2LB Late Breaking

# Phase III, randomized, open-label, parallel-group study of oral gefitinib (IRESSA) versus intravenous docetaxel in patients with locally advanced or metastatic non-small-cell lung cancer who have previously received platinum-based chemotherapy (INTEREST)

J.Y. Douillard[1], E.S. Kim[2], V. Hirsh[3], T. Mok[4], M. Socinski[5], R. Gervais[6], L.Y. Wu[7], L. Li[8], M. Sellers[9], E. Lowe[10]

*[1]Centre René Gauducheau, Site Hospitalier Nord, Nantes-Saint-Herblain, France; [2]M.D. Anderson Cancer, Thoracic Head and Neck Medical Oncology, Houston, TX, USA; [3]McGill University, Medical Oncology, Montreal, Canada; [4]Prince of Wales Hospital, Clinical Oncology, Hong Kong, China; [5]Lineberger Comprehensive Cancer Center, Medical Oncology, Chapel Hill, NC, USA; [6]Centre F. Baclesse, Medical Oncology, Caen, France; [7]Guangdong People's Hospital, Lung Cancer Research Institute and Cancer Center, Guangzhou, China; [8]Peking Union Medical College Hospital, Lung Cancer Research Institute and Cancer Center, Beijing, China; [9]AstraZeneca, Research and Clinical Development, Macclesfield, United Kingdom; [10]AstraZeneca, Medical Science Oncology, Wilmington, DE, USA*

**Background:** Phase III, randomized, open-label, parallel-group study compared gefitinib with docetaxel in patients with locally advanced or metastatic recurrent NSCLC who had received platinum-based chemotherapy (INTEREST [IRESSA NSCLC Trial Evaluating REsponse and Survival against Taxotere]).

**Methods:** Patients (⩾18yrs) with locally advanced or metastatic NSCLC that progressed or recurred following 1 or 2 prior chemotherapy regimens (⩾1 platinum-based) were randomized to gefitinib (250 mg/day orally) or docetaxel (75 mg/m$^2$ iv every 3 wks). Primary objective was to compare overall survival (OS) between treatments in the total population (non-inferiority) and in patients with high EGFR gene copy number by FISH (superiority). Secondary endpoints were progression free survival (PFS; assessed by RECIST), objective response rate (ORR; assessed by RECIST), patient-reported functionality and QoL (via FACT-L total score, trial outcome index [FACT-L TOI] and lung cancer subscale [FACT-L LCS]), and tolerability (using CTC version 2.0). OS was compared between treatments primarily using a Cox proportional hazards model analysis, adjusting only for randomized treatment.

**Results:** 1466 patients from 149 centers in 24 countries were randomized to gefitinib (n = 733) or docetaxel (n = 733); 323 patients were of Asian racial origin. In the gefitinib and docetaxel treatment arms, respectively, 54% and 55% had adenocarcinoma, 36% and 33% were female, and 20% and 21% were never-smokers. 30%, 58%, 12% and 25%, 63%, 12% had PS 0, 1, 2 in the gefitinib and docetaxel treatment arms, respectively. 15% (gefitinib) and 17% (docetaxel) had undergone 2 prior chemotherapy regimens. 453 patients provided a tumour sample giving at least one evaluable biomarker. Full results will be presented at the conference.

**Conclusions:** The data available at this time indicate the primary endpoint of the study was met; gefitinib was statistically non-inferior to docetaxel in terms of overall survival in the overall population.