Author's response to reviews

Title: Self-Reported quality of life in adults with attention-deficit/hyperactivity disorder and executive function impairment treated with lisdexamfetamine dimesylate: a randomized, double-blind, multicenter, placebo-controlled, parallel group study

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Author's response to reviews:

Dear Ms. Deesha Majithia:

We thank you and the peer reviewers for the thoughtful comments on our manuscript. We hope that you will find the revised manuscript suitable for journal publication. Please see changes/revisions we incorporated into the manuscript below per reviewers’ comments and suggestions. Thank you for your time and consideration.

Sincerely,

Lenard A. Adler, MD

Reviewer's report
Reviewer: Ronna Fried
Reviewer's report:
The question of quality of life improvement for adults with ADHD and executive functioning deficits (EFDs) is an important clinical and public health issue and
thus treatment studies for it amelioration are very important. The numbers in the study and the methods are well described.

Discretionary Revision: The Background of the abstract states that the study examined the effects of LDX on QOL in adults with ADHD and EFDS, however the primary efficacy measure is described as being the BRIEF-A and thus it is a bit confusing. Perhaps the QOL should be in the first sentence of the Methods

Response:
The abstract methods section has been revised to clarify that this report focuses on the QOL measures/endpoints, which were secondary, and post hoc analyses of the data from this study.

Reviewer's report
Reviewer: Wolfgang Retz

Reviewer's report:
An interesting study regarding the effects of stimulant treatment on several QoL dimensions in a subpopulation of adult ADHD patients. I have no major concerns but I recommend some minor essential revisions.

1. Here the authors report results regarding secondary efficacy parameters from a RCT. However, this does not become clear throughout the manuscript and should be already stated in the abstract. In the methods section the authors notice “Herein, we report on QOL measures”, but they also describe the instruments used as primary outcome measures (which have been already addressed in the introduction) and also the results of the study regarding these measures. On the other hand they refer to a prior publication of the primary results (reference [32]).

Therefore I recommend abolishing the description of the primary measures from the method section and also to remove the results which have been already published elsewhere from the results section, but to keep them in, or remove them into the introduction and the discussion as additional information.

Alternatively, the manuscript has to be upgraded to a full study report with a comprehensive presentation and discussion also of the primary outcome measures and safety issues.

Response: Per the reviewer’s suggestions, the text presenting BRIEF-A results has been deleted from the results section. In the introduction, the description of the primary study results has been expanded to include some detail. Since we believe that it is important to provide context regarding the baseline characteristics of the study population relative to EFD, the description of the
BRIEF-A in the methods section has not been deleted. However, the sentence identifying the BRIEF-A as the primary efficacy endpoint has been deleted.

2. The authors have provided further information about the study on the CONSORT checklist. Unfortunately, some important information regarding methodological issues are still missing, such as the method of randomization, which was signed as NA. Another problem is the fact that the authors refer to an earlier publication (ref. [32]), which was a poster presentation and publication that cannot be inspected by the reader of this paper. Therefore, the information regarding the study population, inclusion/exclusion criteria, baseline measures and so on should be implemented in the manuscript to make them available to the reader.

Response: Additional information on the method of randomization has been added to the Methods section of the draft. Information on study population, inclusion and exclusion criteria are also already present in the Methods section. The citation (ref [32]) has been updated to the primary MS that is currently “In Press” in the Journal of Clinical Psychiatry, is scheduled for publication in July 2013, and will be available for readers to reference for additional basic information and details of the study and population. This final submitted manuscript draft of the primary data is included along with the revision to the current manuscript and the revised CONSORT checklist for the peer reviewer to review.