Reviewer's report

Title: Phase I study of OM-174, a lipid A analogue, with assessment of immunological response, in patients with refractory solid tumors.

Version: 2 Date: 21 December 2012

Reviewer: Dario Sangiolo

Reviewer's report:

In this work Dr. Isambert et al report results from a phase I clinical trial with OM-174, analogue of lipid A, on 17 patients with various type of solid tumors. They reported the safety and pharmacokinetic profile of the drug; MTD and recommended dose was however not established as no limiting toxicity was observed. Preliminary information on the activity is suggested by temporary disease stabilization in 3 patients. Overall the study is interesting and well designed. The hypothesis of synergism with chemotherapy is interesting and needs to be supported by published preclinical data to support new clinical studies.

Minor comments and suggestions:

Page 8. It would be helpful for the reader to reduce the length of the first sentence, and provide a bit more background information about the referenced phase I trials.

Methods:

- Were enrolled patient required to have measurable disease at study entry? This information should be added in the methods or in the table of patients’ characteristics. Similarly it could be informative to add information, either in the text or table, regarding the disease status at study entry (i.e. metastatic sites, minimal disease vs bulky etc.). It would also be interesting to mention the distance by last chemotherapy treatment for each patient.

- Among the evaluated cytokines reported in the methods, IL10 is not included while it is afterwards reported in the results.

Discussion:

- Last sentence of discussion appears too long. It would be useful to reference the preliminary data, even if published just in abstract form, or at least add more details about the mentioned preclinical experiments. Knowledge or publication of such preclinical data would be recommended before a new trial.
Level of interest: An article of importance in its field

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