5b the best sensitivity (71%) and specificity (96%) was seen with the cut-off point = 4.98 U/L, and for MMP-9 the best sensitivity (43%) and specificity (82%) with the cut-off point = 96.1 ng/ml. Patients with TRACP 5b ($p = 0.002$) or tALP ($p < 0.001$) levels above determined cut-off values showed significantly shorter survival than patients with low marker levels. MMP-2 and MMP-9 were not associated with survival.
Conclusions: TRACP5b is a novel marker of skeletal metastases and a predictor for survival in advanced PC.

861 POSTER

Retrospective study of inhaled IL-2 as treatment of lung metastasis of renal cell carcinoma. Spanish and Portuguese experience

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Background: Systemic IL-2 has been used for the last decade to treat metastatic renal cell carcinoma (MRCC). Locoregional administration of this cytokine could improve the risk/ benefit ratio of this drug. The objective of this study was to obtain efficacy and safety data on inhaled rIL-2 used in clinical practice in lung metastatic renal cell carcinoma (LMRCC) patients.
Material and Methods: The study was designed as a retrospective chart review in LMRCC patients being treated with inhaled rIL-2. Between September 2000 and April 2005, 32 centres in Spain and 3 in Portugal provided data from 80 LMRCC patients treated with inhaled IL-2. The treatment schedule was: 3 cycles of 36 MIU rIL-2 per day for 5 days/week for 12 weeks (with one week treatment free between cycles) in Spain and for 3 weeks (out of each 4 weeks) for 12 weeks in Portugal. Efficacy was assessed by best response following each treatment cycle and overall. PFS and OS were measured from the time of administration of the first dose of inhaled rIL-2 until progression, last follow up date or death, respectively The Kaplan-Meier method was used to estimate progression free survival (PFS) and overall survival (OS). Safety data were analysed using descriptive statistics, with toxicities expressed as number of toxicity reported weeks, describing grade and cycle.
Results: A total of 1290 treatment weeks were studied. Cough was the most frequent adverse event (reported in 27.8% treatment weeks), tending to be less frequent after the first 12 weeks of treatment. The majority of adverse events were reported to be only grade 1 or 2 in severity. Response rates after 12 weeks treatment were: 2 (2.7%) Complete Response; 10 (13.6%) Partial Response; 21 (28.7%) Stable Disease. At the present moment there were only 48 patients' data for survival calculations. Median PFS and OS were 4.5 (range 0.5–17.3) and 10.7 (range 0.4–42.9) months. At least 10 patients (20.8%) were alive for further than 24 months.
Conclusions: These initial results confirm that IL-2 locoregional administration in LMRCC can improve the risk/ benefit ratio of this drug compared to systemic therapy, maintaining its efficacy with an outstanding toxicity reduction.

862 POSTER

Biochemical response to neoadjuvant hormonoterapy may predict biochemical control rate and distant metastasis free survival after total short term androgen deprivation and conformal radiotherapy in the treatment of prostate adenocarcinoma

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Background: We assessed the prognostic factors affecting survival after short term total androgen deprivation (TAD) and radiotherapy in the treatment of localized prostate cancer.
Materials and Method: One hundred twenty-eight patients with T2-T3N0M0 prostate adenocarcinoma patients were treated. Stage T3, PSA $\geqslant$10 ng/dL and Gleason Score (GS) 7 and above were considered as high risk criteria and in case of positivity in one of them the patient was considered as high risk, otherwise treated as low risk. All patients were prescribed neoadjuvant TAD before radiotherapy. In high risk patients, TAD was continued for 6 months after completion of radiotherapy. Total radiotherapy dose was 73.6 Gy at ICRU reference point.
Results: Median follow-up was 48 months. Nineteen patients were in the low and 109 were in the high risk group. Five-year cause specific survival, biochemical control rate (bCR), and distant metastasis free survival rate were 94%, 80%, and 87% respectively. bCR was 87% for patients with PSA $\leqslant$1 ng/dL after 3 months neoadjuvant TAD, and 69% for patients with PSA >1 ng/dL after 3 months neoadjuvant TAD. Multivariate analysis showed that pre-radiotherapy PSA level measured after 3 months neoadjuvant TAD, age and T stage were significant prognostic factors determining bCR, and distant metastasis-free survival.
Conclusions: Response to neoadjuvant TAD may predict biochemical failure and distant metastasis free survival in patients with prostate carcinoma receiving conformal radiotherapy.

863 POSTER

A phase II study of BAY 43–9006 (sorafenib) in patients with androgen-independent prostate cancer (AIPC)

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Background: BAY 43–9006 (sorafenib) is a bis-aryl urea and a potent inhibitor of b – and c – Raf kinase, PDGFR and VEGFR-2. Accumulating evidence suggests that the Ras-Raf-MAPK-ERK signaling pathway is dysregulated in the setting of AIPC. Furthermore, published studies have shown a role for anti-angiogenic therapy for AIPC. We have launched a phase II study to determine the clinical and biological activity of BAY 43–9006 in patients with AIPC.
Methods: Patients are enrolled in an open-label, single arm phase II study. The primary objective is to determine if BAY 43–9006 is associated with a 50% 4 month probability of progression free survival as determined by clinical, radiographic, and PSA criteria. Patients must have good performance status and normal end-organ function. Patients with uncontrolled hypertension and those requiring therapeutic anticoagulation are excluded. All patients are treated with orally administered BAY 43–9006 at a dose of 400 mg bid given continuously on 28-day cycles. Clinical assessment occurs every 28 days with radiographic measurements of disease every 2 cycles. Treatment continues until progression.
Results: This study opened in September 2004 and 19 patients (median age 64 years, range 52–74) have been enrolled to date and all have completed at least 1 cycle of therapy. Grade 3 hand–foot syndrome and grade 3 hypertension have each been noted in 1/19 patients. Drug-related rash has been seen in 3/19 patients and has responded to temporary withdrawal of therapy. Other reported grade 1/2 toxicities include fatigue, flatulence, weight loss, anorexia, body aches, bradycardia, and diarrhea. Fifteen patients are off study due to disease progression. Thirteen patients have been treated for at least 4 months; 5 have exhibited stable disease by both PSA and radiographic criteria.
Conclusions: BAY 43–9006 appears to be well-tolerated in patients with AIPC with a reversible skin rash and hypertension as the most prevalent toxicities. Accrual continues, to better assess the activity and the toxicity profile of this agent.

864 POSTER

Phase II study of BAY 43–9006 (sorafenib) in patients with chemo-naïve hormone refractory prostate cancer

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Background: BAY 43–9006 (BAY) is an orally bioavailable multikinase inhibitor of raf, VEGFR-2, PDGFR, c-kit and ret which prevents tumor cell proliferation and angiogenesis in pre-clinical models. Activation of the MAPK and VEGF signaling pathways have been implicated with androgen independent progression of prostate cancer, and therefore provides a rationale for evaluating BAY in patients (pts) with prostate cancer who have progressed after castration therapy.
Methods: Multi-centre, phase II study using a two-stage design. Pts with hormone refractory prostate cancer with or without documented