Reviewer's report

Title: Randomised Phase I/II trial assessing the safety and efficacy of radiolabelled anti-carcinoembryonic antigen I131 KAb201 antibodies given intra-arterially or intravenously in patients with unresectable pancreatic adenocarcinoma

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Reviewer: Stefan Boeck

Reviewer's report:

1. General:
This well written paper reports the results of a rather small single-center phase I/II trial with 19 pancreatic cancer patients receiving a radiolabelled anti-carcinoembryonic antigen I131 KAb201 antibody. Patients were randomised between an intra-venous and an intra-arterial route of drug delivery, the primary endpoint was toxicity (DLT). The trial design can be regarded as an interesting and innovative approach for a new treatment in advanced pancreatic cancer.

2. Major:
In my opinion, the manuscript is too long for an original research paper: the word count is > 4500 words, and the manuscript contains 10 figures and 5 tables. Furthermore, the reference list with 53 citations is also extensive. The authors should try to shorten the paper - as far as possible - in all sections.

3. Minor:
- Abstract: The "Methods" section should contain a clear definition of the primary study endpoint.
- The authors conducted a phase I trial in treatment-naïve patients with an experimental treatment approach. Since 1997, single-agent gemcitabine is regarded as an international standard of care for this patient population. However, only 4 patients in that study received previous gemcitabine treatment, the remaining 15 patients did not receive the standard of care as first-line treatment. From an ethical point of view, the "ethical correctness" of such an approach may be discussed.
Previous phase III trials using gemcitabine as a reference arm reported a (clinically relevant) disease control rate (DCR) of about 50% in patients with advanced pancreatic cancer. The DCR of 11% in the (small) study population of this trial in clearly inferior compared to these published data. Maybe, the authors wish to discuss these observations.

4. Discretionary:
None.
**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.