Supplementary Appendix

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

Supplement to: Kowdley KV, Gordon SC, Reddy KR, et al. Ledipasvir and sofosbuvir for 8 or 12 weeks for chronic HCV without cirrhosis. N Engl J Med. DOI: 10.1056/NEJMoa1402355

Contents

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Calculation of Historical Control Rate and Non-inferiority Analysis

For the primary efficacy analysis, the SVR12 rate in each of the 3 treatment groups was compared to the adjusted historical SVR null rate of 60% for superiority using the 2-sided 1-sample binomial test. To ensure strong control of the family-wise type I error rate at the 0.05 level, the 3 primary hypotheses were tested following a sequential testing procedure. If the primary test for SVR12 rate in Group 1 (ledipasvir-sofosbuvir for 12 weeks) was statistically significant at the 0.05 significance level, the SVR12 rates in Group 2 (ledipasvir-sofosbuvir plus ribavirin for 8 weeks) and Group 3 (ledipasvir-sofosbuvir for 8 weeks)were compared to the null SVR rate, respectively, each at the 0.025 significance level.

The basis for this 60% SVR null rate was derived from the historical SVR rate calculated from the telaprevir (ADVANCE study) and boceprevir (SPRINT2 study) data after adjusting for a 5% trade-off in efficacy exchanged for an expected improved safety profile and shorter duration of treatment. The weighted average of the telaprevir and boceprevir data was estimated to be approximately 70% in noncirrhotic subjects. With an estimated minimum of 8% subjects being IFN ineligible (based on enrollment data from the GS-US-337-0102 study [ION-1]), and assuming a 5% response rate in these subjects, the adjusted rate was estimated to be approximately 65% (70%*0.92 + 5%*0.08 = 64.8%). As noted above, the 60% null SVR rate was obtained after allowing for a 5% trade-off in efficacy exchanged for an expected improved safety profile and shorter treatment duration.

If the primary assessment for SVR12 rate in Group 1 was statistically significant at the 0.05 significance level, the SVR12 rates in Group 2 and Group 3 were compared to the null SVR rate, respectively, each at the 0.025 significance level. If the assessment for SVR12 in Group 2 was statistically significant at the 0.025 significance level, the key secondary analysis of non-

inferiority test of Group 2 versus Group 1 was performed at the 0.025 significance level. Similarly, if the primary test for SVR12 in Group 3 was statistically significant at the 0.025 significance level, the key secondary analysis of non-inferiority in which Group 3 was compared to Group 1 was performed at the 0.025 significance level.

If both non-inferiority tests were statistically significant, the key secondary analysis of non-inferiority in which Group 3 was compared to Group 2 was performed at the 0.05 significance level.

Non-inferiority was assessed using the conventional confidence interval (CI) approach, and a non-inferiority margin of 12% was applied.

Table S1. Reasons for Screen Failure

Of the 831 patients screened, 184 were screen failures.

Screen failure patients who did not meet criteria	Inclusion criteria
51	Lab parameters at screening: ALT ≤10 × ULN, AST ≤10 × ULN, Hgb ≥12 g/dL (M) & 11 g/dL (F), Platelets ≥50,000/uL, INR ≤1.5, Albumin ≥3 g/dL, Direct bilirubin ≤1.5 × ULN, HbA1c ≤8.5%, Creatinine clearance ≥60 mL /min, INR ≤1.5 × ULN
34	Absence of cirrhosis
30	HCV RNA ≥10^4 IU/mL at Screening
12	HCV genotype 1a, 1b, or mixed 1a/1b at Screening as determined by the Central Laboratory.
4	Subject must be able to comply with the dosing instructions for study drug administration and able to complete the study schedule of assessments.
3	Willing and able to provide written informed consent
2	HCV treatment-naïve
2	Confirmation of chronic HCV infection
2	Not pregnant or nursing
1	Body mass index (BMI) ≥18 kg/m^2.
1	Screening ECG without clinically significant abnormalities
	Exclusion criteria
21	Presence of cirrhosis
20	Clinically relevant drug abuse within 12 months of screening.
8	History of clinically-significant illness or any other major medical disorder that may interfere with treatment, assessment, or compliance with the protocol
7	Alcohol misuse as defined by a Alcohol Use Disorders Identification Test (AUDIT) score ≥ 8
1	Pregnant or nursing female or male with pregnant female partner.
1	Chronic liver disease of a non-HCV etiology
1	Prohibited concomitant medication
Screen failure patients who did meet criteria	**Reason for non-enrollment**
7	Withdrew consent
2	Lost to follow-up
1	Other
1	Outside visit window
1	Study enrollment closed

