Reviewer’s report

**Title:** Everolimus in hormone receptor-positive metastatic breast cancer: PIK3CA mutation H1047R was a potential efficacy biomarker in a retrospective study

**Version:** 1  **Date:** 13 Sep 2018

**Reviewer:** Anthony D. Elias

**Reviewer's report:**

1. The title is misleading -- the paper appears to represent the institutional experience with endocrine therapy plus everolimus with a small number having analysis of ctDNA. Please retitle the paper.

2. Please describe the clinical "trials" more thoroughly. The 120 patients appear to represent a retrospective chart review of institutional experience. Was this chart review IRB approved? Was consent waived? or was this prospective accrual with consent to collect data? The 16 who had ctDNA -- was this a separate trial and the 16 represent a subset of patients consenting to this collection? Parents typically do not provide consent for adult subjects.

3. p4 line 42 -- please provide reference for the methods "as previously described".

4. p5 line 23 -- please provide time frame over which these patients were accrued.

5. months and p values should not carry more than two significant digits -- the trial is too small to have statistical power for non-rounded numbers.

6. Table 2 appears to show very little toxicity -- for example zero fatigue, 2/120 with high glucose, etc. Please describe monitoring and data capture methods if prospective. If retrospective, then would only report G3 and G4 toxicity and state that more minor toxicities were not captured.

7. p8, line 9 -- please provide reference for the kangfuxinye experience, as well as the experience with American cockroach.

8. p8, line 35 -- if this is multivariate analysis after accounting for many other factors including prior treatment and ESR1 mutations, then state, otherwise too few patients to state state statistical significance if using univariate analysis.

9. p8 line 44: change "certified" to "confirmed".
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

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 recommend additional statistical review

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Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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