Reviewer's report

Title: A phase II open label trial evaluating safety and efficacy of a telomerase peptide vaccination in patients with advanced hepatocellular carcinoma

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Reviewer: paal fr brunsvig

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The study describes an open label phase II trial evaluating the safety and efficacy of GV 1001 in patients with advanced hepatocellular carcinoma. As could be expected, the safety was acceptable and the response to the given treatment was PD (20 pts) and SD (17 patients).

The primary end-points were tumour response, secondary end points were TTP, TTSP (which I am not familiar with but seems to be useful in HCC studies) PFS, OS, and immune responses. T-cell responses were only done at one centre and were reported for 11 of 12 patients, (11/40 patients 27%) Usually immune responses are seen in 50-90% of patients in other studies.

Major Compulsory revisions: At what time points were T-cell responses performed?

The conclusion that lack of tumor response may be due to the fact that no clear immune responses were observed needs to be clarified. If I understand the time points correctly, T-cell responses were performed shortly after cyclophosphamide infusion, or were they taken at regular intervals after? In our experience, T-cell responses are to be expected from 6 weeks or later, which means that timing is essential.

Regarding the lack of T-cell responses, less than a third of the patients (11/40) patients have been included in this important part of the study.

Minor. Tumor response was the primary end-point at 6 months. Median TTP was 57 days and PFS also 57 days, the time-points of planned CT scans in the study would be interesting.

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

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:
I declare that I have no competing interest