

IRESSA™ (GEFITINIB) RECEIVES MARKETING AUTHORISATION FOR THE TREATMENT OF NON-SMALL CELL LUNG CANCER IN EUROPE

AstraZeneca announced today that the European Commission has granted marketing authorisation for the oral anti-cancer drug, IRESSA™ for the treatment of adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of EGFR-TK (epidermal growth factor receptor-tyrosine kinase) across all lines of therapy. The authorisation is based on a submission package including two pivotal Phase III studies comparing IRESSA with chemotherapy, IPASS¹ and INTEREST².

IRESSA acts by inhibiting the tyrosine kinase enzyme in the EGFR, thus blocking the transmission of signals involved in the growth and spread of tumours. A mutation in the EGFR is a characteristic occurring in 10-15% of lung cancers in non-Asians³, and studies have shown that these types of tumours are particularly sensitive to IRESSA^{1,4}.

Anders Ekblom, Executive Vice President for Development at AstraZeneca, said: "IRESSA is the first truly targeted treatment for lung cancer, and the EU marketing authorisation today represents an important step forward in the treatment of this devastating disease. For the first time, patients with EGFR mutation positive tumours will have a more effective and better tolerated alternative to chemotherapy as a first-line treatment."

AstraZeneca will work closely with clinicians and pathology groups on a country-by-country basis to facilitate appropriate access to EGFR mutation diagnostic testing.

AstraZeneca has agreed to conduct a Follow-up Measure Study to generate further data in a Caucasian NSCLC patient population and is currently in discussion with the EMEA to finalise the study design and endpoints.

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NOTES TO EDITORS:

In 2005, AstraZeneca withdrew its EU marketing authorisation application for IRESSA following data from the Phase III international ISEL study in pre-treated patients not eligible for further chemotherapy. ISEL did not meet its primary objective of a statistically significant improvement in OS for IRESSA compared to placebo, but did confirm a number of important clinical benefits for IRESSA including tumour shrinkage and a significant improvement in time to treatment failure. The refractory* nature of the ISEL population is the most likely explanation for the magnitude of the survival improvement with IRESSA compared to placebo not reaching statistical significance.

** Patients whose tumours had grown during or soon after receiving prior chemotherapy*

Following delivery of the INTEREST data, AstraZeneca submitted a new regulatory package to the EMEA in May 2008; the IPASS data were added to the submission package when they became available in Q3 2008.

There is a rolling programme of approvals and licence updates for IRESSA around the world in a broad second-line population based on data from the INTEREST study.

IRESSA is already an established therapy for pre-treated NSCLC in the Asia-Pacific region, where AstraZeneca is in consultation with regulatory authorities to discuss the potential use of IRESSA in first-line therapy.

About the INTEREST² and IPASS¹ studies

The INTEREST (IRESSA Non-small-cell lung cancer Trial Evaluating REsponse and Survival against Taxotere) study was a randomised, open-label, parallel-group, Phase III trial evaluating survival with IRESSA versus docetaxel in 1,466 patients with locally advanced or metastatic recurrent NSCLC who had previously received platinum-based chemotherapy. The primary endpoint of INTEREST was OS, with the objective of demonstrating that IRESSA was non-inferior to docetaxel chemotherapy.

IPASS (IRESSA Pan-ASia Study) was an open label, randomised, parallel-group study that assessed the efficacy, safety and tolerability of IRESSA versus carboplatin/paclitaxel as first-line treatment in a clinically selected population of patients from Asia. The primary endpoint of IPASS was PFS (the length of time a patient lives without their tumour progressing), with the objective of demonstrating that IRESSA was non-inferior to carboplatin/paclitaxel doublet chemotherapy.

The study enrolled 1,217 patients in Asia with advanced NSCLC who had not received prior chemotherapy for advanced disease, whose tumours were of adenocarcinoma histology and who had either never smoked, or were former light smokers (ceased smoking at least 15 years ago and <= 10 pack-years exposure).

About AstraZeneca

AstraZeneca is a major international healthcare business engaged in the research, development, manufacturing and marketing of meaningful prescription medicines and supplier for healthcare services. AstraZeneca is one of the world's leading pharmaceutical companies with healthcare sales of US\$ 31.6 billion and is a leader in gastrointestinal, cardiovascular, neuroscience, respiratory, oncology and infectious disease medicines. For more information about AstraZeneca, please visit: www.astrazeneca.com

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- (4) Sequist LV. et al. First-line gefitinib in patients with advanced non-small cell lung cancer harbouring somatic EGFR mutations. *Journal of Clinical Oncology*; 26: 2442-2449. 2008.