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: 28 February 2013

Reviewer: Kathleen Pritchard

Reviewer's report:

This is an interesting little paper, but somewhere along the way we lose first 3, and then 3 more of the 46 patients in the toremifene high-dose arm. We need them.

This study should be analyzed by intention to treat, and interestingly 3 patients have been dropped out because of inadequate data or choosing to take another treatment, all in the high-dose toremifene arm. Then 3 more stopped toremifene early because of adverse effects. A consort diagram that would show where these patients went and what for would be very helpful. That does not seem to be included.

I see from Table 2 that the intention to treat analysis is done, but still only with the 43 patients, not all 46. I think the total intention to treat analysis should still be done and some comments made whether it looks different or the same. Because this is a very interesting result, I think it is important that this be done to see if it makes any difference.

In addition, I would suggest that this was not actually a Phase II trial, but a rather small Phase III trial designed to show a big difference which it did not quite show. I think that should be more clearly stated. The statistical section certainly suggests this.

These are my only major comments on revising this manuscript.

Level of interest: An article of importance in its field

Quality of written English: Not suitable for publication unless extensively edited

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests: No conflict