Reviewer's report

Title: A randomized, phase 2 study comparing pemetrexed plus best supportive care versus best supportive care as maintenance therapy after first-line treatment with pemetrexed and cisplatin for advanced, non-squamous, non-small cell lung cancer

Version: 1 Date: 23 May 2012

Reviewer: Buelent Polat

Reviewer's report:

Major Compulsory Revisions:
1. Initially n=106 patients were included into this study. Of this 76 patients had no progression after 4 cycles of cisplatin/pemetrexed induction chemotherapy. But only 55 patients were randomized. What happened with the remaining 21 patients who also were eligible for inclusion into the study?

Minor Essential Revisions:
1. For clarification please consider to give the PFS duration of the both groups in months in the abstract and the main text and not only in table 2.
2. Please cite the recently published full paper of the PARAMOUNT Study: Lancet Oncology 2012 Mar;13(3)
3. Please consider citing also the article on the according quality of life data of the above mentioned study?
4. A further study was recently published by Zhang et al. in a similar setting on maintenance therapy with Gefitinib in Lancet Oncology May 13(5)
5. There is a comparable rate of grade 3/4 toxicities in both arms of about 18%. Can you explain why the patients in the BSC arm experienced these?
6. On page 17 you state that maybe the patient cohort in your study did not have sufficient access to supportive care. But since your investigational question was comparison of best supportive care against BSC plus pemetrexed you have to assure that the patients have access to supportive treatments.
7. On page 12, what is meant by inadequate response? Did 64% of patients have disease progression?

Discretionary Revisions
1. page 12 line 7: please write randomized instead of “randomization”
2. page 18 and 19: missing brackets when citing ref. 10 and 11.
3. page 15 line 6: please consider not to combine “best response” and “progressive disease” in one sentence since could be confusing.
4. Please give the p-values or HR in the figure legends.
Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:
I declare that I have no competing interests