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The current approach to treatment of non-small cell lung cancer (NSCLC) is a combination of platinum-based chemotherapy with a targeted agent. A recent Phase III study has established that the combination of erlotinib and platinum-based chemotherapy is superior to chemotherapy alone in the treatment of patients with advanced NSCLC. Subsequently, two subgroup analyses have shown a modest survival advantage with erlotinib in combination with the standard chemotherapy regimen of carboplatin and paclitaxel (Taxol; Bristol Myers Squibb) compared to chemotherapy alone, and erlotinib in combination with gemcitabine and cisplatin (GC) compared to GC alone. This project will

evaluate the combination of erlotinib with GC in a pilot, Phase II trial of 15 patients with Stage IIIA or IIIB NSCLC without evidence of distant metastases, or Stage IV, erlotinib-naive NSCLC with distal metastases. Patients will be treated with erlotinib, 100 mg/d, continuously in combination with GC, 60 mg/m²/wk for 4 weeks, followed by 2 weeks of rest, for 6 cycles, and will be evaluated for safety and response to treatment. Patients will be stratified according to age and tumor histology and subjected to randomization for carboplatin AUC = 5 (Day 1, q21 days for 4 cycles) and paclitaxel 175 mg/m² (Day 1, q21 days for 4 cycles) (Arm A) versus cisplatin 50 mg/m² (Day 1, q21 days for 4 cycles) and paclitaxel 150 mg/m² (Day 1, q21 days for 4 cycles) (Arm B). Patients will be followed for 3 years and will be evaluated at baseline, 4 and 24 weeks during the first and third cycle, at 6

weeks during the second cycle, and at 7, 10 and 12 weeks during the sixth cycle. In addition, the patients will have clinical follow-up every 3-4 months for 3 years. Patients who are recruited to this project will be followed for at least 3 years to determine long term survival. Additional subgroup analyses will be performed. A follow-up trial of the combination of erlotinib with GC in an expanded group of patients with advanced NSCLC will be planned.

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