%)
	Protease inhibitor	35/39	90% (76-97%)
	Integrase	17/21	81% (58-95%)
	Other	2/3	67% (9-99%)

eTable 2. Logistic regression on genotype 1 subjects to assess factors associated with SVR12

Factor	N in the test group	Univariate Analysis (N=114)		Multivariable analysis (N=114)	
		Odds Ratio (95% CI)	P value	Odds Ratio (95% CI)	P value
Age <50	63	0.99 (0.41, 2.35)	0.97	—	—
Female	21	2.09 (0.56, 7.72)	0.27	—	—
Non-Black Race	77	2.44 (1.00, 5.92)	0.050	2.87 (1.01, 8.20)	**0.049**
Hispanic	25	0.58 (0.22, 1.54)	0.27	—	—
No Cirrhosis	109	2.24 (0.35, 14.16)	0.39	—	—
HCV <6 $\log_{10}$	22	1.07 (0.35, 3.23)	0.91	—	—
IL28B CC	30	1.41 (0.51, 3.91)	0.51	—	—
Genotype 1a	90	3.91 (1.49, 10.30)	0.006	3.42 (1.15, 10.16)	**0.027**
BMI <30	88	0.96 (0.34, 2.70)	0.93	—	—
ALT ≤1.5 ULN	64	0.69 (0.29, 1.68)	0.41	—	—
Completing treatment	103	11.76 (2.86, 47.62)	0.0006	17.54 (3.77, 83.33)	**0.0003**
IFN eligible	85	1.03 (0.39, 2.78)	0.95	—	—
Not on ARV	2	0.30 (0.018, 5.00)	0.4	—	—
Baseline creatinine clearance (in increments of 1 mL/min)		1.00 (0.98, 1.01)	0.85	—	—
Baseline RBV (in increments of 1 mg/kg)		1.12 (0.92, 1.36)	0.26	—	—

All factors assessed in univariate logistic regression were included in the multivariable logistic-regression using a stepwise forward selection procedure to identify independent predicators of SVR12. Entry into the multivariable model was permitted if the selection entry P value was <0.20 and the predictors will stay in the model if the P value for that predictor was <0.1. Results from the multivariable model only provided odds ratio and P values those predicators which met above criteria.

eTable 3. Subgroup analysis of SVR12 for genotype 2 patients

Factor		Treatment Naïve (N=26)		Treatment Experienced (N=24)	
		SVR12	% (95% CI)	SVR12	% (95% CI)
Overall		23/26	88% (70-98%)	22/24	92% (73-99%)
Age	<50	9/10	90% (56-100%)	3/3	100% (29-100%)
	≥50	14/16	88% (62-98%)	19/21	91% (70-99%)
Sex	Male	19/21	90% (70-99%)	21/23	91% (72-99%)
	Female	4/5	80% (28-100%)	1/1	100% (3-100%)
Race	Black	5/6	83% (36-100%)	6/6	100% (54-100%)
	Non-Black	18/20	90% (68-99%)	16/18	89% (65-99%)
Ethnicity	Hispanic/Latino	7/8	88% (47-100%)	5/5	100% (48-100%)
	Non-Hispanic/Latino	16/18	89% (65-99%)	17/19	90% (70-99%)
Cirrhosis	No	22/25	88% (69-98%)	18/20	90% (68-99%)
	Yes	1/1	100% (3-100%)	4/4	100% (40-100%)
HCV RNA	<6 $\log_{10}$ IU/mL	5/6	83% (36-100%)	5/5	100% (48-100%)
	≥6 $\log_{10}$ IU/mL	18/20	90% (68-99%)	17/19	90% (67-99%)
Body Mass Index	<30 kg/m^2	18/20	90% (68-99%)	15/16	94% (70-100%)
	≥30 kg/m^2	5/6	83% (36-100%)	7/8	88% (47-100%)
Baseline ALT	≤ 1.5 ULN	8/11	73% (39-94%)	13/14	93% (66-100%)
	>1.5 ULN	15/15	100% (78-100%)	9/10	90% (56-100%)
IL28B	CC	8/10	80% (44-98%)	9/10	90% (56-100%)
	Non-CC	15/16	94% (70-100%)	13/14	93% (66-100%)
Study Drug Completion	Completed	22/23	96% (78-100%)	22/23	96% (78-100%)
	Not Completed	1/3	33% (1-91%)	0/1	(3-100%)
ARV Type	NNRTI	7/9	78% (40-97%)	11/11	100% (72-100%)
	Protease inhibitor	10/10	100% (69-100%)	4/5	80% (28-100%)
	Integrase	2/2	100% (16-100%)	3/4	75% (19-99%)
	Other	1/1	100% (3-100%)	3/3	100% (29-100%)

eTable 4. Univariate and multivariable analysis for genotype 2 patients.

