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Clinical Management and Treatment Outcomes in Patients Receiving Treatment for Non-small Cell Lung Cancer (NSCLC) Across Europe − EPICLIN-Lung Study

G. Cruciani[1], A. Vergnenègre[2], M. Thomas[3], E. Blasco-Colmenares[4], J. Medina[5], A. Carrato[6]. [1]*Ospedale Civile Santa Maria delle Croci, Oncology Department, Ravenna, Italy;* [2]*Hôpital Le Cluzeau, Service de l'Information Médicale et de l'Evaluation, Limoges, France;* [3]*University of Heidelberg, Clinic for Thoracic Diseases, Heidelberg, Germany;* [4]*The John Hopkins Medical Institutions, Welch Center for Prevention Epidemiology, Baltimore, USA;* [5]*AstraZeneca Farmacéutica Spain, Medical Department Value Demonstration Unit, Madrid,* [6]*Ramon y Cajal University Hospital, Medical Oncology Department, Madrid, Spain*

Background: The EPICLIN-Lung study (NCT00831909) provides real-world data on the characteristics and clinical management of patients (pts) with NSCLC in Europe.
Materials and Methods: A non-interventional, prospective cohort study conducted in 8 European countries. Pts with confirmed NSCLC attending participating centres for the first time 1 Jan–31 Mar 2009 were enrolled and followed for a minimum of 12 months or until death. Treatments (tx) received are reported by Stage at diagnosis.
Results: 3508 pts were included in the overall analysis; mean age 64.5 y (±10.5); males:females ratio 3.4; 11% never-smokers. 308 (8.8%) pts were tested for biomarkers; 122 (3.2%) for EGFR mutations. 2645 pts received chemotherapy (CT) at any point, managed as follows: 259 (9.8%) had Stage I/II disease, of which 155 (59.8%) also had surgery; 862 (32.6%) had Stage III disease, of which 238 (27.61%) had surgery, plus adjuvant CT in 30.1% of cases; 1398 (52.8%) had Stage IV disease, of which 533 (38.13%) also received radiotherapy. Median (med) survival was analysed by systemic tx regimen, tumour histology and Stage at diagnosis. Effect of tx regimen on med survival: 0.69 y (cisplatin [Cis]-based doublets); 0.55 y (carboplatin [Car]-based doublets); 0.80 y (bevacizumab-containing triplets); 0.36 (monotherapy with gemcitabine [Gem] or vinorelbine [Vin]); 0.27 y (erlotinib [Erl]); 0.44 y (investigational products), 0.55 y (other). Effect of tumour histology: 0.58 y (adenocarcinoma); 0.64 y (squamous cell carcinoma); 0.4 y (large cell carcinoma); 0.62 y (NOS); 0.56 y (other). Effect of Stage: 1.05 y (Stage II), 1.07 y (IIIa), 0.7 y (IIIb) and 0.47 y (IV). Med survival was not reached for Stage I pts (>1.25 y). Variables associated with a lower risk of death/clinical progression were age ($p \leqslant 0.0001$), 1% increased risk per year; female sex ($p = 0.011$); CTCAE $\leqslant 2$ ($p = 0.008$). Variables associated with a higher risk were Stage at diagnosis (IIIb, $p = 0.035$; IV $p \leqslant 0.0001$); performance status (PS) > 0, CTCAE > 2, attending a regional hospital, receiving, Erl, Gem, Vin, or best supportive care (all $p \leqslant 0.0001$); or receiving Car + Gem ($p = 0.009$).
Conclusions: In 2009, tx of NSCLC pts in Europe was broadly in line with international guidelines. Biomarker testing was uncommon. Tumour histology, systemic tx regimen, age, sex, PS, AEs, and hospital type affected risk of death/clinical progression. A better understanding of prognostic and predictive factors will enable optimal selection of pts for tx in clinical practice in the future.

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A Phase II Trial of Erlotinib as Maintenance Treatment After Concurrent Chemo-radiotherapy in Stage III Non-small Cell Lung Cancer (NSCLC) − a Galician Lung Cancer Group (GGCP) Study

J. Casal[1], J.L. Fírvida[2], M. Lázaro[1], F.J. Barón[3], G. Alonso-Curbera[4], L. Santomé[5], F.J. Afonso[6], M. Amenedo[7], S. Figueroa[8], S. Vázquez[9]. [1]*Complexo Hospitalario de Vigo, Medical Oncology, Vigo,* [2]*Complexo Hospitalario de Ourense, Medical Oncology, Ourense,* [3]*Complexo Hospitalario Universitario de Santiago, Medical Oncology, Santiago de Compostela,* [4]*Complexo Hospitalario Universitario A Coruña, Medical Oncology, A Coruña,* [5]*Hospital Povisa, Medical Oncology, Vigo,* [6]*Complexo Hospitalario Arquitecto Marcide-Novoa Santos, Medical Oncology, Ferrol,* [7]*Centro Oncológico de Galicia, Medical Oncology, A Coruña,* [8]*Roche Farma S.A., Medical Department, Madrid,* [9]*Hospital Lucus Augusti, Medical Oncology, Lugo, Spain*

