possible differences toward zero. In summary, this study does not support but can neither fully refute the possibility of an association between androgens and the development of esophageal adenocarcinoma.

6566 POSTER

Updated Safety and Efficacy Results From RADIANT-2 − a Randomized, Double-blind, Multicenter, Phase III Trial of Everolimus + Octreotide LAR Vs Placebo + Octreotide LAR in Pts With Advanced Neuroendocrine Tumours (NET)

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Background: In the RADIANT-2 (NCT00412061), the largest phase III trial in advanced NET, treatment with everolimus + octreotide LAR (E+O) delayed disease progression by 5.1 months vs placebo + octreotide LAR (P+O) (Pavel ESMO 2010 LB8). However, imbalances in several important prognostic baseline factors favoring the P+O arm occurred.
Materials and Methods: Pts were randomized to everolimus 10 mg/d orally + octreotide LAR 30 mg IM q28d (n = 216) or to P+O 30 mg IM q28d (n = 213). Primary endpoint was PFS (RECIST v1.0). At the time of disease progression, pts randomly assigned to P+O could cross over to open-label E+O. At the time of this updated overall survival (OS) analysis (March 10, 2011), 223 events had occurred: 117 in E+O and 106 in P+O arms. Adverse events (AEs) were coded to a preferred term and graded using the National Cancer Institute Common Toxicity Criteria (v3.0). Safety population included 426 pts (215 E+O; 211 P+O).
Results: There was an imbalance between arms in poststudy anticancer treatments. Of the 213 pts assigned to the P+O arm, 143 (67.1%) crossed over to open-label E+O. In contrast, only 69 (32%) of E+O pts received subsequent therapy. Additionally, there was an imbalance in subsequent poststudy treatment with SSA favoring P+O arm. No significant differences were observed in median OS (HR, 1.17; 95% CI, 0.90–1.52). Adjusting for the imbalances in prespecified prognostic factors, HR =1.06 (95% CI, 0.81–1.39). Median safety follow-up now extends to 31.1 mo; updated safety data consistent with the original analysis. Common drug-related AEs (E+O vs P+O, %) were stomatitis (47.4 vs 10.9), rash (37.2 vs 12.3), and fatigue (31.6 vs 24.2). Most frequent drug-related grade 3/4 events were fatigue (6.5 vs 2.8), diarrhea (6.0 vs 2.4), hyperglycemia (5.1 vs 0.5), and thrombocytopenia (4.7 vs 0).
Conclusions: There were no significant differences in the ITT or the adjusted survival analysis between the two treatment arms. Final survival analysis will be completed after 252 events and likely will continue to be confounded by the crossover study design, imbalances in important prespecified baseline prognostic factors, and imbalances in poststudy anticancer therapies and SSA use. The safety profile of E+O was consistent with the primary study results and everolimus safety overall.
Study supported by Novartis.

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A Phase II Trial of Erlotinib in Combination With Gemcitabine and Cisplatin for Unresectable Pancreatic Cancer

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Background: We performed a phase II study of erlotinib in combination with gemcitabine and cisplatin (GPT) for treating chemo-naïve patients with unresectable pancreatic cancer to evaluate the efficacy and toxicity.
Material and Methods: Patients were treated with erlotinib 100 mg daily, administered orally on days 1−21, and 1250 mg/m^2 of gemcitabine and 25 mg/m^2 of cisplatin administered via an intravenous infusion on days 1 and 8. The treatment was repeated every 3 weeks and continued until disease progression, withdrawal due to toxicity, or withdrawal of consent.
Results: Twenty-two patients were enrolled between June 2009 and August 2010. The median age of patients was 63 years (range, 32−73 years). Male to female ratio was 18:4. Reasons of unresectability were metastasis to other organ in 14 patients (63.6%), relapse in 5 patients (22.7%), or locally advanced inoperable 3 patients (13.6%). Median numbers of treatment was 4 cycles (range, 1−10 cycles). No complete response was observed and a partial response was observed in 5 patients (22.7%), Stable disease in 7 patients (31.8%), and progressive disease in 7 patients (31.8%). 3 patients did not disease evaluation. The median time to progression was 4.0 months (95% CI: 2.9−5.1 months), and the median overall survival was 6.8 months (95% CI: 3.7−9.9 months). Although the response rate in stage I reached the target ($\geqslant$ 3/22, p0=10%) established for movement to stage II, this study had to be discontinued because four patients had expired during treatment related with experimental drugs and the follow-up loss rate was higher (18.2%) than we had anticipated.
Conclusions: Even though erlotinib in combination with gemcitabine and cisplatin regimen is effective for unresectable pancreatic cancer, treatment related mortalities and high follow-up loss rate suggested this GPT protocol early closure and modification.
ClinicalTrials.gov Identifier: NCT00922896

6568 POSTER

DocOX − a Phase II Trial With Docetaxel and Oxaliplatin as a 2nd-line Systemic Therapy for Patients With Advanced And/or Metastatic Adenocarcinoma of the Pancreas − Interim Analysis

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Background: The ductal pancreatic adenocarcinoma is the fifth most common cause for cancer-related cases of death in Europe and the United States. For patients with a metastatic disease (UICC stadium IV), a cytostatic systemic therapy in palliative intention is the only treatment option.
At progressive disease under first-line chemotherapy it is often common to start a second-line systemic therapy with Fluoropyrimidine if applicable eventually in combination with Oxaliplatin. But actually there is no well-established standard for treatment in the second-line situation. There are well-known positive data about combination of Gemcitabine with Oxaliplatin and also of Gemcitabine with Docetaxel regarding to progression free survival (PFS) and tumour response in the palliative first-line situation.
For the first time, the DocOx-trial investigates the combination of Oxaliplatin with Docetaxel as an option for the second-line treatment option after progressive disease under palliative first-line cytostatic systemic therapy with Gemcitabine.
Methods: Prospective, single arm, non-randomized, multicenter, phase II trial with Docetaxel (75 mg/m^2, 60 min, d 1) plus Oxaliplatin (80 mg/m^2, 120 min, d 2, qd 22). Duration of trial is scheduled over 8 cycles maximum.
Primary endpoint: tumour response according to response evaluation criteria in solid tumours (RECIST). Secondary endpoints: PFS, overall survival (OS), safety/toxicity, quality of life/clinical benefit.
Interim analysis after inclusion of 22 patients (overall scheduled n = 44) in reference to tumour response and PFS.
Results: Among 22 patients included 2009 and 2010 50% (n = 11) had a stable disease (SD) at the first staging point (cycle 3, d 1), 5% (n = 1) had a partial remission (PR) and 41% (n = 9) a progressive disease (PD). At the second staging point (cycle 5, d1) of the remaining 11 patients 25% (n = 3) had a partial remission, 42% (n = 5) were stable (SD) and 25% (n = 3) showed a progress (PD). At the third staging point (cycle 7, d1) 6 patients were left, 17% (n = 1) with PR, 50% (n = 3) with SD and 33% (n = 2) showed a progressive disease.
In summary we saw a tumour response rate of 18% (n = 4, 95%-confidence interval 5.19–40.28%) among our patients and a progression free survival (PFS) of 14.3 weeks (3.57 month).
Conclusions: The results of our interim analysis fulfill the given requirements to proceed the DocOx-trial. Oxaliplatin plus Docetaxel as adjunction in the second-line treatment of pancreatic adenocarcinoma seems to be a possible therapeutic option.