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ABSTRACT BOOK

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Conclusions: Patients in the Italian cohort of CONSIGN appeared similar to those in the overall cohort, except that a higher proportion of patients in the Italian cohort had a baseline ECOG PS of 0 (76% vs 47% in the overall cohort). The AE profile in the Italian cohort was consistent with that of the overall cohort, and median PFS in the Italian cohort (2.9 months) was similar to that in the overall cohort (2.7 months).

Treatment-emergent AE	Percentage of patients	
	Italian cohort (N = 683)	All patients (N = 2864)
Grade ⩾3	74	80
Drug-related	55	57
Fatigue	16	18
Hypertension	14	17
HFSR	10	14
Diarrhea	5	6
Hypophosphatemia	10	7
Serious	23	44
Drug-related	4	9
Leading to discontinuation	19	25
Drug-related	6	9

Conflict of interest: *Ownership: Siena: Ignyta. Moscovici: Bayer. Advisory Board: Ciardiello: Roche, Merck Serono, Bayer, Sanofi, Astellas, Amgen, Lilly. Falcone: Amgen, Bayer, Roche, Merck-Serono, Sanofi, Lilly. Cascinu: Bayer, Roche, Sanofi. Sobrero: Roche, Bayer, Merck, Sanofi, Celgene, Amgen. Barone: Novartis, Merck, Amgen, Roche, Bayer. Siena: Roche, Bayer, Amgen, Sanofi, Ignyta. Di Bartolomeo: Lilly S.p.a. Corporate-sponsored Research: Falcone: Roche, Merck-Serono, Sanofi. Siena: Bayer. Van Cutsem: Bayer. Other Substantive Relationships: Siena: patents (Amgen). Moscovici: Bayer employee. Boni, Barone, Luppi, Maiello, Zagonel, Carteni, Di Costanzo, Santoro, Russo, Zaniboni: Nothing to disclose.*

2144 POSTER

High levels of D-dimer correlated with disease status and poor prognosis of inoperable metastatic colorectal cancer patients treated with bevacizumab

Z. Liming[1], J. Haixing[2]. *[1]ZheJiang Cancer Hospital, Departments of Chemotherapy, Hangzhou, China; [2]Zhejiang cancer hospital, Departments of colorectal surgery, Hangzhou, China*

Background: To assess the levels of D-dimer baseline levels in inoperable metastatic colorectal cancer (mCRC) patients treated with bevacizumab and its relationship with prognosis.
Materials and Methods: From June 1, 2011 to December 31, 2013, a total of 121 patients with mCRC received beacizumab combined with chemotherapy and 74 of them were included in the present study. A nonparametric statistical test was performed to analyze the relationship between plasma D-dimer levels and clinical pathological factors. The Cox proportional model was used to analyze the effects of D-dimer on progression-free survival (PFS) time and overall survival (OS).
Results: Of the 74 cases, 40 were men and 34 women (aged 31−74 years), with a median age of 55.5 years. The median of PFS and OS were 6.3 and 17.8 months respectively. High levels of baseline plasma D-dimer were correlated with high scoring of Eastern Cooperative Oncology Group-Performance Status (P = 0.001), IV phase of disease at the first visit (P = 0.001), unremoval primary focal (P = 0.006), the number of metastatic organs ⩾2 (P = 0.034), abdominal cavity effusion (P = 0.004) and no history of adjuvant chemotherapy (P = 0.003). It was found by single factor analysis that plasma baseline D-dimer levels ⩾1.9 μg/mL were closely related with a short PFS (hazard ratio [HR] 2.14, 95% confidence interval [CI] 1.04–4.40, P = 0.038) and OS (HR 5.22, 95% CI 2.05–13.28, P = 0.001). After adjustment for other factors, plasma baseline D-dimer levels ⩾1.9 μg/mL were still closely correlated with a short OS (HR 3.52, 95% CI 1.28–9.67, P = 0.015).
Conclusion: High levels of plasma baseline D-dimer correlated with high tumor load, advanced disease status and poor prognosis of inoperable mCRC patients treated with bevacizumab. However, clinical research on a much larger cohort of patients will be required to verify these findings.
No conflict of interest.