Figure S1. Patient Disposition

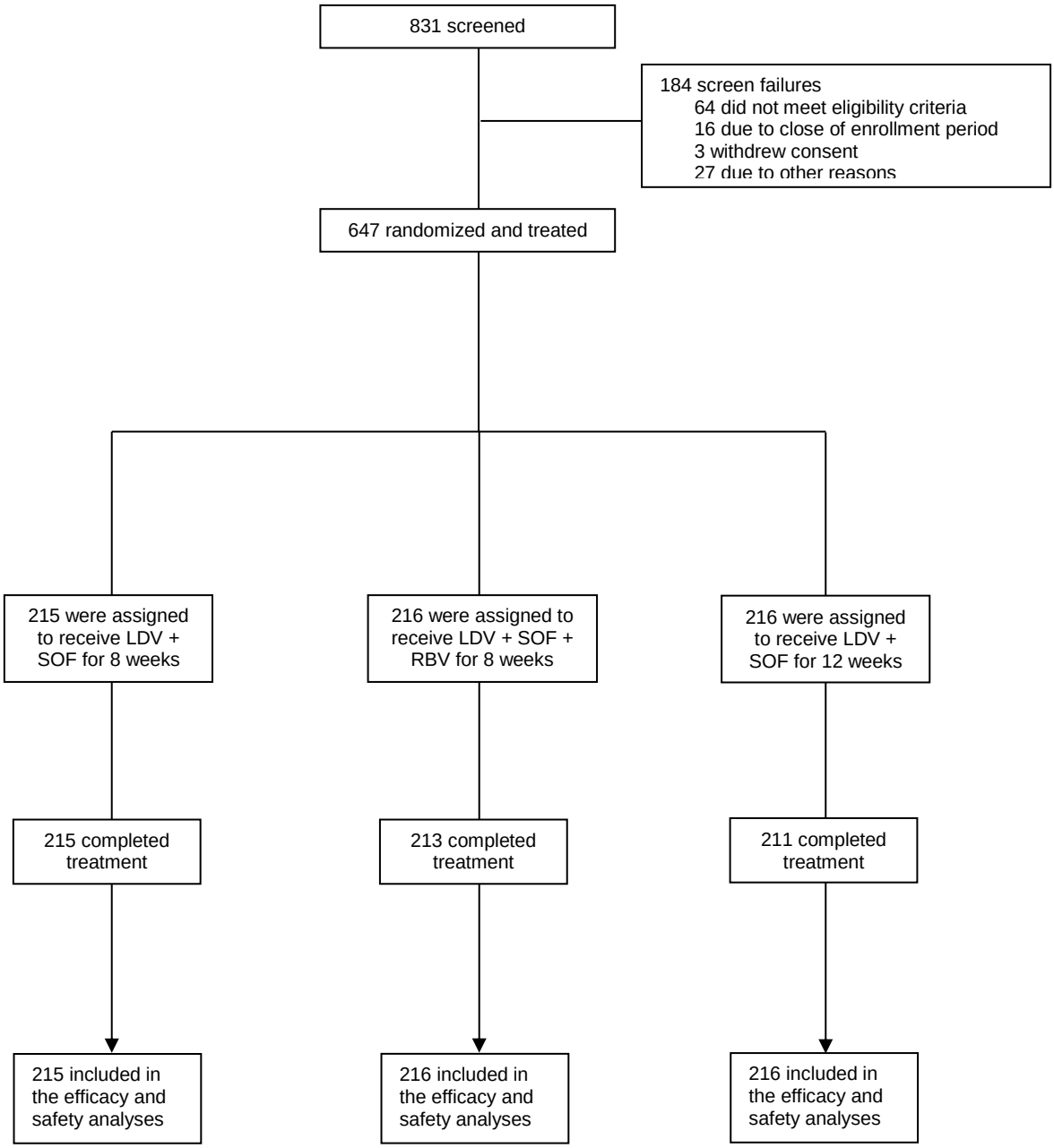

Table S2. Sustained Virologic Response by Subgroups

	SOF/LDV 8 Weeks (N=215)	SOF/LDV+RBV 8 Weeks (N=216)	SOF/LDV 12 Weeks (N=216)
Overall	202/215 (94.0%)	201/216 (93.1%)	206/216 (95.4%)
95% CI	89.9% to 96.7%	88.8% to 96.1%	91.7% to 97.8%
Age at Baseline (Years)			
< 65	185/196 (94.4%)	189/203 (93.1%)	189/199 (95.0%)
95% CI	90.2% to 97.2%	88.7% to 96.2%	91.0% to 97.6%
>= 65	17/19 (89.5%)	12/13 (92.3%)	17/17 (100.0%)
95% CI	66.9% to 98.7%	64.0% to 99.8%	80.5% to 100.0%
Sex at Birth			
Male	119/130 (91.5%)	106/117 (90.6%)	122/128 (95.3%)
95% CI	85.4% to 95.7%	83.8% to 95.2%	90.1% to 98.3%
Female	83/85 (97.6%)	95/99 (96.0%)	84/88 (95.5%)
95% CI	91.8% to 99.7%	90.0% to 98.9%	88.8% to 98.7%
Race			
Black	41/45 (91.1%)	32/36 (88.9%)	40/42 (95.2%)
95% CI	78.8% to 97.5%	73.9% to 96.9%	83.8% to 99.4%
Non-Black	161/170 (94.7%)	169/180 (93.9%)	165/173 (95.4%)
95% CI	90.2% to 97.6%	89.3% to 96.9%	91.1% to 98.0%
Ethnicity			
Hispanic or Latino	13/13 (100.0%)	12/12 (100.0%)	13/14 (92.9%)
95% CI	75.3% to 100.0%	73.5% to 100.0%	66.1% to 99.8%
Not Hispanic or Latino	187/200 (93.5%)	189/204 (92.6%)	193/202 (95.5%)
95% CI	89.1% to 96.5%	88.2% to 95.8%	91.7% to 97.9%
Interferon Eligibility Status			
Eligible	190/202 (94.1%)	188/203 (92.6%)	192/201 (95.5%)
95% CI	89.9% to 96.9%	88.1% to 95.8%	91.7% to 97.9%
Ineligible	12/13 (92.3%)	13/13 (100.0%)	14/15 (93.3%)
95% CI	64.0% to 99.8%	75.3% to 100.0%	68.1% to 99.8%
HCV Genotype			
