Reviewer's report

Title: Final results of a phase I/II pilot study of capecitabine with or without vinorelbine after sequential dose-dense epirubicin and paclitaxel in high-risk early breast cancer

Version: 1 Date: 31 March 2010

Reviewer: Simon Van Belle

Reviewer's report:

Major compulsory revisions:
- in the section Study treatment (p6) the authors describe the use of darbepoetin: "All patients received darbepoetin alfa from day 1 of chemotherapy until the end of radiotherapy". In the paper itself it is not described when or how radiotherapy is included in the total protocol. This should be added to this section.

- it is advisable to include a figure outlining the different parts of the treatment in view of time (otherwise the readers have to compose the therapy puzzle themselves)

- in the Discussion there is only a minimalistic discussion about the use of Erythropoetin Stimulating Agents (ESA's) (Darbepoetin in this case) in the setting of adjuvant therapy, with reference to the Sankt Gallen conference. Meanwhile there have been several adaptations of the guidelines (EORTC, ASCO ...) and warnings about the use of ESA's. This discussion should be expanded including reference to these warnings.

Minor essential revisions:
- p3§2: ref. 3 is followed by the sentence "and accepted for publication in JCO: must be included as a normal reference (= ref 4).

- p7§1: "The planned dose of epirubicin or paclitaxel was reduced in 43 of 300 cycles": add percentage (14.33 %) as was done in the next sentence.

- p7§2: describes the dose of darbepoetin: does this mean that all patients received a 100 % in the epirubicin-paclitaxel part of the therapy? This is not clear.

- p8§2: it is stated that the median Hb level was 13.5 g/dL at the last cycle. Which last cycle? The last of epirubicin-paclitaxel or the real final one?

- p9: Discussion: §2 and 3 discusses the possible value of adding capecitabine to a certain "basic" treatment referring to several published studies, but there is no conclusion about this. We propose to add a tentative conclusion or at least a statement that this is still unclear.

- p11§1: the statement "The efficacy data from the present study after 35.2
months’ median follow-up are very promising" cannot be made in the setting of a phase I/II study only that is in the expected range.

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

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests.