the reservoir on an out patient basis, and repeated every 4 weeks. Patients continued to receive carboplatin emulsion until disease progression or the appearance of unacceptable toxicity including hepatic failure.
**Results:** Thirty-two patients were enrolled between January 2000 and December 2004. One patient deteriorated before receiving chemo infusion and was excluded from further evaluation. The average number of arterial infusions given during the follow-up period ranged from 3 to 31 (median, 13.7). Out of 31 eligible patients, 15 patients had partial responses, for an objective responses rate of 48.4%; 7 patients had no change, and 9 had progressive diseases. The median survival time was 17.7 months (95%c.i. 14.1–21.2 months). The cumulative survival rates were 76.6% and 47.2% for the periods of 12 and 24 months, respectively. The grade 3–4 toxicities (NCI-CTC) observed were leucopoenia (12.9%), thrombocytopenia (19.4%), and increased AST (3.2%).
**Conclusions:** Repeated hepatic arterial infusion of carboplatin mixed with degradable starch microsheres by using reservoir is active and well tolerated in patients with advanced HCC underlying liver cirrhosis.

**745** POSTER

**Final report of Phase I/II study of docetaxel and S-1 for patients with advanced gastric cancer**

Y. Sakata[1], K. Yamaguchi[2], I. Hyodo[3], W. Koizumi[4], H. Narahara[5], T. Doi[6], Y. Komatsu[7], T. Kato[8], S. Saitoh[9], T. Akiya[10]. [1]*Misawa Municipal Hospital, Depertment of Medical Oncology, Aomori, Japan;* [2]*Saitama Cancer Center, Saitama, Japan;* [3]*National Shikoku Cancer Center, Ehime, Japan;* [4]*Kitasato Univ. East Hospital, Kanagawa, Japan;* [5]*Osaka Med Ctr for Cancer and Cardiovascular Disease, Osaka, Japan;* [6]*National Cancer Center East Hospital, Chiba, Japan;* [7]*Hokkaido Univ Graduate School of Medicine, Hokkaido, Japan;* [8]*Niigata Cancer Center, Niigata, Japan;* [9]*Aomori Prefectural Central Hospital, Aomori, Japan;* [10]*Gunma Prefectural Cancer Center, Gunma, Japan*

**Background:** This phase I/II study was conducted to evaluate efficacy and safety of new combined regimen with docetaxel (DOC) plus S-1 in patients (pts) with advanced gastric cancer (AGC). DOC and S-1 have different modes of actions respectively, and showed both of anti-tumor activities for AGC and synergistic effect in combined administration.
**Methods:** Eligibility criteria included; pathologically confirmed AGC, measurable lesions, PS 0–1, $\leqslant$1 prior chemotherapy, $\geqslant$20 years old, adequate organ functions and written IC. In phase I part, the dose of DOC was elevated from the starting dose of 50 mg/m$^2$ and S-1 dose was fixed to 80 mg/m$^2$. DOC was administered on day 1 and S-1 was administered orally on days 1–14 consecutively, and the treatment was repeated every 4 weeks. Identifying recommended dose (RD) of combined DOC+S-1, phase II part was started to evaluate the profiles of efficacy and safety of this combined regimen.
**Results:** 50 pts were enrolled in this study from 9/02 to 6/04. In phase I part, all 3 pts enrolled in the starting dose level showed intolerable toxicities (grade 3 neutropenia with infection in one pt and grade 4 neutropenia on day 8 during S-1 administration in 2 pts). Then the dose of DOC was de-escalated to 40 mg/m$^2$ and this dose level was determined as RD for phase II part. 46 out of 47 pts enrolled were eligible and evaluable for safety and efficacy, respectively. Pt characteristics were as follows; median age 65 (range 42–79), M/F 31/15, PS0/1 29/17, histological type intestinal/diffuse 29/17 and chemonaïve/pre-treated 25/21 pts. ORR, MST and 1 year survival rate were 45.7% (95%CI: 30.9–61.0%), 14.2 months and 56.6%, respectively. Common grade 3/4 toxicities were neutropenia (67.4%), leukopenia (41.3%), anemia (21.7%), and anorexia (21.7%). These toxicities were tolerable and manageable. No treatment-related death was observed. The interim results were presented at ASCO2005 meeting (Abstract 4064), and final and mature results will be presented at ECCO13 meeting.
**Conclusions:** This new regimen with DOC and S-1 showed manageable toxicities and favorable survival benefit to warrant a further phase III study with this regimen in pts with AGC.

