AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: N/A
ACTIVE INGREDIENT: N/A

Study No: NIS-OES-XXX-2012/1
Observational retrospective study to describe the management of advanced or metastatic EGFR mutated non-small cell lung cancer patients in Spain

Developmental Phase: Non-Interventional Study
Study Completion Date: 01/10/2013
Date of Report: 30/07/2014

OBJECTIVES:

Main Objetive:

- To describe management patterns (clinical and diagnostic) of advanced/metastatic EGFR M+ NSCLC patients in Spain.

Secondary objectives:

- To describe the use of resources related with the management of advanced/metastatic EGFR M+ NSCLC patients in Spain.
- To evaluate disease control rate, progression free survival (PFS: median PFS and 1 year PFS rate), and overall survival (OS: median OS and 1 year OS rate) in advanced/metastatic EGFR M+ NSCLC patients in Spain.
- To describe the clinical outcome data in all EGFR M+ patients by regimen, type of EGFR TK mutation, line of therapy and other relevant demographics or clinic pathologic characteristics.

METHODS:

Non Interventional Study, treatments were not assigned by the study plan but were determined at the discretion of the physicians according to current standard medical practice.

Study population

Once sites were selected, all patients newly diagnosed (*de novo* or progressing from non-advanced disease) with advanced/metastatic EGFR mutated NSCLC from April 2010 to December 2011 were included as study population.

These patients were retrospectively followed up a minimum of 9 months until the date of data collection. This means that the total follow-up length was different for any patient.

Inclusion criteria

The subject population observed in the Non Interventional Study, had to fulfill all of the following criteria:

1. Obtain signed informed consent from the subject or their guardian/legal representative before any study specific procedures were performed. Nevertheless, given the natural history of the disease, and taking in account that data were collected in a retrospective way, in some cases it was not able to locate the subject or their related: in this case, the investigator recorded in writing this circumstance.

2. Female and/or male aged 18 years and over

3. Histologically or citologically confirmed newly locally advanced or metastatic NSCLC (stage IIIB/IV)

4. Confirmed EGFR mutation by a validated test

5. Availability of medical record

The prescription of the medicinal product was clearly separated from the decision to include the subject in the NIS.

Exclusion criteria

1. Participating on a blinded randomized clinical trial at any time during the study period.
2. Pregnant women (due to they do not reflect daily clinical practice).

RESULTS:

A total of 181 evaluable pts were enrolled in the study. Median age was 71.6 (IQR 16.8) years. The majority of pts were Caucasian (98.3%), female (61.9%), never-smokers (54.9%), PS 0-1(80.1%) and had non-squamous histology (93.9%). Mutation testing was performed preferentially in biopsy material (68.7%) in external laboratories in 68.0% with RT-PCR-based tests 87.9% (Therascreen EGFR PCR KitTM 51.5%). Median turnaround time was 9 days. We observed 9.4% any exon 18 mut, 53.3% exon 19 deletion, 21.1% L858R mut, 3.9% any exon 20 mut, 3.9% L861Q mut and 8.3% other exon 21 mut. The vast majority of pts (92.8%) received first line (1L) treatment being EGFR TKIs in 81.5% (82.6% gefitinib and 17.4% erlotinib), chemotherapy (CT) in 13.7%, and CT follow by TKI in 4.8 %.
Only 47.0% of pts received second line (2L) treatment. Pts who progressed on TKI, in 2L, were treated with CT (33.9%), TKI+CT (8.9%), or different TKIs (9.8%). At the time of analysis, the median follow-up time was 13.3 months (range 0.4-38 months). Efficacy results by line and treatment for pts evaluable for response (150) are shown in Table 1.

First line			
Treatment (n)	**ORR (%)**	**DCR (%)**	**mPFS (m)**
TKI (124)	46.8	87.9	9.9
Gefitinib (100)	50	86	9.9
Erlotinib (24)	36.4	95.5	9.9
CT (18)	22.2	77.8	5.2
CT → TKI (8)	25.0	100.0	7.6
Second line			
TKI (18)	22.2	55.6	4.9
CT (36)	13.9	69.4	4.8
TKI+CT (8)	25	87,5	5,1