Factor	N in the test group	Univariate Analysis (N=50)		Multivariable analysis (N=50)	
		Odds Ratio (95% CI)	P value	Odds Ratio (95% CI)	P value
Age <50	13	1.444 (0.13, 77.52)	1.000	—	—
Female	6	0.509 (0.038, 29.49)	0.9749	—	—
Black	12	1.288 (0.11, 69.45)	1.000	—	—
Hispanic	13	1.444 (0.13, 77.52)	1.000	—	—
No Cirrhosis	45	1.292 (0, 11.62)	1.000	—	—
HCV <6 $\log_{10}$	11	1.140 (0.097, 61.84)	1.000	—	—
IL28B CC	20	0.412 (0.031, 3.99)	0.6199	—	—
Treatment experienced	24	1.425 (0.15, 18.59)	1.000	—	—
BMI <30	36	1.809 (0.14, 17.91)	0.8657	—	—
ALT ≤1.5 ULN	25	0.225 (0.004, 2.51)	0.3487	—	—
Completing treatment	46	50 (2.89, >1000)	0.004	200 (4, >1000)	**0.0022**
Not on ARV	5	0.4 (0.028, 23.97)	0.8467	—	—
Baseline creatinine clearance (in increments of 1 mL/min)		0.98 (0.95, 1.01)	0.1876	0.995 (0.91, 1.001)	0.057
Baseline RBV (in increments of 1 mg/kg)		1.014 (0.70, 1.46)	0.939	—	—

All factors assessed in univariate logistic regression were included in the multivariable logistic-regression using a stepwise forward selection procedure to identify independent predicators of SVR12. Entry into the multivariable model was permitted if the selection entry P value was <0.20 and the predictors will stay in the model if the P value for that predictor was <0.1. Results from the multivariable model only provided odds ratio and P values those predicators which met above criteria.

eTable 5. Subgroup analysis of SVR12 for genotype 3 patients

Factor		Treatment Naïve (N=42)		Treatment Experienced (N=17)	
		SVR12	% (95% CI)	SVR12	% (95% CI)
Overall		28/42	67% (51-80%)	16/17	94% (71-100%)
Age	<50	14/23	61% (39-80%)	3/3	100% (29-100%)
	≥50	14/19	74% (49-91%)	13/14	93% (66-100%)
Sex	Male	23/34	68% (50-83%)	13/14	93% (66-100%)
	Female	5/8	63% (25-92%)	3/3	100% (29-100%)
Race	Black	1/2	50% (1-99%)	0/1	(3-100%)
	Non-Black	27/40	68% (51-81%)	16/16	100% (79-100%)
Ethnicity	Hispanic/Latino	8/11	73% (39-94%)	5/5	100% (48-100%)
	Non-Hispanic/Latino	20/31	65% (45-81%)	11/12	90% (62-100%)
Cirrhosis	No	24/36	67% (49-81%)	11/11	100% (72-100%)
	Yes	4/6	67% (22-96%)	5/6	83% (36-100%)
HCV RNA	<6 $\log_{10}$ IU/mL	11/15	73% (45-92%)	2/2	100% (16-100%)
	≥6 $\log_{10}$ IU/mL	17/27	63% (42-81%)	14/15	93% (68-100%)
Body Mass Index	<30 kg/m^2	22/33	67% (48-82%)	15/15	100% (78-100%)
	≥30 kg/m^2	6/9	67% (30-93%)	1/2	50% (1-99%)
Baseline ALT	≤ 1.5 ULN	7/12	58% (28-85%)	4/5	80% (28-100%)
	>1.5 ULN	21/30	70% (51-85%)	12/12	100% (74-100%)
IL28B	CC	9/15	60% (32-84%)	10/10	100% (69-100%)
	Non-CC	19/27	70% (50-86%)	6/7	86% (42-100%)
Study Drug Completion	Completed	27/39	69% (52-83%)	16/17	94% (71-100%)
	Not Completed	1/3	33% (1-91%)	0/0	0
ARV Type	NNRTI	9/16	56% (30-80%)	7/7	100% (59-100%)
	Protease inhibitor	10/15	67% (38-88%)	5/5	100% (48-100%)
	Integrase	4/6	67% (22-96%)	3/3	100% (29-100%)
	Other	2/2	100% (16-100%)	1/1	100% (3-100%)

