



Date: September 7, 2005  
Subject: IRESSA Access Program

Astra Zeneca announced that after discussion with the U.S. Food and Drug Administration (FDA), the company is making a labeling change to IRESSA® (getfitinib tablets). Based upon the lack of survival benefit in the Phase III Trial 709 (ISEL) comparing IRESSA® to placebo in advanced recurrent NSCLC and the availability of other drugs that do prolong life, the revised label indicates that IRESSA® is only to be used in patients who are benefiting or have benefited from IRESSA®.

After September 15, 2005, no new patients will allowed access to IRESSA® unless they are being enrolled into a clinical trial that was approved by an Institutional Review Board (IRB) prior to June 17, 2005, or they are part of a clinical study that is being conducted under an investigational new drug application (IND).

To implement the new labeling, as of September 15, 2005, AstraZeneca will initiate the **IRESSA Access Program** to fill renewal prescriptions for IRESSA through a single mail order pharmacy (Priority Healthcare) for patients meeting the criteria set forth by the label. IRESSA® will remain available in the United States through the IRESSA Access Program pending availability of new data that would support an additional revision to the label, or possible future withdrawal.

**Prior to September 15, 2005, patients can continue to obtain IRESSA® by prescription from local pharmacies. The IRESSA Access Program will become effective September 15, 2005, after which date commercial supply of IRESSA will be provided only through Priority Healthcare.**

Further information may be obtained at: [www.IRESSA-access.com](http://www.IRESSA-access.com)