Reviewer’s report

Title: Safety and effectiveness of vinflunine in patients with metastatic transitional cell carcinoma of the urothelial tract after failure of one cisplatin-based systemic therapy in clinical practice

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Reviewer: Axel Hegele

Reviewer’s report:

General Remarks:
Disease progression after initial cisplatin based chemotherapy in metastatic TCC remains a medical challenge. After approval of Vinflunine in Europe for 2nd line treatment of these patients it is of interest to collect data about safety, activity and efficacy. The current manuscript describes the outcome of patients with metastatic TCC under daily clinical routine.

Nevertheless the presented manuscript has several limitations:

Major Revisions:
1. It is not clearly stated what kind of study is presented. Is it a retrospective data analysis ? A retrospective non interventional study ? It can only be heard in the discussion part that data collection was performed retrospectively. The study design have to be pointed out clearly and detailed in the material and methods part as well as in the abstract and be discussed critically.
2. How was the data collecting ? This should also be stated clearly – are there uniform CRFs ?
3. The data were collected over a time period of 3.5 years in 15 medical centers. What kind of institutions participated in this study ? Only hospitals or also outpatient units ? Please try to explain the relative low number of patients.
4. The starting vinflunine dosage as mentioned in the manuscript was different in the patient cohort (320-250 mg/m2). The 280mg/m2 is doubled in the material part – I think the authors mean 250 mg/m2. How many patients received what dosage ? Was there a need of dosage reduction after starting ? Do you see differences in response concerning different starting dosage ?
5. Data show better outcome in patients without liver metastases and ECOG 0. Bellmunt and Sonpavde and coworkers defined several risk factors including liver metastases, ECOG, Haemoglobin value and time from prior chemotherapy. Please summarize the data (e.g. response rate, OS) concerning existence of number of risk factors (Sonpavde et al).
6. Pleas clarify disease control – how long was e.g. SD ?
7. Data of the patient achieving CR should be deleted out of the manuscript – this is not a case report.
Minor Revisions
1. Figures: A figure with the OS concerning risk factors should be added. Figure 1 and Figure 3 should be deleted.

Level of interest: An article of outstanding merit and interest in its field

Quality of written English: Acceptable

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

Declaration of competing interests:

Yes: I received honoraria as scientific lecturer from Pierre Fabre Pharma GmbH, Germany.