Response to the letter to the editors from Inge Marie Svane on our manuscript “Adoptive T-cell therapy for malignant melanoma patients with TILs obtained by ultrasound-guided needle biopsy”

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Dear Editors,

Our current study was not a formalized clinical phase I/II trial. However, we and the reviewers believe that our main finding is valid. It is possible to generate relevant numbers of TILs from needle biopsies that mediate objective responses in patients with metastatic malignant melanoma. Of note, it is not uncommon that early immunotherapy studies in cancer patients are carried out and published without reaching the criteria for formal clinical trials. TIL treatment was indeed included in the Ethical

Committee approval. In fact, the Ethical Committee required that patients undergoing biopsy for TIL generation would have the opportunity to receive treatment with these TILs. Further, we had permission from the Medical Products Agency to perform the study. It was not, however, reported to <http://www.clinicaltrials.gov> since this was not a required standard procedure when the study was planned and initiated several years ago.

Conflict of interest None.

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