STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Not applicable

ACTIVE INGREDIENT: Not applicable

Study No: NIS-OFR-DUM-2010/1
Observational study on the management of patients with Non Small Cell Lung Cancer (NSCLC) adenocarcinoma tested for the activating mutation of Epidermal Growth Factor Receptor Tyrosine kinase (EGFR TK)

Developmental phase: Not applicable
Study Completion Date: 31/08/2012
Date of Report: 28/06/2013

OBJECTIVE:

The main objective of the study was to determine the proportion of patients with M + mutation status among patients with Non Small Cell Lung Cancer adenocarcinoma

Secondary objectives were:

- To describe the therapeutic management according to the mutational status (EGFR M +, EGFR M- and Mx).
- To describe the therapeutic management of patients with EGFR M +
- To describe the clinical course of patients EGFR-M +, treated for first-line treatment, and then 2nd line treatment, until 31-AUG-2012

METHODS:

MUTACT was an observational, multicentre, French study. Patients ≥18 years old with histologically confirmed adenocarcinoma NSCLC (any stage) and EGFR mutation testing complete or ongoing, and who gave oral informed consent were included.
Follow-up (until the end of second-line treatment or until study closure) was limited to patients with locally advanced or metastatic EGFR M+ adenocarcinoma receiving first-line treatment.
EGFR mutation testing was performed in accordance with usual practice.
Demographics, disease characteristics and EGFR mutation status were recorded for all patients.

RESULTS:

Between September 2010 and August 2011, 1382 patients were enrolled at 76 sites in France.
All patients were tested for EGFR mutation status: EGFR M+/M-/non-evaluable (Mx) disease rates were respectively 20.6%, 76.1% and 3.3%. Mutation status data were not available for 7 patients (1%).
The observed rate of EGFR mutation of 20.6% was higher than previously reported in unselected French patients (around 10% according to INCa data, National French cancer institute). This may be explained by the clinical characteristics of the patients enrolled.

Patient demographics and disease characteristics

The majority of patients in the overall population were men (57%) of Caucasian ethnicity (95%). At diagnosis, most patients had stage IV disease (72%) and WHO (World Health Organization) performance status 0–2 (93%).
More women (57%) and more patients who had never smoked (30%) than would be expected in a mainly adenocarcinoma population were enrolled.
The proportion of never smokers was highest in the EGFR M+ population (70%) than in the overall population (30%).

EGFR mutation testing

Most samples were analyzed by direct sequencing (69%) using primary tumor tissue (77%), with a median turnover time of 12 days. EGFR M+/M-/non-evaluable (Mx) disease rates were respectively 20.6%, 76.1% and 3.3%.
Patients with EGFR M+ disease were mostly female (67%) and never-smokers (70%).
As expected, the majority of mutations were detected at exons 19 (54%) and 21 (37%), but mutations were also found at exons 18 (3%) and 20 (7%).
Overall, 1% patients had mutations conferring decreased sensitivity to EGFR TKIs (exon 20).

First-line treatment decision according to mutational status

At baseline, 633 patients (46%) were in 1st line treatment (others had surgery or were in 2nd/3rd line).
Out of the 283 patients with EGFR M+ disease, 186 (66%) were in 1st line treatment at inclusion; 158 (84%) of these received EGFR TKI.
The first-line treatment of patients with stage IIIB/IV adenocarcinoma and WHO PS0–2 was highly dependent on EGFR mutation status: 76% of patients with EGFR M+ status received gefitinib and 88% of patients with EGFR M- status received combination chemotherapy.

Clinical course of patients EGFR-M +

Data of 182 Patients EGFR M+ were collected until progression of 1st line or of 2nd line treatment (following amendment) or until the end of the study follow-up period (31 August 2012). Median duration of first-line treatment was 8.2 months and best overall response was partial response in 54.1% or stable disease 26.7%. 11 patients (7.5%) had a complete response to first-line treatment.
102 (56.0%) patients had a disease progression on first line, including 13 patients who died. Following amendment, 46.2% (84 patients) started a second line treatment. The most used 2nd line combination treatments were: carboplatin + pemetrexed (16.7%) and carboplatin + paclitaxel (14.1%). Monotherapy with erlotinib was administered to 20.5% of patients, and pemetrexed to 5.1%.