**746** POSTER

**Oxaliplatin and Irinotecan in advanced gastric cancer. A multicenter phase II trial**

E. Wöll[1], W. Eisterer[2], W. Hilbe[2], T. Kühr[3], K. Gattringer[4], R. Greil[5], A. Zabernigg[4], C. Baldinger[3], J. Thaler[3]. [1]*General Hospital St. Vincent Zams, Department of Internal Medicine, Zams, Austria;* [2]*University Hospital Innsbruck, Clinical Division of General Internal Medicine, Innsbruck, Austria;* [3]*Hospital Barmherzige Schwestern vom heiligen Kreuz Wels, Department of Internal Medicine IV, Oncology, Hematology & Immunology, Wels, Austria;* [4]*General Hospital Kufstein, Department of Internal Medicine, Kufstein, Austria;* [5]*University Hospital Salzburg, Department of Internal Medicine III, Division of Oncology, Salzburg, Austria*

Treatment options for advanced gastric cancer are limited therefore inclusion of novel substances is mandatory. Several agents have recently emerged as potential new options for advanced gastric cancer. The combination of Doxetaxel/Cisplatin and 5-FU showed high respons rates and a small survival benefit at the cost of increased toxicity. The aim of this study was to evaluate the safety, feasibility and efficacy of an Oxaliplatin/Irinotecan combination in patients suffering from unresectable, locally advanced and/or metastatic gastric cancer. Both substances show activity in gastric cancer as single agent or in combination with other drugs but the combination of Oxaliplatin and Irinotecan has not been evaluated in this setting. The combination of Oxaliplatin 85 mg/m$^2$ biweekly with Irinotecan 125 mg/m$^2$ biweekly was chosen for the present study since it has been shown in colorectal cancer that a biweekly dose of at least 85 mg/m$^2$ oxaliplatin is superior to a lower dose and toxicity of Irinotecan is much lower if given fractionated into two doses. Furthermore the Irinotecan dose below MTD considers concerns about increased toxicity of Irinotecan in gastric cancer patients. 43 patients with histologically proven unresectable and/or metastatic gastric adenocarcinoma and no previous palliative chemotherapy and/or immunotherapy were selected. Median age: 61 years (range 32 –81 years), male/female ratio: 24/19, PS 0:11 patients, PS <3: 32 patients, single metastatic site: 19 patients, multiple metastases: 19 patients, previously adjuvant radiochemotherapy: 4 patients. This outpatient regimen was generally well tolerated. Frequently reported adverse events (more than 20% of patients) were grade 1 or 2 and included neutropenia (44% of patients), thrombocytopenia (30%), anemia (77%), nausea 67%), diarrhea (51%), alopecia (35%). Grade 3 and 4 toxities included neutropenia in 2/43 pts., anemia in 3/43 pts., nausea in 2/43 pts., and diarrhea in 4/43pts. 3 patients were taken off-study due to toxicity (asthenia, nausea, reversible renal failure). Sensory neuropathy occurred only as grade 2 in 15%, no grade * toxicity was observed. 35 patients are assessable for response with 2 pts. (5.7%) showing a CR, PR in 19 pts. (54%), SD in 11 pts. (31%), PD in 3 pts. (8.6%). Final results on TTP and OS will be presented during the meeting.
**Conclusion:** Oxaliplatin/Irinotecan is a feasabile outpatient regimen with low overall toxicity and manageable side effects and a response rate within the range of other combination therapies and represents an alternative 1st line regimen.

**747** POSTER

**Final efficacy results of a neoadjuvant chemoradiation phase II trial: paclitaxel, carboplatin and 5-FU with concomitant 45 Gy radiotherapy for stage II-III oesophageal cancer**

L. van de Schoot[1], M. van der Sangen[2], G. Creemers[3], O. Repelaer van Driel[4], H. Rutten[1], G. Nieuwenhuijzen[1,5]. [1]*Catharina Ziekenhuis, Surgery, Eindhoven, The Netherlands;* [2]*Catharina Ziekenhuis, Radiotherapy, Eindhoven, The Netherlands;* [3]*Catharina Ziekenhuis, Internal Medicine, Eindhoven, The Netherlands;* [4]*Maxima Medisch Centrum, Surgery, Eindhoven, The Netherlands;* [5]*On behalf of the collaborating hospitals of the Comprehensive Cancer Center, region South-East, The Netherlands*

**Introduction:** The outcome for patients with oesophageal cancer undergoing surgical resection with curative intention is poor. In an attempt to improve outcome, neoadjuvant strategies have been studied. Neoadjuvant chemoradiation is most promising. Pathologic complete response (pCR) rates of 20–30% have been published. We aimed to assess the feasibility and efficacy of a new treatment strategy, neoadjuvant chemoradiation followed by surgery in patients with stage II-III oesophageal cancer.
**Methods:** In the period from Jan 2002 – Nov 2004, 50 patients with a potential resectable stage II-III oesophageal cancer received chemotherapy with paclitaxel 175 mg/m$^2$ iv and carboplatin AUC 5 iv on day 1 and 22, 5-Fu 200 mg/m$^2$ on day 1 to 42 in combination with radiotherapy 45 Gy in 25 fractions starting on day 1. Surgery followed 6–8 weeks after completion of neoadjuvant treatment.