Reviewer’s report

Title: Efficacy and safety of weekly nab-paclitaxel plus gemcitabine in Chinese patients with metastatic adenocarcinoma of the pancreas: a phase II study

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Reviewer: Linara Gabitova

Reviewer's report:

In this phase II bridging study Shen et al. evaluate the safety and efficacy of nab-paclitaxel/gemcitabine (Metastatic Pancreatic Adenocarcinoma Clinical Trial [MPACT] regimen) in Chinese patients with metastatic pancreatic cancer (MPC). Given known differences in cancer drug tolerability between Asian and European populations, this study has a high significance.

In general the manuscript is well written, provides all details of the study's design and obtained results. However, the authors should consider some comments and questions in order to improve the quality of publication.

1. There is inconsistency through the whole manuscript in the total number of patients involved in Part 1 and Part 2 of the study. In some cases the manuscript says it is 82 and in other cases 83 patients. The authors should correct this discrepancy.

2. As a result of the study Shen et al. determine that the median duration of response (DOR) for Chinese patients with MPC is 8.9 months and progression-free survival (PFS) is 5.5 months. The authors should explain why the PFS is shorter that DOR.

3. In the Introduction section the authors refer to recent phase I/II study of nab-paclitaxel/gemcitabine treatment in Chinese patients. It is important to explain why this other study used a dose and schedule of treatment different from the MPACT study and what was the difference. And since that phase I/II study already came up with the regimen of treatment, comparable by intensity and safety with MPACT regimen, it should be more carefully explained what is the principal relevance of the current analysis.

4. The study assessment section could benefit from a more detailed explanation of how often the other metrics than computed tomography scan or magnetic resonance imaging were evaluated.

5. The sample size and statistical analysis section is only described for Part 2. How was Part 1 analyzed?
6. Table 1 of the manuscript describes baseline characteristics of all patients enrolled in Part 2. What are the distribution and characteristics for patients enrolled in Part 1 of the study?

7. The study design section explains that the number of patients needed for the Part 1 study is 10. However, the efficacy results section mentions that 15 patients were evaluated in Part 1 study. The authors should consider clarifying this discrepancy.

8. The treatment exposure section describes changes (dose reductions and delays) of treatment for some patients which occurred during the study. It would be important to discuss what the reasons of changing the regimen of treatment were and how these changes correlated with outcome results (including DOR, PFS, overall survival etc.)

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
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