Background: Locally advanced NSCLC that is not amenable to surgical resection is treated with combined modality therapy involving chemotherapeutic agents and radiation therapy, which is associated with improvement in overall survival compared with radiotherapy alone. Efforts to improve the benefit of the approach have focused on integration of targeted therapies in these regimes.
This Galician study has evaluated the EGFR-TKI erlotinib (E) as maintenance therapy after combined modality therapy, a setting where gefitinib has previously failed. E is approved as maintenance treatment for advanced disease following a platinum-based doublet.
Material and Methods: Patients with unresectable stage IIIA o dry IIIB NSCLC, having been treated with a standard concurrent chemo-radiotherapy regimen (CRT) and with no evidence of tumour progression, were included in this single arm, phase II trial. Patients were treated with oral E 150 mg/day within 4 to 6 weeks after the end of the combined treatment, and received the drug for a maximum of 6 months if no disease progression or intolerable toxicity occurred. The protocol was approved by the corresponding IRBs and patients signed the informed consent. Primary endpoint was the progression-free rate at 6 months; secondary: time to progression (TTP) and overall survival (OS), measured from the time of enrolment.
Results: The study has completed accrual, with 66 patients (p) enrolled. Baseline characteristics (62 p): median age 62 yrs. (range 41−79); male 90%; smokers 95%; ECOG PS 0/1 92%; adenocarcinoma/squamous 24/63%; stage IIIA/IIIB 26/74%. Most common previous CRT regimen was cisplatin/docetaxel/RT (79%); 71% had achieved partial response with the CRT.
55 p (89%) were evaluable for tumour response: RR 33%; SD 55%; 54% of p concluded the treatment as per protocol, being the progression-free rate at 6 months of 74%. With a median follow-up of 14.8 m (95% CI: 12.8–17.8), the median TTP was 9.9 m (95% CI: 5.9–12.10), and median OS 22.9 m (95% CI: 16.0-Not reached). Most common adverse events (AE) related to E were rash (58%; 10% grade 3), and diarrhoea (26%; only 1 p grade 3), asthenia (15%) and anorexia (16%). 4 p (7%) were withdrawn due to AE.
Conclusions: Single agent erlotinib as maintenance therapy is an active treatment after concurrent CRT in p with stage III NSCLC, reaching a promising median OS of 23 months. The safety profile of maintenance erlotinib was as expected and manageable. Final results of the study will be presented during the meeting.

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Phase 1b Study of Oral PPAR-gamma Agonist Efatutazone (CS-7017) in Combination With Carboplatin and Paclitaxel in Chemotherapy-Naive Korean Patients With Metastatic or Unresectable Locally Advanced Non-Small Cell Lung Cancer

K. Park[1], M.J. Ahn[1], J.S. Ahn[1], J. Lee[1], J.M. Sun[1], J.H. Yi[1], S.H. Cho[1], J.Y. Lee[1], S. Park[1], D.W. Hwang[1]. [1]*Samsung Medical Center, Sunkyunkwan University School of Medicine, Seoul, Korea*

Background: Efatutazone is a novel, third-generation thiazolidinedione (TZD) showing higher potency over second-generation TZDs, such as pioglitazone. In non-Asian patients, the recommended dose is 0.50 mg twice-daily (BID) in accordance with pharmacokinetics (PK), pharmacodynamics (PD) and safety analyses in a US phase 1 study.
This study assessed the safety, tolerability, antitumour activity, PK, and PD, and determined the recommended dose of efatutazone in combination with CBDCA/PAC in Korean patients.
Materials and Methods: This was an open-label, dose-escalation study using a 3+3 design in combination with carboplatin (CBDCA) and paclitaxel (PAC). Each patient participated in only 1 dose group and received oral efatutazone 0.25 mg BID or 0.50 mg BID with every 3-week administration of CBDCA (target AUC 6 mg/mL/min) and PAC (200 mg/m^2). After determining the recommended dose of efatutazone, 9 additional patients were enrolled for further assessment of efatutazone. Patients with preexisting severe fluid retention were excluded. PK samples for efatutazone and PAC were collected to assess the drug–drug interaction (DDI). PD samples were also collected. All subjects provided written informed consent.
Results: A total of 16 patients were enrolled (11 male and 5 female; age range: 40−70 years) and received treatment at doses ranging from 0.25 to 0.50 mg BID. Dose-limiting toxicities were not observed, and the maximum tolerated dose (MTD) was not reached. Efatutazone was well tolerated. The majority of patients experienced edema and weight increase, often requiring diuretics. Six out of 16 patients showed partial response (PR; 3 confirmed) and 4 patients showed stable disease (SD). Efatutazone increased plasma adiponectin levels. Plasma concentration of efatutazone was dose-proportional, and DDI between efatutazone and PAC was not observed.
Conclusions: Efatutazone in combination with CBDCA/PAC is a novel anticancer therapy, which is tolerated and demonstrates early evidence of antitumour activity. Although the MTD was not reached, 0.50 mg BID, corresponding to the global recommended dose, was selected as the recommended dose for Korean patients based on PK/PD, and safety analyses. Full safety data and clinical activity data will be presented.
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