New Drug Application for IRESSA accepted by US FDA

NEW DRUG APPLICATION FOR IRESSA ACCEPTED BY

US FOOD AND DRUG ADMINISTRATION

AstraZeneca today announced that the US Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for IRESSA® (gefitinib) as a targeted monotherapy for the first line treatment of patients with advanced or metastatic epidermal growth factor receptor mutation positive (EGFRm) non-small cell lung cancer (NSCLC), as identified through a companion diagnostic test. The Prescription Drug User Fee Act goal date for IRESSA will be in the third quarter 2015.

IRESSA is an EGFR tyrosine kinase inhibitor that acts by blocking the transmission of signals involved in the growth and spread of tumours. AstraZeneca's NDA submission for IRESSA was based on data from the Phase III IFUM1 (**I**RESSA **F**ollow-**U**p **M**easure) clinical trial, providing evidence of IRESSA's efficacy in Caucasian patients. This was supported by results from the IPASS2 (**I**RESSA **P**an-**AS**ia **S**tudy) clinical trial, as well as other collaborative group studies.

IRESSA is already approved in 90 countries for the treatment of adult patients with locally advanced or metastatic NSCLC with activating mutations of the EGFR tyrosine kinase.

1 Douillard JY, *et al*. Efficacy, safety and tolerability results from a phase IV, open-label, single arm study of 1st-line gefitinib in Caucasian patients with epidermal growth factor receptor mutation-positive non-small-cell lung cancer. European Multidisciplinary Conference in Thoracic Oncology, Lugano, Switzerland, May 9-11, 2013; abstract 68O.

2 Maemondo M, *et al*. Gefitinib or chemotherapy for non-small-cell lung cancer with mutated EGFR. *N Engl J Med* 2010;362:2380-8.

About IRESSA
IRESSA is a targeted monotherapy for the treatment of patients with advanced or metastatic epidermal growth factor receptor mutation positive (EGFRm) non-small cell lung cancer (NSCLC). 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. EGFR mutations occur in approximately 10-15 percent of NSCLC patients in Europe and 30-40 percent of NSCLC patients in Asia.

IRESSA was launched in 2002 and is now approved in 90 countries worldwide.

In the US, AstraZeneca is working with Qiagen to develop a companion diagnostic test to guide the use of IRESSA in the treatment of patients with advanced NSCLC.

In Europe, the collaboration between AstraZeneca and Qiagen has resulted in IRESSA becoming the first EGFR tyrosine kinase inhibitor to have a European label allowing the use of circulating tumour DNA (ctDNA) obtained from a blood sample, to be used for the assessment of EGFR mutation status in those patients where a tumour sample is not an option.

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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