Reviewer's report

Title: Phase I Dose-Escalating Study of Docetaxel in Combination with 5-Day Continuous Infusion of 5-Fluorouracil in Patients with Advanced Gastric Cancer

Version: 1 Date: 11 May 2005

Reviewer: Li-Tzong Chen

Reviewer's report:

General
1. The authors did not clearly define MTD (maximum tolerated dose) through the manuscript.
   a. In the Section of Abstract (p3, lines 5-6), the maximum tolerated dose (MTD), the recommended dose for phase II studies.
   b. In the Section of Methods (p8, lines 14-16), If 2 or more DLTs occurred at a given dose level, the MTD would be considered to be reached and The dose just below would be considered to be the recommended dose for further evaluation in phase II trials.
   c. In the Section of Results (p11, lines 6-7), MTD was reached at dose level 3. Dose level 2 was therefore the recommended regimen with ..
   d. In the Section of Discussion (p12, line 2), This phase I trial determined the MTD of 5-FU to be 500 mg/m2/day (dose level 2).

Usually, MTD was defined as one dose level below that was associated with 2 or more DLTs. The recommended dose for phase II study can be either the MTD or one dose level below MTD. The authors should make it clear.

2. Data listed in Table 2 are confusion.
   a. Why there were 10 patients in level 2? Calculated from the text (Toxicity in Section of Results, p10, lines 12-14), only 6 patients were included in dose level 2.
   b. If the table content is right, among the 10 patients in dose level 2, NCI-CTC grade 3 or 4 neutropenia occurred in 4, stomatitis occurred in 6 and asthenia occurred in 4. How many of them occurred at first cycle of treatment?
   c. Three patients in dose level 3 received total 4 cycles of treatment. According to the text (p11, lines 2-5), DLTs occurred in 2 with stomatitis in 1 and neutropenia in 1. Why all 3 patients (all 4 cycles of therapy) had grade 3 or 4 stomatitis, and 2 of them (3 cycles of treatment) had grade 3 or 4 diarrhea.
   d. Other DLTs listed below the table are confusion, too. It is impossible to judge at which dose level did they occur.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
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Discretionary Revisions (which the author can choose to ignore)
What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

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

Quality of written English: Needs some language corrections before being published

Statistical review: Yes

Declaration of competing interests:

I declare that I have no competing interests.