had palliative resection because of synchronous metastasis (hepatic or peritoneal). Nodal involvement 2/56 (4%). Medium time of recurrence was 26 months. One nod recurrence was detected. Median follow-up 42 months.

	Stom. (n)	LR	MR	Rect. (n)	LR	MR	Duod. (n)	LR	MR	Small int. (n)	LR	MR	Total (n)	LR	MR
Wedge	(5)	4	0	(2)	2	0	(3)	3	0	(0)	0	0	(10)	9	0
P	(6)	0	4	(3)	1	1	X	X	X	(19)	0	15	(9)	1	5
OR T	(7)	0	4	(1)	0	0	(3)	0	1	X	X	X	(8)	0	4

Conclusion: Wedge resection should not be performed because of high rate of local recurrence and organ resection is prefered.

Each time it is possible, partial organ resection is a functionnal alternative because patients are mainly exposed to metastatic recurrence whenever partial or total organ resection is performed.

Lymph node dissection is not systematic.

1080 POSTER

Ecteinascidin (ET-743) in heavily pretreated refractory sarcomas: Preliminary evidence of activity

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ET-743 is a tetrahydro-isoquinolone of marine origin, currently in late phase I, early phase II development, with neutropenia (N) and thrombocytopenia (T) as limiting toxicities. Fatigue and reversible transaminitis (Tm) were also noticed. Antitumoral activity has been detected during the 24 hours continuous infusion (CI)-every 3 weeks schedule phase I (ASCO 1999, abst 690), which has completed accrual. We report here our current overall experience in treatment-refractory advanced sarcoma patients (pts).

Pts charact: Eleven pts (9 soft tissue sarcomas (STS) and 2 osteosarcomas (OS)) received ET-743, 10 at the recommended dose (1500 $\mu g/m^2$), one at the maximum tolerated dose (1800 $\mu g/m^2$). 9 of them were treated in the phase I trial, while 2 received ET-743 on a compassionate use basis. Sex: 6 men/5 women, median age: 37 years (16–71), median number of previous chemotherapy regimens: 2 (1–4) (all pts pretreated with anthracyclines and alkylators); median PS: 1 (0–2), median number of metastatic sites 2 (1–3).

Results: Toxicity is evaluable for the 38 given cycles. Grade 3–4 toxicities are acute reversible Tm peaking at day 3–5 (52%), N (39.5%) and T (10.5%). Febrile N occurred in 2 cycles (5%). All 11 pts are evaluable for antitumor activity. Two PR (1 ongoing), 2 MR (2 ongoing) and 3 SD (lasting >4 months) were observed. Among the 2 osteosarcomas there was 1 PR and 1 MR. ET-743 is a promising new agent for heavily pretreated refractory OS and STS. Based on this experience, a phase II program is ongoing, assessing the 1500 $\mu g/m^2$/24-hours CI schedule in such pts.

1081 POSTER

Toxicity profile of a high-dose (HD) chemotherapy regimen with peripheral blood stem cell rescue (PBSCR) for adults with soft tissue sarcoma (STS)

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Purpose: Prognosis of patients (pts) with metastatic STS is poor with conventional therapy. HD therapy combined with PBSCR may improve prognosis. We report on toxicity of a intensified chemotherapy regimen in pts with metastatic STS that responded to standard dose chemotherapy.

Patients and Methods: Thirty pts with metastatic grade II or III STS received 4 to 6 cycles of DI standard dose chemotherapy (doxorubicin 75 mg/m"; ifosfamide 6 g/m" with G-CSF day 7–14). After assessment of tumor response to DI therapy, responding pts received HD-ICE chemotherapy (ifosfamide 12 g/m", carboplatin 1200 mg/m" and etoposide 1200 mg/m") followed by PBSCR. Toxicity was monitored according to Common Toxicity Criteria.

