Author’s response to reviews

Title: Efficacy and safety of Vinflunine for advanced or metastatic urothelial carcinoma in routine practice based on the French multi-centre CURVE study

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UROLOGICAL ONCOLOGY
"Efficacy and safety of Vinflunine for advanced or metastatic urothelial carcinoma in routine practice based on the French multi-centre CURVE\textsuperscript{1} study

Dear Professor Solera,

Please find attached a copy of the above mentioned Urological Oncology article which we are pleased to submit to the BMC Cancer for publication. I hereby confirm that the all authors have read and approved the final manuscript and that it has not been submitted elsewhere for publication.

To date, the CURVE (urothelial carcinoma patients treated by vinflunine in French) study represents the largest cohort of 134 patients that were assessed following cytotoxic treatment after failure of a prior platinum-based CT regimen in urothelial carcinoma. The recent study by Castellano \textit{et al.} published in October, 2014 in BMC Cancer included 102 patients.

Vinflunine is a cytotoxic agent for treatment of advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy failure. Overall survival prognostic factors were identified. Our aim was to retrospectively assess vinflunine efficacy and safety under routine conditions.

Twenty centres participated in the retrospective study (minimum 4 patients undergoing vinflunine treatment for advanced/metastatic urothelial carcinoma after platinum-based regimen progression. Primary endpoint was overall survival. Secondary endpoints: progression-free survival radiological response rate based on RECIST criteria and toxicity (CTC NCI v3). This study reflects routine urothelial carcinoma management and confirmed vinflunine patient efficacy. The drug is safe with gastro-intestinal and haematological prophylaxis. Analysis of prognostic factors for overall survival is consistent with pivotal trials. French Government approval was received to use the patient data for the French multi-centre CURVE study and this is confirmed in detail in the manuscript).

This study was previously presented, in part, at a poster discussion session at the European Cancer Congress (ESMO) in Amsterdam, on the 10\textsuperscript{th} September, 2013 and is not currently being submitted to another journal for publication.

As regards any Conflict of Interest:

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Disclosure
In 2012 Drs. J. Médioni, M. Di Palma, A. Guillot, D. Spaeth, C. Théodore all received a fee from Pierre Fabre Laboratories - France for their participation as members of the CURVE study Scientific Committee.
However, there are no financial competing interests on the part of any of the authors.

Thank you for considering our article for publication in *BMC Cancer*.

With best regards,
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For and on behalf of all authors

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