Reviewer’s report

Title: Randomized phase II trial of toremifene 120 mg compared with exemestane 25 mg after prior treatment with a non-steroidal aromatase inhibitor in postmenopausal women with hormone receptor-positive metastatic breast cancer

Version: 1 Date: 5 March 2013

Reviewer: Anthony Fyles

Reviewer’s report:

General Comments
This is an interesting although small trial suggesting response of high-dose toremifene (T) at least similar to the standard of exemestane following progression on AIs.

However there appears to be greater toxicity from toremifene (predominantly nausea), to the extent that 3 of 46 women stopped the drug. Although analysis was performed with and without these 3 women, a further 3 were excluded from the T arm due to non-compliance (one wonders if toxicity was also an issue) and never included in the analysis. Given the marginal benefits seen with T, I would suggest that all 6 patients be included in the primary analysis as “intention-to-treat”.

Specific Comments
Abstract
The phrase “tended to be superior” sounds optimistic, as the evidence does not support a significant difference
Please add the OS data to the p value
Results
The OS data are incorrect, should be 32.3 and 21.9 months as per Fig 1b. I would not call a HR with CI of 0.24-1.34 and p of 0.19 as showing a marginal difference.
Some discussion of the difference in grade ½ toxicity between the two arms needs to be added. From table 3 it appears that there were 18/43 women with toxicities in the T arm vs only 6/45 in the Exe arm (?p value)
Discussion
A brief review of the results in the first paragraph would help the reader

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable
**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

None