1a	159/171 (93.0%)	159/172 (92.4%)	163/172 (94.8%)
95% CI	88.1% to 96.3%	87.4% to 95.9%	90.3% to 97.6%
1b	42/43 (97.7%)	42/44 (95.5%)	43/44 (97.7%)
95% CI	87.7% to 99.9%	84.5% to 99.4%	88.0% to 99.9%
1 (no confirmed subtype)	1/1 (100.0%)	0/0	0/0
95% CI	2.5% to 100.0%		

Table S2. Sustained Virologic Response by Subgroups (continued)

	SOF/LDV 8 Weeks (N=215)	SOF/LDV+RBV 8 Weeks (N=216)	SOF/LDV 12 Weeks (N=216)
Baseline HCV RNA (IU/mL)			
< 800,000	33/34 (97.1%)	43/45 (95.6%)	42/44 (95.5%)
95% CI	84.7% to 99.9%	84.9% to 99.5%	84.5% to 99.4%
>= 800,000	169/181 (93.4%)	158/171 (92.4%)	164/172 (95.3%)
95% CI	88.7% to 96.5%	87.4% to 95.9%	91.0% to 98.0%
Baseline BMI (kg/m2)			
< 30	141/151 (93.4%)	139/152 (91.4%)	151/159 (95.0%)
95% CI	88.2% to 96.8%	85.8% to 95.4%	90.3% to 97.8%
>= 30	61/64 (95.3%)	62/64 (96.9%)	55/57 (96.5%)
95% CI	86.9% to 99.0%	89.2% to 99.6%	87.9% to 99.6%
Baseline ALT			
<= 1.5 x ULN	120/128 (93.8%)	116/121 (95.9%)	112/117 (95.7%)
95% CI	88.1% to 97.3%	90.6% to 98.6%	90.3% to 98.6%
> 1.5 x ULN	82/87 (94.3%)	85/95 (89.5%)	94/99 (94.9%)
95% CI	87.1% to 98.1%	81.5% to 94.8%	88.6% to 98.3%
IL28B			
CC	54/56 (96.4%)	57/60 (95.0%)	54/56 (96.4%)
95% CI	87.7% to 99.6%	86.1% to 99.0%	87.7% to 99.6%
Non-CC	148/159 (93.1%)	144/156 (92.3%)	152/160 (95.0%)
95% CI	88.0% to 96.5%	86.9% to 96.0%	90.4% to 97.8%
CT	112/120 (93.3%)	120/128 (93.8%)	118/124 (95.2%)
95% CI	87.3% to 97.1%	88.1% to 97.3%	89.8% to 98.2%
TT	36/39 (92.3%)	24/28 (85.7%)	34/36 (94.4%)
95% CI	79.1% to 98.4%	67.3% to 96.0%	81.3% to 99.3%

