European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 23 April 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
IRESSA

International Nonproprietary Name (INN): ***gefinitib***

On 23rd April 2009 the Committee for Medicinal Products for Human Use (CHMP), adopted a positive opinion,*** recommending to grant a marketing authorisation for the medicinal product Iressa, 250mg, film coated tablets intended for the treatment of non-small cell lung cancer (NSCLC). The Applicant for this medicinal product is AstraZeneca AB.

The active substance of Iressa is gefinitib, an anti-neoplastic medicinal product *(ATC Code* L01XX31) which targets the epidermal growth factor receptor (EGFR) tyrosine kinase and acts as an inhibitor of cell growth by competing with ATP and blocking activation through the receptor.

The benefits with Iressa are its significant improvement in objective response rates, progression free survival and quality of life in patients with tumours that have tested positive for EGFR with an activating mutation. The safety of gefitinib was acceptable and, overall, gefitinib was considered well tolerated. The most common side effects are rash and diarrhoea which were reported at high frequencies. For patients treated with gefitinib, there is an increased risk for interstitial lung disorders (ILD), which is fatal in approximately 1 in every 3 patients affected with ILD.

A pharmacovigilance plan for Iressa, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: Iressa is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of EGFR-TK (see section 5.1).
Treatment with Iressa should be initiated and supervised by a physician experienced in the use of anticancer therapies.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Iressa and therefore recommends the granting of the marketing authorisation.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

*** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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