2145 POSTER

Masitinib plus FOLFIRI for second-line treatment of metastatic colorectal cancer: 2-year follow-up of phase 2, open label trial

J. Taieb[1], C. Borg[2], T. Lecomte[3], C. Lepère[1], T. Chatellier[4], D. Smith[5], P. Dubreuil[6,7], C. Mansfield[7], A. Moussy[7], O. Hermine[7,8]. *[1]European Hospital Georges Pompidou, Department of Medical Oncology, Paris, France; [2]University Hospital Besançon, Department of Medical Oncology, Besançon, France; [3]Hôpital Trousseau, Department of Medical Oncology, Tours, France; [4]Clinique Mutualiste de l'Estuaire, Department of Medical Oncology, Saint Nazaire, France; [5]Hôpital Saint André, Department of Medical Oncology, Bordeaux, France; [6]CRCM Inserm U1068, Institut Paoli-Calmettes, Université Aix-Marseille, CNRS UMR7258, Département d'Oncologie Génétique, Marseille, France; [7]AB Science, Clinical Development, Paris, France; [8]Hôpital Necker, Department of Hematology, Paris, France*

Background: Masitinib (MAS) is a selective inhibitor of c-Kit and mast cell function. Increased mast cell activity in the tumor microenvironment is linked to poor prognosis and a protumoral immune response in colorectal cancer (CRC). In vitro, MAS acts as a chemosensitizer of 5-fluorouracil and irinotecan in CRC cell lines. This open label phase 1b/2 trial evaluated MAS in combination with chemotherapies for second-line treatment of metastatic CRC. Updated survival and safety data after a median follow-up of 2 years are reported for the cohort receiving MAS + FOLFIRI.
Methods: Patients with nonresectable, metastatic CRC after progression to first-line treatment received MAS + FOLFIRI until progression, refusal or unacceptable toxicity. Patients previously treated with irinotecan were excluded. Phase 1 evaluated safety of the combination with Dose Limiting Toxicity (DLT) determining subsequent dose and recruitment. DLT was defined as grade 3 non hematological adverse event (AE) or any grade 4 AE related to MAS. The phase 2 study evaluated efficacy.
Results: Eighteen patients (50% with mutated KRAS) from 6 centers in France were treated with MAS + FOLFIRI. No DLT was reported for the phase 1 stage (3 patients) at 9 mg/kg/day. Overall, 6/18 patients (33%) reported grade 3−4 AE and 4/18 patients (22%) experienced serious AE. No treatment related deaths were reported. After a median follow-up of 24.3 months, median OS was 17.6 months (95% CI [6.8; 21]) and median PFS was 5.6 months (95% CI [1.8; 9.2]). Objective response rate was 28%, including 1 patient with a confirmed complete response. For the final 3 patients MAS dose was reduced from 9 to 6 mg/kg/day based on new mechanistic understanding and to minimize risk of toxicity. Efficacy was still evident in these patients as evidenced by PFS of 9.2, 6.2 and 5.6 months with no grade 3−4 AE reported in this cohort.
Conclusions: The safety profile of MAS + FOLFIRI was acceptable. Efficacy findings seem to compare favorably against historic benchmarks (see table below) with the comparatively high objective response rate and notable confirmed complete response in one patient. MAS may therefore offer patients a new active compound for mCRC. A confirmatory phase 3 trial evaluating FOLFIRI +/− MAS at 6 mg/kg/day as second-line for mCRC is ongoing with OS as a primary efficacy criterion. A second objective of this ongoing phase 3 study will be to identify those subgroups that best respond to MAS.

	MAS + FOLFIRI	FOLFIRI wt KRAS*	FOLFIRI mutant KRAS*
OS (months)	17.6	12.5	11.1
PFS (months)	5.6	3.9	4.9
Objective Response Rate	28%	10%	14%
Complete	6%	0%	0%
Partial	22%	10%	14%

wt = wild-type.
*Peeters et al. (2010) J Clin Oncol 28: 4706.

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2146 POSTER

Association between proton-pump inhibitors (PPI) and metronomic capecitabine (MCAP) as salvage treatment for patients with advanced gastro-intestinal tumours: A randomized phase II study

A. Milano[1], C. D'Antonio[1], M. Roberto[2], R. Falcone[2], F.R. Di Pietro[2], V. Durante[2], A. Romiti[2], P. Marchetti[2]. *[1]"Sapienza" University of Rome, Sant'Andrea Hospital, Medical and Surgical Sciences and Translational Medicine, Rome, Italy; [2]"Sapienza" University of Rome, Sant'Andrea Hospital, Molecular and Clinical Medicine, Rome, Italy.*

Background: Several researches have shown that acidification of tumor microenvironment is the basis for tumor invasiveness, ability to metastasize