eTable 6. Univariate and multivariable analysis for genotype 3 patients

Factor	N in the test group	Univariate Analysis (N=59)		Multivariable analysis (N=59)	
		Odds Ratio (95% CI)	P value	Odds Ratio (95% CI)	P value
Age <50	26	0.42 (0.13, 1.39)	0.1556	—	—
Female	11	0.89 (0.20, 3.90)	0.876	—	—
Black	3	0.15 (0.013, 1.80)	0.1353	—	—
Hispanic	16	1.68 (0.41, 6.95)	0.4757	—	—
No Cirrhosis	47	0.97 (0.23, 4.20)	0.97	—	—
HCV <6 log10	17	1.15 (0.31, 4.30)	0.8317	—	—
IL28B CC	25	1.14 (0.35, 3.76)	0.8295	—	—
Treatment experienced	17	8.0 (0.96, 66.62)	0.0545	8.0 (0.96, 66.62)	0.055
BMI <30	48	1.92 (0.47, 7.80)	0.3606	—	—
ALT ≤1.5 ULN	17	0.5 (0.15, 1.72)	0.2725	—	—
Not completing treatment	3	0.15 (0.013, 1.80)	0.1353	—	—
Not on ARV	4	1.02 (0.098, 10.67)	0.984	—	—
Baseline creatinine clearance (in increments of 1 mL/min)		0.99 (0.97, 1.01)	0.3021	—	—
Baseline RBV (in increments of 1 mg/kg)		1.07 (0.84, 1.36)	0.6071	—	—

All factors assessed in univariate logistic regression were included in the multivariable logistic-regression using a stepwise forward selection procedure to identify independent predicators of SVR12. Entry into the multivariable model was permitted if the selection entry P value was <0.20 and the predictors will stay in the model if the P value for that predictor was <0.1. Results from the multivariable model only provided odds ratio and P values those predicators which met above criteria.

eTable 7. Adverse Events Leading to Permanent Discontinuation of Both Study Drugs, n (%)

Event	SOF+RBV for 12 Weeks in GT 2/3 Treatment-Naïve Patients (N=68)	SOF+RBV for 24 Weeks in GT 1 Treatment-naïve and GT 2/3 Treatment-Experienced Patients (N=155)
Acute Myocardial Infarction	1 (1.5)	0
Sensation of foreign body	0	1 (0.6)
Pneumonia	1 (1.5)	0
Septic Shock	1 (1.5)	0
Staphylococcal bacteremia	1 (1.5)	0
Intentional overdose	1 (1.5)	0
Abnormal loss of weight	1 (1.5)	0
Decreased appetite	1 (1.5)	0
Encephalopathy	1 (1.5)	0
Headache	1 (1.5)	0
Agitation	0	1 (0.6)
Anxiety	0	1 (0.6)
Insomnia	0	1 (0.6)
Drug abuse	1 (1.5)	0
Suicide attempt	1 (1.5)	0
Renal failure acute	1 (1.5)	0
Dyspnea	0	1 (0.6)
Respiratory failure	1 (1.5)	0

eTable 8. Serious Adverse Events, n (%)

