50.A Phase II Study of Erlotinib for Previously Treated Patients with Non-Small Cell Lung Cancer

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[Purpose] To evaluate the efficacy and safety of erlotinib in patients with previously treated non-small cell lung cancer (NSCLC), a phase II trial was studied in Kochi prefecture.

[Patients and methods] Patients with stage IIIB/IV NSCLC and performance status 2 or lower, previously treated with 1 or 2 non- EGFR-TKI regimens were eligible. The enrollment has started since august 2009. Patients received erlotinib (150mg/day) until disease progression or intolerable toxicity. Primary end point was the response rate (RR). In addition, disease control rate (DCR), progression free survival (PFS), and safety were evaluated.

[Results] Thirty eight patients were enrolled, and 32 patients were evaluated. Median age was 69 years (range, 57 years to 80 years). Characteristics of patients were as follows: men /women, 21/11; PS0/1/2, 11/16/5; adenocarcinoma/ non- adenocarcinoma, 23/9. The objective RR and DCR were 31% and 65%, respectively. Twenty one patients could be evaluated for EGFR status (9 mutated/ 11 wild type). The RR of EGFR mutated patients was 67%, while wild type 17%. PFS of 24 cases were evaluated as 117 days. Major adverse events were tolerable skin toxicities, diarrhea, and stomatitis.

[Conclusion] Erlotinib was efficacious in patients with previously treated NSCLC. Efficacy and safety were similar to previous reports.