AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: EGFR-TKI
ACTIVE INGREDIENT: N/A

Study No: NIS-OTW-IRE-2009/1

A multi-centre, naturalistic study to explore the correlation between smoking pattern and clinical efficacy of EGFR TKI in male patients with locally advanced or metastatic non-small cell lung cancer of adeno histology failed 1st line chemotherapy

Developmental Phase: IV
Study Completion Date: 31 Dec 2010
Date of Report: 29 Nov 2011

OBJECTIVES:

The objective was to investigate the correlation between smoking pattern and clinical efficacy of EGFR TKIs in male patients with locally advanced or metastasized non-small cell lung cancer of adeno histology who have failed 1st line chemotherapy.
Health care resource usage, quality of life (EQ-5D) and practice of EGFR mutation test were also evaluated.
Current practice of EGFR mutation testing in Taiwan was surveyed.

METHODS:

This was an observational, multicenter, open-label, non-comparative study of EGFR-TKI (gefitinib or erlotinib) in patients with advanced NSCLC of adeno histology who had failed 1st line chemotherapy regimen. This study investigated only daily practice. The prescription of anti-cancer medicine was separated from the decision to include the patient in this study. In addition, the assignment of the patient to a particular therapy or therapeutic strategy was not decided in advance by this study protocol, but fell within current practice. The patients were enrolled after the decision to put them on either gefitinib or erlotinib. Namely, a patient can only be enrolled after he/she received prescription of either gefitinib or erlotinib as 2nd line therapy.
These patients were seen at a frequency determined by their physician and in accordance with standard medical care. The frequency of tumor response evaluation by RECIST criteria followed the investigator's discretion as daily practice. This study design was chosen with the aim of recruiting rapidly a large cohort of patient representative of the population being prescribed with EGFR-TKI.

All analyses were performed for all the enrolled patients.
The correlation between smoking patterns and time to event (PFS, OS) were analysed by using Cox regression model. The logistic regression model was used for evaluating the correlation between smoking patterns and best overall tumor response. For categorical variables, summary statistics included the number of subjects and percentage for each category. For continuous variables, summary statistics included the number of observations, mean, standard deviation, median, minimum, and maximum values. The change from baseline of QoL score was analyzed using paired t-test.

RESULTS:

A total of 186 subjects were included in the current study analysis, among which 124 subjects received Iressa® and 62 subjects received Tarceva®. Number of subjects analysed for EQ-5D assessment were 79 and 40 patients for Iressa® and Tarceva® group, respectively.

The average was 65.0 years old, ranging from 39 to 93 years old. The age at NSCLC original diagnosis was 64.1 years old, ranging from 38 to 91 years old. The majority of the subjects (122 subjects, 65.59%) were at stage IV at original diagnosis. All the subjects were diagnosed as adenocarcinoma except that 5 subjects were bronchioloalveolar. 48 subjects (25.81%) received relevant surgery previously. Most of the subjects (89.25%) had 0 or 1 scale for WHO performance status at enrolment. 48.39% of subjects presented local lymph node involvement while 44.62% of subjects presented distant lymph node involvement. Most commonly reported metastatic sites were bone (30.65%) and contralateral lung (27.42%). The mean duration of drug administration was 122.2 days in overall and was 133.0 days and 100.6 days for Iressa® and Tarceva® group, respectively. Only 7 subjects (3.76%) had done EGFR mutation test in the pass.
The mean EQ-5D index was 0.768 while VAS scale was 64.5 at baseline. Problems were observed for 24.73%, 22.04%, 29.03%, 52.69%, and 37.10% for mobility, self-care, usual mobility, pain/discomfort, and anxiety/depression.

Summary of efficacy results

Among the 186 subjects, there were 22 patients (11.83%) reached best overall response in the current study.
Slightly higher response rate was observed for former smokers or patients with higher pack-years and CSI. However, the median time to progression disease and the median of the overall survival were relatively shorter in these subjects.
EQ-5D index and EQ-5D VAS did not reveal any statistically significant changes from baseline after subjects received EFGR-TKI.
The CSI sensitivity analysis showed that the CSI was increasing with half-life parameter, but the half-life parameter was fixed as 1.5 years in analysis

Summary of safety results

Not applicable.