Event	SOF+RBV for 12 Weeks in GT 2/3 Treatment-Naïve Patients (N=68)	SOF+RBV for 24 Weeks in GT 1 Treatment-naïve and GT 2/3 Treatment-Experienced Patients (N=155)
Anemia	0	1 (0.6)
Leukocytosis	0	1 (0.6)
Atrial Fibrillation	0	1 (0.6)
Atrial Flutter	0	1 (0.6)
Acute Myocardial Infarction	1 (1.5)	0
Abdominal Pain	0	1 (0.6)
Colitis	0	1 (0.6)
Enteritis	0	1 (0.6)
Chest Pain	0	1 (0.6)
Cellulitis	0	2 (1.3)
Pneumonia	1 (1.5)	1 (0.6)
Gastroenteritis salmonella	0	1 (0.6)
Respiratory Tract Infection	0	1 (0.6)
Incision site infection	1 (1.5)	0
Septic shock	1 (1.5)	0
Staphylococcal bacteremia	1 (1.5)	0
Intentional Overdose	1 (1.5)	1 (0.6)
Fracture	1 (1.5)	0
Diabetic Ketoacidosis	0	1 (0.6)
Altered state of consciousness	0	1 (0.6)
Encephalopathy	1 (1.5)	0
Bipolar Disorder	0	1 (0.6)
Completed suicide	1 (1.5)	0
Drug abuse	1 (1.5)	0
Suicide attempt	1 (1.5)	0
Renal failure acute	1 (1.5)	2 (1.3)
COPD	0	1 (0.6)
Pulmonary embolism	1 (1.5)	0
Respiratory failure	1 (1.5)	0
Leukocytoclastic vasculitis	0	1 (0.6)

eTable 9. Total bilirubin values in patients who discontinued atazanavir due to hyperbilirubinemia

Patient	Week of ARV Change	Total Bilirubin (mg/dL)		
		Baseline	Maximum on Atazanavir	Maximum on Darunavir
8752	2	4.0	10.0	1.9
8885	2	4.0	13.7	2.8
8822	16	1.9	9.4	1.2
8843	2	0.2	3.4	1.0

eTable 10. CD4 T-cell counts and CD4 T-cell percent over time, median (IQR)

Timepoint	CD4 count (cells/mm^3)	CD4%
Baseline (N=223)	579 (442-753)	32.8 (27.3-39.3)
Week 1 (N=209)	618 (479-851)	32.5 (26.4-38.7)
Week 2 (N=215)	594 (473-837)	32.9 (27.5-39.2)
Week 4 (N=222)	560 (414-752)	33.8 (27.9-40.2)
Week 8 (N=215)	512 (376-682)	34.8 (28.2-40.1)
Week 12 (N=205)	475 (365-674)	34.8 (28.2-40.7)
Week 16 (N=144)	479 (358-645)	35.3 (29.5-39.8)
Week 20 (N=140)	510 (374-672)	35.7 (30.0-40.8)
Week 24 (N=134)	510 (368-711)	30.2 (30.2-41.4)
FU Week 4 (N=215)	530 (406-712)	34.0 (27.2-39.7)
FU Week 12 (N=183)	597 (460-778)	32.8 (27.0-39.3)

eTable 11. Change in HIV-1 RNA over time in patients not taking ART who had HIV RNA >50 copies/mL at baseline (n=6)

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Patient Characteristics						
HCV Genotype	2b	1a	3a	2b	2a	3a
Sex	M	M	M	M	F	M
Cirrhosis	No	No	No	No	No	No
IL28B genotype	CT	CT	CT	CC	CT	CC
HIV RNA by Visit, copies/mL						
Screening	2750	648	2780	8670	415	2340
Day 1	3250	901	13,000	6030	501	-
Week 1	15,800	1950	13,600	14,900	636	2780
Week 2	21,300	1590	12,300	13,600	816	5610
Week 4	21,200	728	3190	17,000	939	18500
Week 6	19,300	999	4220	8180	804	12,100
Week 8	10,300	1120	7780	18400	1180	9840
Week 10	5330	778	15,600	13200	1650	5270
Week 12	8250	1470	30,500	9140	2430	4120
Week 16	—	839	—	—	—	—
Week 20	—	229	—	—	—	—
Week 24	—	1050	—	—	—	—
Follow-up week 4	9020	867	8110	11000	2420	3080
Follow-up week 12	8080	903	12,400	—	813	6300

eTable 12. Reasons for screen failure

Of the 330 patients screened, 106 were screen failures. Some patients failed screening for more than one reason.

