severity of adverse events across the dose levels were noted. No dose-limiting toxicities were observed at any dose level.
Conclusion: The combination of cilengitide, cisplatin, 5 FU, and cetuximab was well tolerated. Cilengitide in combination with cetuximab and chemotherapy did not change the known safety profile of this standard treatment in SCCHN. Cilengitide 2000 mg was the recommended dose for the phase II study.

8518 POSTER

Prognostic value of the expression of SDF 1 and CXCR 4 in head and neck squamous cell carcinoma (HNSCC)

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Background: HNSCC have a hardly predictable evolution, and new prognostic factors are warranted to guide treatment options. Using cell lines or immunohistochemistry data, SDF 1 and its receptor CXCR 4 has been involved in the metastatic spread of various tumors, including HNSCC. We focused on the expression of SDF1 and CXCR4 in HNSCC to assess its prognostic value.
Methods: Fifty-seven patients treated for HNSCC were retrospectively analyzed for SDF1 and CXCR 4 expression by real-time PCR (RT-PCR). Tissue samples were collected at the time of initial diagnosis. At least 50% of the sample was tumoral. Total RNA was reverse-transcribed with TaqMan quantitative RT-PCR (Applied Biosystems). Results were recorded as average threshold cycle, and relative expression was determined using Normalized Expressions method. Expression of SDF1 and CXCR 4 was related to survival after at least 1 year of follow-up.
Results: In the 57 patients, expression of SDF1 (mean value 3.54, median 1.75, range 0.02−32.32) and CXCR 4 (mean value 0.58, median 0.23, range 0−9.89) demonstrated a great variability between patients. After a median follow-up of 30 months (range 12−56), 37 patients were alive (group A) and 20 were dead because of cancer evolution (group D). In group A, median level of SDF1 was 2.5 whereas it was 1.6 in group D ($p = 0.01$). Median level of CXCR 4 was 0.84 in group D and 0.25 in group A ($p = 0.4$). In addition, patients with low level of SDF1 had a worse survival ($p = 0.004$) whereas level of CXCR 4 was not related to evolution. Among usual prognostic factors, only node involvement tend to be related with a worse survival ($p = 0.06$).
Conclusions: In this series, SDF1 expression seems to have significant prognostic value to predict survival of HNSCC patients which is in agreement with in vitro data suggesting a role for SDF1/CXCR4 signaling in the metastatic process. If confirmed in further studies, SDF1 expression may help in management decision for HNSCC patients.

8519 POSTER

A phase 2, randomized trial (CONCERT-1) of chemoradiotherapy with or without panitumumab in patients (pts) with unresected, locally advanced squamous cell carcinoma of the head and neck (SCCHN): Interim pooled safety analysis

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Background: Panitumumab (pmab), a fully human monoclonal antibody against the epidermal growth factor receptor (EGFR), is indicated as monotherapy for the treatment of metastatic colorectal cancer. This ongoing study sponsored by Amgen is designed to estimate the difference in 2 year local regional control (LRC) rates in pts receiving chemoradiotherapy (CRT) alone or CRT plus panitumumab (PCRT) as first-line treatment of locally advanced SCCHN (ClinicalTrials.gov Identifier: NCT00500760).
Methods: This is a phase 2, open-label, randomized, international, multicenter study. Eligible pts were randomized 2:3 to CRT or PCRT. CRT included radiotherapy (RT) and cisplatin (100 mg/m^2 – days 1, 22, and 43 of RT). PCRT included RT and pmab (9.0 mg/kg Q3W) + cisplatin (75 mg/m^2 Q3W), both administered on days 1, 22, and 43 of RT. Standard fractionation RT (70 Gy delivered in 2 Gy fractions for 5 days/week $\times$7 weeks) was planned for all pts and was delivered by either the intensity-modulated (IMRT) modality or the three-dimensional conformal (3D-CRT) modality. The primary endpoint is LRC rate at 2 years. Key secondary endpoints include PFS, OS, and safety. An external, independent data monitoring committee (DMC) conducts planned safety and efficacy reviews during the course of the trial.
Results: Pooled data from this planned interim safety analysis includes the first 54 of 150 planned pts; 50 (93%) pts are male; median (range) age is 56 (37−74) years; ECOG PS 0: 69%, PS 1: 31%; 32 (59%) pts received IMRT, and 22 (41%) pts received 3D-CRT. Forty-eight (89%) pts completed all RT, and 48 pts received RT per protocol without a major deviation. The median (range) total RT dose administered was 70 (16, 70) Gy. The most common grade $\geqslant$ 3 adverse events (AEs) graded using the CTCAE version 3.0 are shown (Table).
Conclusions: After this interim safety analysis, the DMC recommended the CONCERT-1 study continue per protocol. Enrollment into the study completed (n = 153) on 26 March 2009. Updated pooled safety data for this group will be presented.

Table: Most common grade $\geqslant$ 3 adverse events[1] – safety analysis set (n = 53)

Adverse event	Any grade n (%)	Grade 3 n (%)	Grade 4 n (%)
Mucosal inflammation	35 (66)	21 (40)	0 (0)
Radiation-induced skin injury[2]	34 (64)	6 (11)	1 (2)
Dysphagia	31 (58)	14 (26)	0 (0)
Stomatitis	12 (23)	6 (11)	0 (0)
Hypokalemia	10 (19)	4 (8)	0 (0)
Dehydration	7 (13)	4 (8)	0 (0)
Infection	5 (9)	5 (9)	0 (0)

[1]There was one grade 5 treatment-related AE of syncope; [2]Any skin toxicities determined to be caused by radiation therapy.

8520 POSTER

Preliminary results of a pilot study with a modified induction docetaxel/cisplatin/5-FU (TPF) followed by concomitant chemoradiotherapy (CT/RT) in locally advanced head and neck cancer (LAHNC)

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Background: TPF induction CT followed by CT/RT has been evaluated in several trials showing high activity although associated with non-irrelevant toxicity. To aim the efficacy, toxicity profile and organ preservation of a modified neoadjuvant TPF to concurrent CT/RT in both resectable (R) and unresectable (UR) LAHNC.
Patient and Methods: One hundred seventy patients (p) with stage III-IV, PS ECOG 0−2, were included to receive 3 cycles of docetaxel 75 mg/m^2 iv day (d) 1, cisplatin (P) 75 mg/m^2 iv d2 and 5 FU 750 mg/m^2 iv continuous infusion d2−5, every 3 weeks with prophylactic ciprfloxacin 500 mg twice daily from d6−15 of each cycle and granulocyte colony-stimulating factor as secondary or primary setting, followed by P 100 mg/m^2 iv d1, 22, 43 concomitant with RT (66−70 Gy, conventional fractionation). Neck dissection was planned for p with stage N2−3 after induction CT or salvage surgery for resectable p with persistent disease at the end of treatment.
Results: Main p characteristics were: median age 58 years (39−77), male 89%, ECOG 0/1/2 47%/50.6%/2.4%, stage IV 62.7%, larynx/hipopharynx/oral cavity/oropharynx 45%/12%/17.3%/25.7% and R/UR 41.8%/58.2%. Median TPF/P cycles administered were 3/3. Neoadjuvant CT/total treatment overall response rate evaluation (R/UR): 70% (73%/68%)/86% (84%/88%). Neck dissection was performed in 16 p and salvage surgery in 6 p. Organ preservation was achieved in 90.8% of R p. Main G3−4 toxicity during TPF treatment was neutropenia 11.2%, febrile neutropenia 11.2%, mucositis 11.2%, and during CT/RT mucositis 16.5%, neutropenia 16.5%. Median time to progression was 19.5m (R:15.6,