Author's response to reviews

Title: A phase II study evaluating neo-/adjuvant EIA chemotherapy, surgical resection and radiotherapy in high-risk soft tissue sarcoma

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Author's response to reviews: see over
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Heidelberg, June 24, 2011

Dear Dr. Chap,

we would like to submit our manuscript entitled

“A phase II study evaluating neo-/adjuvant EIA chemotherapy, surgical resection and radiotherapy in high-risk soft tissue sarcoma”

by Thomas Schmitt et al.

for publication in BMC Cancer.

This report presents the results of a single-center, prospective phase II trial carried out at our institution. Though many patients with soft tissue sarcoma undergo initial curative resection up to 60% will develop distant metastasis. Outcome for those patients is grim with an overall survival of only 8-13 months after start of palliative first-line chemotherapy. Neo-/adjuvant regimens have been applied to eradicate micrometastases, facilitate definitive surgery and assess chemosensitivity. Still, the definite role of chemotherapy in high-risk soft tissue sarcoma remains uncertain.

Patients in the current protocol were treated with four cycles of neo-adjuvant chemotherapy (EIA; etoposide, ifosfamid, adriamycin), local therapy with surgery, intra-operative radiotherapy and adjuvant irradiation followed by further four cycles of adjuvant chemotherapy. Fifty patients were included. Overall survival and disease-free survival at 2 years were 83% and 63%, respectively. Local and distant failure occurred in 12% and 28%. The toxicity profile was manageable with
predominant hematological side effects including neutropenic fever and transient nausea/vomiting, ifosfamid-induced encephalopathy and anthracycline-induced cardiotoxicity.

Though this is not a randomized trial, our results seem favorably comparable to what is expected in high-risk patients in this very rare entity and are in line with similar studies in this setting. Thus, BMC Cancer, appears to be the adequate forum for publication of this trial.

The trial has been registered with Clinicaltrials.gov. The corresponding identifier is NCT01382030. EudraCT registration number is 2004-002501-72.

As reviewers we would like to suggest:

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Thank you very much for your attention.

Sincerely yours,

Thomas Schmitt, MD