

## STUDY REPORT SUMMARY

### ASTRAZENECA PHARMACEUTICALS

**FINISHED PRODUCT:**  
**ACTIVE INGREDIENT:**

**Study No:**

**NIS-OBR-DUM-2008/1**

**Developmental phase:** N/A

**Study Completion Date:** 01/Feb/2011

**Date of Report:** 23<sup>rd</sup> of March, 2011

### OBJECTIVES:

The primary objective of this study is to analyze the frequency and type of KRAS mutation in a sample of the Brazilian population with advanced NSCLC.

### METHODS:

Multicenter, cross-sectional observational study in 105 patients diagnosed with advanced NSCLC, eligible for first-line chemotherapy and WHO Performance Status 0-1, older than 18 years and included between 3<sup>rd</sup> Dec. 2010 and 18<sup>th</sup> Feb. 2011.

Data regarding demographic data, histological/cytological history of NSCLC, smoking status, previous metastatic disease treatments and tumor sample information were collected for each patient.

A sample of tumor tissue, paraffin fixed, was sent to *Laboratório Progenética* (Rio de Janeiro – Brazil) for mutational analysis.

All statistical analyses were performed using IBM® SPSS® Statistics 18.0.

### RESULTS:

Patients' average age was approximately 60 (min-max: 37-85) years. 59% of the patients were male and 78.1% Caucasian. Approximately 80% of the patients were smokers or ex-smokers.

Patients' age at diagnosis was approximately 58.7 years (min-max: 35 – 83). The mean duration of NSCL was approximately 1.5 years.

Regarding the histological type of NSCLC, adenocarcinoma registered the highest prevalence rate (57.1%) and large cell carcinoma the lowest prevalence (10.5%). Most of the NSCLC cases were metastatic (72.4%).

In 11.4% of the patients the result of KRAS mutation was positive (95% CI: 5.3% - 17.5%), being Gly13Asp (GGC>GAC) the most common mutation, registered in 33.3% of all positive cases.

About 97% of the patients were being treated for metastatic disease.