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The efficacy of ZD1839 (Iressa) in patients with advanced non-small cell lung cancer (NSCLC) who have progressed after previous chemotherapy

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Recently, the small molecule EGFR-tyrosine kinase inhibitor (ZD1839) with the antitumor activity against NSCLC has been developed. We evaluated the efficacy and toxicity of ZD1839 in patients with advanced NSCLC who had progressed after previous chemotherapy between January 2002 and January 2003 in Korea Cancer Center Hospital. ZD1839 was administered with the dose of 250 mg p.o. daily, which was continued until disease progression or untreatable side effects. The median age was 56 (range 33-81) and the initial stage of most patients was IV. The performance status (ECOG) was 1 in 44 patients and 2 in 21 patients. The number of previous chemotherapy regimen was 1 in 22 patients, 2 in 28 patients, 3 in 12 patients and 4 in 3 patients. Of the enrolled 65 patients, 52 patients had one or more bidimensionally measurable lesions, whose responses were as follows; partial response in 11(21%) patients, stable disease in 21(40%) patients. Twenty patients (39%) progressed during the treatment. Among 13 patients with non-measurable, but evaluable lesions, 4 patients showed improvement of the disease and 9 patients showed progression during treatment. Median time to progression was 4.4 (range 0-16+) (95% C.I., 2.1-6.8) months. Median overall survival after initiation of ZD1839 treatment was 8.4 (range 1-18.6+) (95% C.I., 8.1-11.5) months. The most common adverse effect of ZD1839 was skin eruption which represented in 19 patients (29%). Other adverse events were mild. ZD1839 showed modest activity and tolerable toxicity in the treatment for patients with NSCLC progressed after previous chemotherapy.

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Phase II trial of gemcitabine and cisplatin as first-line treatment of advanced non-small -cell lung cancer (NSCLC)

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Background The prognosis of patients with advanced NSCLC is extremely poor. Many prospective randomized trials for patients with advanced NSCLC suggested systemic chemotherapy improve survival and quality of life.
Methods We conducted a phase II trial on the efficacy and safety profile of combination chemotherapy of gemcitabine and cisplatin in advanced NSCLC. Patients with stage IIIB with malignant effusion or IV. ECOG performance status (PS) of 0-2, measurable disease, age 18-75, no prior chemotherapy and good organ function were enrolled. The patients received cisplatin 75 mg/m^2 IV over 30 minutes on days 1, followed by gemcitabine 1,250 mg/m^2 IV over 30 minutes, days 1 and 8 every 3 weeks.
Results Between Feb. 2001 and Oct. 2002, 44 patients were enrolled. Of these, 41 patients were evaluable and median age 64 years (range 27-75), median ECOG PS 1 (range 0-2), 21 stage IIIB and 20 IV, 24 adenocarcinoma and 17 squamous cell carcinoma, Total of 179 cycles have been and median cycles of chemotherapy was 4 cycles (range 2-9). Hematological toxicities are grade 3/4 neutropenia in 7/10 (17/24%) patients, grade 3/4 thrombocytopenia in 1/7 (2/17%) patients. The most common non-hematological toxicities are grade 2/3 fatigue in 5/8 (12/19%) and grade 3 pruritus in 3 (7%). Treatment related mortality was not observed. The median duration of follow up was 9.4 months (range 1.6-30.3). The response rate was 54%, the CR 0% (0/41), the PR 54% (22/41), the SD 10% (4/41), and the PD 36% (15/41). The median time to progression was 5.6 months (range 1-15.4). The median survival was 14.2 months (95% CI:13.8-22.5). Also we observed that patients with NSCLC who responded to chemotherapy significantly have improved survival ($p<0.04$).
Conclusion In this trial, the combination of gemcitabine and cisplatin showed a significant activity with acceptable and manageable toxicities as first line regimen for patients with advanced NSCLC. The response to chemotherapy seems to be a prognostic factor.