Table S3. Proportion of Patients with SVR12 and Differences in Proportions between Treatment Groups and Associated CIs

	SOF/LDV 8 Weeks (N = 215)	SOF/LDV+RBV 8 Weeks (N = 216)	SOF/LDV 12 Weeks (N = 216)
SVR12	202/215 (94.0%)	201/216 (93.1%)	206/216 (95.4%)
95% CI	89.9% to 96.7%	88.8% to 96.1%	91.7% to 97.8%
p-value (Compared to 60%)	<0.001	<0.001	<0.001
SOF/LDV+RBV 8 Weeks vs. SOF/LDV 12 Weeks			
p-value		0.30	
Prop Diff (97.5% CI)		-2.3% (-7.5% to 2.9%)	
SOF/LDV 8 Weeks vs. SOF/LDV 12 Weeks			
p-value	0.52		
Prop Diff (97.5% CI)	-1.4% (-6.4% to 3.6%)		
SOF/LDV 8 Weeks vs. SOF/LDV+RBV 8 Weeks			
p-value	0.70		
Prop Diff (95% CI)	0.9% (-3.9% to 5.7%)		

Note: SVR12 is sustained virologic response (HCV RNA < LLOQ) 12 weeks after stopping study treatment.
Note: A missing SVR12 value was imputed as a success if it was bracketed by values that were termed successes (ie, '< LLOQ TND' or '< LLOQ detected'), otherwise, the missing SVR12 value was imputed as a failure. TND = target not detected.
Note: The exact 95% CI for the proportion within treatment group was based on the Clopper-Pearson method.
Note: Difference in proportions between treatment groups and associated CI were calculated based on stratum-adjusted Mantel-Haenszel proportions.
Note: p-values for the comparison over adjusted historical null rate were based on a 2-sided 1-sample binomial test.
Note: p-values for superiority of the between treatment group comparisons were based on a stratified Cochran-Mantel-Haenszel test.

Table S4. Baseline Characteristics of Patients with Virologic Relapse after Treatment

Subject ID	Treatment Group	Age (years)	Sex	Race	Ethnicity	Genotype	IL28B
0380-73408	SOF/LDV 8 Weeks	56	Male	White	Nonhispanic	1a	TT
0535-73514	SOF/LDV 8 Weeks	60	Male	White	Nonhispanic	1a	CT
2493-73033	SOF/LDV 8 Weeks	54	Male	White	Nonhispanic	1a	CT
2689-73313	SOF/LDV 8 Weeks	65	Male	Black	Nonhispanic	1a	CC
2689-73538	SOF/LDV 8 Weeks	53	Female	Black	Nonhispanic	1a	CT
2728-73453	SOF/LDV 8 Weeks	59	Male	White	Nonhispanic	1a	CC
2728-73490	SOF/LDV 8 Weeks	66	Male	White	Nonhispanic	1a	CT
3869-73227	SOF/LDV 8 Weeks	60	Male	White	Nonhispanic	1a	CT
4326-73274	SOF/LDV 8 Weeks	34	Male	White	Nonhispanic	1a	CT
5292-73114	SOF/LDV 8 Weeks	48	Male	White	Nonhispanic	1a	CT
7864-73300	SOF/LDV 8 Weeks	55	Male	Black	Nonhispanic	1b	TT
0334-73185	SOF/LDV+RBV 8 Weeks	51	Male	White	Nonhispanic	1a	TT
0380-73277	SOF/LDV+RBV 8 Weeks	52	Male	White	Nonhispanic	1a	CT
0380-73335	SOF/LDV+RBV 8 Weeks	71	Female	Black	Nonhispanic	1b	TT
0549-73445	SOF/LDV+RBV 8 Weeks	61	Male	Black	Nonhispanic	1a	CT
2130-73416	SOF/LDV+RBV 8 Weeks	56	Male	Black	Nonhispanic	1a	CT
2186-73564	SOF/LDV+RBV 8 Weeks	59	Male	Black	Nonhispanic	1a	TT
2689-73385	SOF/LDV+RBV 8 Weeks	64	Male	White	Nonhispanic	1a	CT
3995-73610	SOF/LDV+RBV 8 Weeks	52	Male	White	Nonhispanic	1a	CT
5505-73049	SOF/LDV+RBV 8 Weeks	60	Male	White	Nonhispanic	1b	TT
1086-73124	SOF/LDV 12 Weeks	56	Male	Black	Nonhispanic	1b	TT
2760-73078	SOF/LDV 12 Weeks	44	Male	Black	Nonhispanic	1a	CT
5760-73230	SOF/LDV 12 Weeks	51	Male	Other	Hispanic	1a	CT

