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

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Reviewer: YoungHak Hak Kim

Reviewer's report:

This is a paper on maintenance chemotherapy with pemetrexed after pemetrexed/carboplatin treatment in patients with advanced, non-squamous NSCLC. The study population is Middle Eastern.

The authors concluded that continuation pemetrexed maintenance therapy showed promising PFS with low toxicity in this randomized phase II study.

However, I wonder whether the authors' statistical assumption using a one-sided alpha of 0.2 is appropriate. Is it too lax to appeal the need for further clinical trials? In fact, the results of both PFS and OS were almost identical between the two arms.

Moreover, there's no new information including toxicity after the publication of PARAMOUNT study.

Major Compulsory Revisions

RESULTS

Patient Disposition

# Five (17.9%) patients in the pemetrexed/BSC arm and 10 (37.0%) patients in the BSC arm fully completed the study.

What means fully completed?

# The most common reason for premature study discontinuation in both arms was death (pemetrexed/BSC, 60.7%; BSC, 55.6%), which was predominantly due to the study disease.

Is that mean treatment-related death, or else what does that mean?

Tumor Response

# Therefore, the disease control rate for the induction phase was 7.7% (76/106). Of the 55 patients randomized to the maintenance phase, 7 (25.0%) patients in the pemetrexed/BSC arm and 11 (40.7%) patients in the BSC arm responded to
the induction therapy.

There are 21 patients who achieved disease control and did not randomized to the maintenance phase. The reason should be disclosed.

**Level of interest:** An article of limited interest

**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.