Author's response to reviews

Title: Phase I dose-finding study of cabazitaxel administered weekly in patients with advanced solid tumours

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Author's response to reviews: see over
Dear Dr Chap,

Please find attached for your consideration for publication in *BMC Cancer* a manuscript entitled *Phase I dose-finding study of cabazitaxel administered weekly in patients with advanced solid tumours.*

Cabazitaxel is a novel taxane that has been approved at a dose of 25 mg/m$^2$ for the treatment of men with metastatic hormone-refractory prostate cancer (now known as metastatic castration-resistant prostate cancer) whose disease has progressed after receiving a docetaxel-containing regimen. Approval in this population was based on the results of the TROPIC Phase III study, published in October 2010 (de Bono JS, *et al.* *The Lancet*; **376**:1147–1154), in which treatment with cabazitaxel plus prednisone demonstrated a significant survival benefit compared with mitoxantrone plus prednisone (15.1 months vs 12.7 months; HR 0.70 95% CI 0.59–0.83; $P < 0.0001$) in patients with mCRPC. However, few data are currently published on the early phase clinical development of cabazitaxel.

The submitted manuscript describes results from a Phase I study that aimed to determine pharmacokinetics, safety and efficacy of cabazitaxel administered in a weekly dosing schedule to patients with a range of advanced solid tumours, including breast, ovary and stomach/small bowel. Publication of this study in the *British Journal of Cancer* would allow these important clinical data to reach a wide international multidisciplinary oncology audience. Furthermore, given that a manuscript by Dr Dieras *et al.* describing results of a Phase I study of cabazitaxel administered every three weeks to patients with advanced solid tumours has recently been published in the *European Journal of Cancer* (Dieras V, *et al.* *European Journal of Cancer* **2012; epub*), publication of the current manuscript at this time provides an opportunity to present concurrently the early clinical findings for cabazitaxel.
Please note, this study enrolled its first patient before the date when clinical trial registration became compulsory. However, in line with journal guidelines, we have retrospectively registered this trial with ClinicalTrials.gov. The registration number is listed both in the Abstract and the Methods section of the manuscript.

The authors wish to declare the following conflicts of interest. P. Fumoleau is IDMC Chairman for Johnson & Johnson and has acted as a consultant/advisory board member for Abbott, GlaxoSmithKline, Roche and Sanofi. D. Semiond and S. Gupta are employees of Sanofi and have stock ownership in Sanofi. M. Campone has received honoraria from Novartis and has a consultant relationship with Novartis and Servier. M. Campone has received research funding from Novartis and Cephalon.

Should you have any questions regarding the manuscript, please do not hesitate to contact me. I look forward to hearing from you soon.

Yours sincerely,

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