Table S5. Serious Adverse Events

	SOF/LDV 8 Weeks (N=215)	SOF/LDV+RBV 8 Weeks (N=216)	SOF/LDV 12 Weeks (N=216)
Number (%) of Subjects Experiencing Any Treatment-Emergent Serious Adverse Event	4 (1.9%)	1 (0.5%)	5 (2.3%)
Number (%) of Subjects Experiencing Any Treatment-Emergent Serious Adverse Event by Preferred Term			
ABDOMINAL PAIN	0	0	1 (0.5%)
ANAPHYLACTIC REACTION	1 (0.5%)	0	0
BILE DUCT STONE	0	0	1 (0.5%)
COLITIS	1 (0.5%)	0	0
DIABETES MELLITUS INADEQUATE CONTROL	1 (0.5%)	0	0
HAEMOTHORAX	0	0	1 (0.5%)
HYPERTENSION	1 (0.5%)	0	0
HYPOGLYCAEMIA	0	0	1 (0.5%)
INTESTINAL PERFORATION	0	0	1 (0.5%)
JAUNDICE	0	0	1 (0.5%)
LOWER GASTROINTESTINAL HAEMORRHAGE	1 (0.5%)	0	0
MENTAL STATUS CHANGES	0	0	1 (0.5%)
PITUITARY TUMOUR	0	1 (0.5%)	0
RESPIRATORY FAILURE	0	0	1 (0.5%)
RHABDOMYOLYSIS	0	0	1 (0.5%)
ROAD TRAFFIC ACCIDENT	0	0	1 (0.5%)
SKELETAL INJURY	0	0	1 (0.5%)
SQUAMOUS CELL CARCINOMA OF LUNG	0	0	1 (0.5%)

Table S6. Phenotypic Analysis of NS5A and NS5B Isolates for Patients Who Relapsed

