"Activity of sunitinib in advanced malignant melanoma and its correlation with potential predictive biomarkers"

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Sub-category: Melanoma
Category: Melanoma/Skin Cancers
Meeting: 2010 ASCO Annual Meeting
Session Type and Session Title: Poster Discussion Session, Melanoma/Skin Cancers
Abstract No: 8518
Citation: J Clin Oncol 28:15s, 2010 (suppl; abstr 8518)

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Abstract Disclosures
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Abstract:

Background: Sunitinib is a small molecule that inhibits several tyrosine kinase receptors, including VEGFR, PDGFR, c-KIT, FLT3 and RET. These kinases play a key role in neoangiogenesis and in tumour cell proliferation and survival. The effects of sunitinib in cancer treatment may be both anti-angiogenic or related to a direct anti-tumour effect of the drug through drug targets activated in the tumour cell. Treatment options for advanced melanoma after dacarbazine-based chemotherapy remain limited. We provide the results of a phase II study with sunitinib in advanced melanoma patients. Methods: Patients with locally advanced or metastatic melanoma who failed at least one line of dacarbazine-based chemotherapy were enrolled in a Belgian academic multi-centre phase II trial, following a Simon's two-stage design. Patients received treatment with sunitinib in 6 weekly cycles comprising of a 50 mg once daily dosing for 4 weeks, followed by a 2 week off-treatment period. The primary endpoint was RECIST-defined objective response. Angiogenic biomarkers were collected to study their potential predictive value for response. Serum VEGF, VEGFR-1, VEGFR-2 and PlGF were determined by ELISA and circulating endothelial cells were enumerated by FACS at baseline and biweekly during the first cycle. Results: Thirty-six patients with metastatic melanoma were enrolled. Seven patients were not evaluable for response because of early discontinuation of sunitinib, due to adverse events. Three patients (8.3%) demonstrated a partial response with a mean duration of 6.5 months. Nine had stable disease (25%) with a mean duration of 4.1 months (range: 3-8.2 months) and 17 had progressive disease (47.2%). The most frequent grade 3/4 toxicities were asthenia, anorexia and thrombopenia. No correlation between response and baseline VEGF, VEGFR-1, VEGFR-2 or PlGF was observed. Further analysis is ongoing. Conclusions: The present phase II trial met its primary endpoint (3 partial remissions) and a clinical benefit rate of 33% was observed. In a minority of patients significant toxicity was observed. Data from angiogenic biomarker analysis and the correlation with response will be reported.
Associated Presentation(s):

1. Activity of sunitinib in advanced malignant melanoma and its correlation with potential predictive biomarkers.

   Meeting: 2010 ASCO Annual Meeting  
   Presenter: Lore Decoster  
   Session: Melanoma/Skin Cancers (Poster Discussion Session)

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