

PEER-REVIEW REPORT

Name of journal: World Journal of Gastroenterology

Manuscript NO: 32607

Title: 8-week Ledipasvir/Sofosbuvir Therapy in Non-Cirrhotic, Treatment-naïve Hepatitis C Genotype-1 Patients with HCV-RNA < 6 million IU/mL: Real World Effectiveness and Safety

Reviewer's code: 02861175

Reviewer's country: Indonesia

Science editor: Ze-Mao Gong

Date sent for review: 2017-01-18

Date reviewed: 2017-01-22

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input checked="" type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input checked="" type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
<input checked="" type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	<input checked="" type="checkbox"/> Plagiarism	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		<input checked="" type="checkbox"/> No	<input type="checkbox"/> Major revision
		BPG Search:	
		<input type="checkbox"/> The same title	
		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		<input checked="" type="checkbox"/> No	

COMMENTS TO AUTHORS

over all this study is good, it's important knowledge for clinicians before treating HVC patients. There are some comments: 1. What is the clinical reason of using 8 week DAAs tx? please explain in the introduction 2.why you choose HCV RNA 8.000.000 as cut off in bi-variate and uni-variate analyses? please explain it? if you want to determine the cut of point, AUROC analyses is the available cut off. 3. Explanation of figure 1 as the subject selection must be placed in study population.

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Reviewer's code: 02860814

Reviewer's country: Greece

Science editor: Ze-Mao Gong

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CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input checked="" type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
<input checked="" type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	<input checked="" type="checkbox"/> Plagiarism	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		[Y] No	<input checked="" type="checkbox"/> Major revision
		BPG Search:	
		<input type="checkbox"/> The same title	
		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		[Y] No	

COMMENTS TO AUTHORS

(1) The overall structure of the manuscript needs to be completed (abstract, keywords). (2) The authors (in the "Study population" section) refer that according to the protocol constructed, the close monitoring of patients during treatment was documented by laboratory testing every 2 weeks. It is strange to me and I need a comment on this, taking account that this is a real life study and in every day clinical practice lab tests are suggested to be performed on wk2, wk4, eot and svr12. (3) Patients who missed doses were excluded. Which was the criterion exactly for this (how many doses?). (4) Which was the method for HCV RNA test and what was the cut-offs? (5) Which were the criteria for the clinical judgment of the presence/absence of cirrhosis. (6) Page 8, 1st sentence "value of HCV-RNA level for SVR is currently available data": It is not comprehensible, need to be reconstructed. (7) The authors should discuss and provide their explanations for the differences of their results with other studies. (8) According to



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which classification the fibrosis score was classified to stage "0", "1", "3", "3-4", "4". (9) Tables should be reconstructed according to journal guidelines (i.e. row 4 in Table 2). (10) P-values for non-significant differences should be added in Table 2. (11) Figure 2: There is a discordance with factors and number of bars. (12) Kowdley et al recently published in Hepatology 2016 data indicating the effectiveness of an 8-week duration of treatment with LDV/SOF. (13) Similarly, Lai et al published their results in Drugs 2017, showing that 8-weeks courses of LDV/SOF are comparable to 12-week courses in real world use among selected patients supported by a multidisciplinary team.

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Science editor: Ze-Mao Gong

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CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input checked="" type="checkbox"/> Grade A: Priority publishing	Google Search:	<input checked="" type="checkbox"/> Accept
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<input type="checkbox"/> Grade E: Poor		BPG Search:	<input type="checkbox"/> Major revision
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		<input type="checkbox"/> Duplicate publication	
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		<input checked="" type="checkbox"/> No	

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Good work... Study Highlights ? Validation of clinical outcome with high overall SVR24 96% in selected subset of patients with HCV infection and good safety profile in a large real-world cohort NOT SVR 24SVR 12 must be... in table ≥ 800.000 and ≤ 800.000 ???..800.000< and ≥ 800.000 Figure 2 so complicated??