Subject	GT	Treatment	Relevant RAVs			
			NS5A		NS5B	
			BL	Post BL	BL	Post BL
0380-73408[a]	1a	SOF/LDV 8 Weeks	None	None	None	
0535-73514[a]	1a	SOF/LDV 8 Weeks	None	None	None	None
2493-73033[a]	1a	SOF/LDV 8 Weeks	L31M (19.25%)	Q30R (> 99%); L31M (> 99%)	None	None
2689-73313[b]	1a	SOF/LDV 8 Weeks	Q30Y (2.04%); Q30H (1.16%); Y93H (3.60%)	Q30Y (> 99%); Y93H (> 99%)	F415Y (95.43%)	F415Y (> 99%)
2689-73538[a]	1a	SOF/LDV 8 Weeks	None	Q30R (> 99%)	None	None
2728-73453[a]	1a	SOF/LDV 8 Weeks	None	Y93H (> 99%)	F415Y (84.99%)	F415Y (> 99%)
2728-73490[b]	1a	SOF/LDV 8 Weeks	None	Q30R (> 99%)	None	None
3869-73227[a]	1a	SOF/LDV 8 Weeks	Y93N (15.37%)	Y93N (> 99%)	None	None
4326-73274[a]	1a	SOF/LDV 8 Weeks	M28T (93.52%) M28A (6.09%)	M28T (> 99%)	None	None
5292-73114[b]	1a	SOF/LDV 8 Weeks	None	None	None	None
7864-73300[a]	1b	SOF/LDV 8 Weeks	None	Y93H (> 99%)	None	None
0334-73185[a]	1a	SOF/LDV+RBV 8 Weeks	Q30R (71.06%); Q30H (28.84%); Y93H (24.58%)	Q30R (> 99%); L31P (1.13%)	None	None
0380-73277[a]	1a	SOF/LDV+RBV 8 Weeks	L31M (1.12%)	L31M (> 99%)	None	None
0380-73335[b]	1b	SOF/LDV+RBV 8 Weeks	Y93H (63.83%)	Y93H (> 99%);	None	None
0549-73445[a]	1a	SOF/LDV+RBV 8 Weeks	None	None	None	None
2130-73416[b]	1a	SOF/LDV+RBV 8 Weeks	Y93C (8.65%)	None	None	None
2186-73564[a]	1a	SOF/LDV+RBV 8 Weeks	None	S38F (> 99%); Y93H (> 99%)	None	None
2689-73385[a]	1a	SOF/LDV+RBV 8 Weeks	Y93N (> 99%)	Y93N (> 99%)	None	None
3995-73610[a]	1a	SOF/LDV+RBV 8 Weeks	None	None	None	None
5505-73049[b]	1b	SOF/LDV+RBV 8 Weeks	None	None	None	None
1086-73124[a]	1b	SOF/LDV 12 Weeks	None	L31I (> 99%); Y93H (> 99%)	None	None
2760-73078[a]	1a	SOF/LDV 12 Weeks	Y93F (10.81%); Y93N (1.71%)	Y93N (> 99%)	None	L159F (2.45%)
5760-73230[a]	1a	SOF/LDV 12 Weeks	None	None	None	V321A (1.10%)

BL = baseline; GT = genotype
a Postbaseline timepoint is 4 weeks post treatment
b Postbaseline timepoint is 12 weeks post treatment

Table S7. SVR12 by Metavir Stage in Subjects Whose Fibrosis was Determined by Liver Biopsy

	ION-3		
	LDV/SOF 8 Weeks (N=215)	LDV/SOF+RBV 8 Weeks (N=216)	LDV/SOF 12 Weeks (N=216)
Metavir Score			
F0	20/22 (90.9%)	12/13 (92.3%)	16/16 (100.0%)
95% CI	70.8% to 98.9%	64.0% to 99.8%	79.4% to 100.0%
F1	60/62 (96.8%)	43/46 (93.5%)	55/59 (93.2%)
95% CI	88.8% to 99.6%	82.1% to 98.6%	83.5% to 98.1%
F2	40/43 (93.0%)	47/49 (95.9%)	51/52 (98.1%)
95% CI	80.9% to 98.5%	86.0% to 99.5%	89.7% to 100.0%
F3	28/29 (96.6%)	24/28 (85.7%)	28/29 (96.6%)
95% CI	82.2% to 99.9%	67.3% to 96.0%	82.2% to 99.9%
F4	0/0	0/0	0/0
95% CI			

Table S8. Graded Laboratory Abnormalities

	SOF/LDV 8 Weeks (N=215)	SOF/LDV+RBV 8 Weeks (N=216)	SOF/LDV 12 Weeks (N=216)
Maximum Postdose Toxicity Grade	215	214	216
Grade 1	83 (38.6%)	103 (48.1%)	94 (43.5%)
Grade 2	32 (14.9%)	60 (28.0%)	36 (16.7%)
Grade 3	5 (2.3%)	17 (7.9%)	15 (6.9%)
Grade 4	2 (0.9%)	1 (0.5%)	1 (0.5%)
Hematology			
Hemoglobin	215	214	216
Grade 1	3 (1.4%)	53 (24.8%)	6 (2.8%)
Grade 2	0	30 (14.0%)	2 (0.9%)
Grade 3	0	14 (6.5%)	2 (0.9%)
Grade 4	0	0	0
Lymphocytes	215	214	216
Grade 1	0	3 (1.4%)	2 (0.9%)
Grade 2	0	1 (0.5%)	0
Grade 3	0	1 (0.5%)	0
Grade 4	0	0	0
Neutrophils	215	214	216
Grade 1	3 (1.4%)	3 (1.4%)	3 (1.4%)
Grade 2	1 (0.5%)	3 (1.4%)	3 (1.4%)
Grade 3	0	1 (0.5%)	1 (0.5%)
Grade 4	0	0	0
Platelets	215	214	216
Grade 1	2 (0.9%)	2 (0.9%)	6 (2.8%)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
WBC	215	214	216
Grade 1	1 (0.5%)	4 (1.9%)	2 (0.9%)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Coagulation			
APTT	210	211	209
Grade 1	2 (1.0%)	1 (0.5%)	4 (1.9%)
Grade 2	0	0	0
Grade 3	0	0	1 (0.5%)
Grade 4	0	0	0

