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: David V Gold

Reviewer's report:

This manuscript describes the use of an anti-CEA monoclonal antibody for a phase I/II trial of radioimmunotherapy for unresectable pancreatic adenocarcinoma. It is noted that the actual accrual of patients took place from 2003 until 2005 with 25 patients enrolled, and that this manuscript is being submitted a full 3 years after the fact. Unfortunately, the study makes use of reagents and technology that is outdated at this time. The investigators employ a chimeric sheep monoclonal antibody when the current activity in this field makes use of humanized MAbs. Further the investigation employed 131I-labeled antibody with acceptable product stated as ">60% labelling efficiency" - in other words as much as 40% free iodine whereas the current technology in this field employs, for the most part, chelated radiometals. Although this is a phase I study to examine safety, efficacy studies are essentially negative. The manuscript is far too large for negative results.

Level of interest: An article of insufficient interest to warrant publication in a scientific/medical journal

Quality of written English: Acceptable

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

Declaration of competing interests:

While I beleive I have given a fair assessment of the manuscript in comparison to the published literature in this field, I am stating for the record that I have published in this field employing a separate antibody for radioimmunotherapy of pancreatic adenocarcinoma and am involved in patent application relating to the field of radioimmunotherapy of pancreatic adenocarcinoma employing a separate antibody.