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PHASE Ⅱ STUDY OF GEMICITABINE(GEM) IN ELDERLY JAPANESE PATIENTS WITH ADVANCED NON-SMALL CELL LUNG CANCER(NSCLC)

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BACKGROUND/AIMS: To evaluate the efficacy and safety of the chemotherapy with a single agent of GEM, we conducted a phase Ⅱ study of GEMin elderly Japanese patients with previously untreated, advanced NSCLC.

METHODS: The study was conducted during the period of January 2004 to December 2005. It involved previously untreated NSCLC patients with measurable stage ⅢB or Ⅳ disease but without brain metastasis, with ECOG PS 0-2, aged over 70 yearsold, with adequate hematological, hepatic and renal function. Patients were treated with GEM 1000 mg/m2 IV, first and eighth day, every 21 days for six cycles.

RESULTS: Twelve patients were enrolled and 9 have been analyzed at the time of report. Of the nine patients, 7 were male and 2 were female, with a median age of 78 years. All of the nine patients had adenocarcinoma, 3 with stage ⅢB and 6 with stage Ⅳ. The median number of administered cycles was 3 of 6 -planned schedules. Three out of nine patients had responses of 0 CR and 3 PR. Grade 3 neutropenia occurred in one patient. Grade 3 pneumonitis was seen in another patient and disappeared after steroid administration. Other side effects (anemia, thrombocytopenia and hepatotoxicity) were within grade 2 level. GEM was administered in 13 cycles out of a total 19 cycles planned in treatment schedule (68%).A dose reduction or skip was required in 6 cycles (32%) because of drug toxicity.

DISCUSSION/CONCLUSION: Single use of GEM appeared to be active for elderly Japanese patients with advanced NSCLC, but dose modification is required to confirm the safety because of relatively high rate of dose reduction and skip.

Key words: Gemicitabine, non-small cell lung cancer, elderly Japanese patients