Table S8. Graded Laboratory Abnormalities (continued)

	SOF/LDV 8 Weeks (N=215)	SOF/LDV+RBV 8 Weeks (N=216)	SOF/LDV 12 Weeks (N=216)
Coagulation (cont)			
INR	210	211	209
Grade 1	1 (0.5%)	1 (0.5%)	2 (1.0%)
Grade 2	1 (0.5%)	0	0
Grade 3	0	0	1 (0.5%)
Grade 4	1 (0.5%)	0	0
Chemistry			
ALT	215	214	216
Grade 1	1 (0.5%)	2 (0.9%)	0
Grade 2	1 (0.5%)	0	0
Grade 3	0	0	0
Grade 4	0	1 (0.5%)	0
AST	215	214	216
Grade 1	5 (2.3%)	4 (1.9%)	4 (1.9%)
Grade 2	2 (0.9%)	1 (0.5%)	1 (0.5%)
Grade 3	0	0	0
Grade 4	0	1 (0.5%)	0
Albumin	215	214	216
Grade 1	1 (0.5%)	5 (2.3%)	5 (2.3%)
Grade 2	0	1 (0.5%)	0
Grade 3	0	0	0
Grade 4	0	0	0
Alkaline Phosphatase	215	214	216
Grade 1	0	0	2 (0.9%)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Creatinine	215	214	216
Grade 1	3 (1.4%)	0	2 (0.9%)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Lipase	215	214	216
Grade 1	12 (5.6%)	10 (4.7%)	10 (4.6%)
Grade 2	6 (2.8%)	5 (2.3%)	9 (4.2%)
Grade 3	2 (0.9%)	1 (0.5%)	5 (2.3%)
Grade 4	0	0	1 (0.5%)

Table S8. Graded Laboratory Abnormalities (continued)

	SOF/LDV 8 Weeks (N=215)	SOF/LDV+RBV 8 Weeks (N=216)	SOF/LDV 12 Weeks (N=216)
Chemistry (cont)			
Serum Glucose (Hyperglycemia)	215	214	216
Grade 1	46 (21.4%)	62 (29.0%)	72 (33.3%)
Grade 2	17 (7.9%)	20 (9.3%)	25 (11.6%)
Grade 3	3 (1.4%)	1 (0.5%)	5 (2.3%)
Grade 4	0	0	0
Serum Glucose (Hypoglycemia)	215	214	216
Grade 1	12 (5.6%)	14 (6.5%)	14 (6.5%)
Grade 2	1 (0.5%)	3 (1.4%)	4 (1.9%)
Grade 3	0	0	1 (0.5%)
Grade 4	1 (0.5%)	0	0
Serum Potassium (Hyperkalemia)	215	214	216
Grade 1	0	1 (0.5%)	2 (0.9%)
Grade 2	1 (0.5%)	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Serum Potassium (Hypokalemia)	215	214	216
Grade 1	11 (5.1%)	20 (9.3%)	18 (8.3%)
Grade 2	0	2 (0.9%)	0
Grade 3	0	0	0
Grade 4	0	0	0
Serum Sodium (Hypernatremia)	215	214	216
Grade 1	5 (2.3%)	1 (0.5%)	3 (1.4%)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Serum Sodium (Hyponatremia)	215	214	216
Grade 1	8 (3.7%)	5 (2.3%)	6 (2.8%)
Grade 2	0	0	0
Grade 3	0	0	1 (0.5%)
Grade 4	0	0	0
Total Bilirubin (Hyperbilirubinemia)	215	214	216
Grade 1	8 (3.7%)	43 (20.1%)	9 (4.2%)
Grade 2	6 (2.8%)	13 (6.1%)	0
Grade 3	0	3 (1.4%)	0
Grade 4	0	0	0