Screen failure patients who did not meet criteria	Inclusion criteria
29	HIV antiretroviral therapy (ARV) criteria of one of the following: a) ARV untreated, for ≥8 weeks preceding the Screening visit, with a CD4 T-cell count >500 cells/mm3 [up to 10% of study subjects may be ARV untreated], or b) On a stable, protocol-approved, ARV for >8 weeks prior to Screening with a CD4 T-cell count >200 cells/mm3 and a documented undetectable plasma HIV-1 RNA level for ≥ 8 weeks by local assay preceding the Screening visit. c) HIV antiretroviral medications allowed in this study include the following and should be administered per the prescribing information in the package insert: emtricitabine/tenofovir plus atazanavir/ritonavir (boosted); or darunavir/ritonavir (boosted); or efavirenz; or raltegravir; or rilpivirine. Alternative combinations of the above listed medications may be allowed on a case by case basis. ARV regimens not on the above list are excluded from this study.
29	Subjects must have the following laboratory parameters at screening: a) ALT ≤10 × the upper limit of normal (ULN) b) AST ≤10 × ULN c) Hemoglobin ≥12 g/dL for male, ≥11 g/dL for female subjects d) INR ≤1.5 × ULN unless subject has known hemophilia or is stable on an anticoagulant regimen affecting INR e) Albumin ≥3 g/dL f) Direct bilirubin ≤1.5 × ULN For subjects receiving an atazanavir/ritonavir (boosted) regimen, a direct bilirubin > 1.5 × ULN will be allowed if <25% of the total bilirubin. g) HbA1c ≤10% h) Creatinine clearance (CLcr) ≥60 mL/min, as calculated by the Cockcroft-Gault equation
9	Ability to determine the presence/absence of cirrhosis a) Cirrhosis is defined as any one of the following: • Liver biopsy within 2 years of screening showing cirrhosis • A FibroTest® score of >0.75 AND an AST:platelet ratio index (APRI) of >2 performed during screening b) Absence of cirrhosis is defined as any one of the following: • Liver biopsy within 2 years of Screening showing absence of cirrhosis • A FibroTest® score of ≤ 0.48 AND APRI of ≤ 1 performed during Screening In the absence of a definitive diagnosis of presence of cirrhosis by the above criteria, a liver biopsy is required. If both a biopsy and FibroTest® plus APRI results are obtained, the liver biopsy results will supersede for the determination of cirrhosis.
5	HCV RNA >1 × 10^4 IU/mL at Screening
3	Infection with HCV genotype 1, 2 or 3 as determined at Screening
2	Documented confirmation of chronic HCV infection
1	A female subject is eligible to enter the study if it is confirmed that she is: a. Not pregnant or nursing b. Of non-childbearing potential

	c. Of child-bearing potential using suitable methods of birth control
1	Liver imaging within 6 months of Baseline/Day 1 is required in cirrhotic patients only, to exclude hepatocellular carcinoma
1	Willing and able to provide written informed consent
1	The subject's medical records must be sufficient to be categorized on IFN eligibility or prior treatment with PEG/RBV
1	Subject must be able to comply with the dosing instructions for study drug administration and able to complete the study schedule of assessments
	Exclusion criteria
10	Clinically-relevant drug or alcohol abuse within 12 months of screening. A positive drug screen will exclude subjects unless it can be explained by a prescribed medication; the diagnosis and prescription must be approved by the investigator.
3	Non-genotype 1/2/3 or mixed genotype at Screening
3	History of significant pulmonary disease, significant cardiac disease or porphyria
2	Genotype 1 with prior treatment for HCV
2	Infection with hepatitis B virus
2	History of malignancy diagnosed or treated within 5 years (recent localized treatment of squamous or non-invasive basal cell skin cancers is permitted; cervical carcinoma in situ is allowed if appropriately treated prior to screen); subjects under evaluation for malignancy are not eligible.
1	Current or prior history of clinical hepatic decompensation (e.g., ascites, jaundice, encephalopathy or variceal hemorrhage)
1	History of a gastrointestinal disorder (or post operative condition) that could interfere with the absorption of the study drug
1	History of difficulty with blood collection and/or poor venous access for the purposes of phlebotomy
1	Use of any prohibited concomitant medications
Screen failure patients who did meet criteria	**Reason for non-enrollment**
3	Withdrew consent
2	Investigator's discretion
2	Lost to follow-up
1	Unable to genotype sample
1	Unwilling to undergo biopy
1	Outside visit window