ABSTRACT

Background: Continuous exposure of tumor cells to therapy in advanced NSCLC might lead to resistance in treatment. Therefore, Pemetrexed 100 mg/m² was administered as second-line therapy in 130 patients (83.9%) to 22 patients with chemotherapy-naive disease in the observation arm (16.1%).

Methods: Stage IIIIB/IV NSCLC patients (≥65 years) who were treated after ≥3 cycles of first-line chemotherapy and showed disease progression were given as second-line treatment of disease progression in all arms and OS and PFS were compared. For patients included in the observation arm, treatment response to second-line therapy was also analyzed.

Results: 120 of 130 patients received second-line therapy. The trial included a pre-defined protocol analysis. OS and PFS were compared. The trial was analyzed according to per-protocol analysis as a second-line therapy in advanced NSCLC.

Conclusion: Maintenance therapy with pemetrexed or erlotinib did not improve efficacy of second-line treatments compared to administration after a first-line treatment.

Introduction:

In advanced NSCLC, maintenance therapy may be indicated for patients whose tumors have not progressed following 3 to 4 cycles of platinum-based chemotherapy (PFC). After achieving manageable clinical response, a platinum-component free-therapy, such as pemetrexed or erlotinib, may be “switching” to a new agent, such as a target or conventional.

Results based on maintenance arm treatment were the concordant validity of maintenance chemotherapy.

Study design:

Stage IIIIB/IV NSCLC patients with Eastern Cooperative Oncology Group (ECOG) performance status 0-1 and adenocarcinoma or squamous disease (50.3%) after 4 cycles of platinum-based chemotherapy were randomized either to observation or maintenance with erlotinib or pemetrexed in PFC 06-02 study design. Maintenance therapy with pemetrexed or erlotinib was administered for second-line treatment in advanced NSCLC.

Patients and methods:

Study design:

Stage IIIIB/IV NSCLC patients with Eastern Cooperative Oncology Group (ECOG) performance status 0-1 and adenocarcinoma or squamous disease (50.3%) after 4 cycles of platinum-based chemotherapy were randomized either to observation or maintenance with erlotinib or pemetrexed in PFC 06-02 study design. Maintenance therapy with pemetrexed or erlotinib was administered for second-line treatment in advanced NSCLC.