Results: Of 30 pts on study, 17 responded to 4 cycles of DI chemotherapy (2 CR, 15 PR) and received 2 further cycles of DI chemotherapy. Up to now, 16 pts received HD-ICE with PBSCT. Pts received median 6.6 × 10^6/kg CD34+ cells (range, 2.8–14 × 10^6/kg). Median no. of days with leukocytes <1 G/l was 9 (7–12), median no. of days with platelets <20 G/l was 5 (3–18). Non-hematological toxicity con-sisted mainly in nausea and vomiting (grade 2/3, 9/7 pts) and mucositis (grade 2/3, 3/4 pts). Other grade 3/4 toxicities included hepatotoxicity (4/2 pts), or enteritis (1/0 pts). No grade 3 or 4 nephrotoxitiy or CNS toxicity was observed. All observed tox-icities were fully reversible. Median no. of day of discharge after HD-ICE + PBSCR was 13 (10–23). At last follow-up, 15/16 pts were alive with 3/16 being in CR.

Conclusion: HD-ICE chemotherapy with PBSCR in pts with metastatic STS is feasible. Toxicity of this protocol is mild. Assessment of efficacy requires further accrual and follow-up.

1082 POSTER

Activity of gemcitabine (G) in sarcoma after failure of doxorubicin-based chemotherapy

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Introduction: G has a documented activity and clinical benefit response in relatively chemo- resistant malignancies. G was found to be active on xenograft of soft tissue sarcoma growing in nude mice. Recently we reported a case where G treatment achieved long-term stabilization of an osteosarcoma resistant to doxorubicin based chemotherapy.

Patients: G was given to 14 patients with recurrent sarcoma of bone or soft tissue that was resistant to any previous therapy and beyond any further surgery or radiotherapy. Of the 14 patients, only one was asymptomatic. All underwent systemic workup and signed an informed consent.

Protocol: Weekly G 1000 mg/m^2 for 7 consecutive weeks followed by one week rest, followed by 3-weekly every month until lack of effect.

Results: Three objective responses were observed: one partial response in lung metastases of leiomyosarcoma of the uterus, one minimal response in case of osteosarcoma of the pubis, and one minimal response in case of angiosarcoma of the face. Clinical benefit responses were observed in 80% of the symptomatic patients, manifested by reduction in narcotic consumption, improvement of performance status and well being. Toxic events included myelotoxicity, rash, and limb edema, but none were serious nor required hospitalization.

Conclusions: G was found to be effective in achieving some responses and stabilization of sarcomas refractory to standard-chemotherapy.

1083 POSTER

Phase II study with prolonged infusion gemcitabine in pretreated advanced soft tissue sarcomas of the adult

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Purpose: The objectives of this phase II trial of gemcitabine were to estimate the reponse rate and to define the toxicities of gemcitabine administered as a prolonged infusion in pretreated patients (pts) with advanced soft tissue sarcomas.

Methods: Pts were eligible if they had locally advanced and/or metastatic, progressive, pretreated soft tissue sarcomas. Only one of the pts had a response to previous chemotherapy/-ies which consisted of at least one anthracycline and/or ifosfamide based regimen. Gemcitabine was administered at a low dose of 200 mg/m^2 as a 360-minute infusion once a week for 3 consecutive weeks followed by a week of rest. Eighteen pts (aged 20–70 years; median 58) with a median Karnofsky score of 80 (40–100) were enrolled, and 17 are fully assessable, to date.

Results: A total of 183 gemcitabine (range 3–24; median 9) applications were given to these 17 pts. Two pts (11.7%) who had only pulmonary matastases had a partial remission (PR) lasting 5 and 5+ months, respectively. One further patient also had a PR of lung metastases and other stable metastatic sites. Six pts had stable disease for 3–6 months. Toxicities were moderate and fully reversible, and included leucopenia grade 3 (n = 4)/grade 4 (n = 1), thrombocytopenia grade 2 (n = 2)/grade 4 (n = 1), anemia grade 2 (n = 3), liver toxicity grade 2 (n = 2)/grade 3 (n = 3), nausea/vomiting grade 2 (n = 3), and edema grade 2 (n = 2)/grade 3 (n = 3).

Conclusion: Prolonged infusion of low dose gemcitabine has some activity in heavily pretreated pts with advanced soft tissue sarcomas and is well tolerated.