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lungcanceralliance.org

June 8, 2005

Richard Pazdur, M.D., F.A.C.P.
Director
Office of Oncology Drug Products
Center for Drug Evaluation and Research (CDER)
U.S. Food & Drug Administration
5600 Fishers Lane, HFD-150
Rockville, MD 20857

Dear Dr. Pazdur;

The Lung Cancer Alliance recently wrote to you regarding the status of gefitinib (Iressa) as it pertained to patients with advanced lung cancer and the possibility of it being pulled from the market.

We shared with you our concerns in four areas: (1) We do not yet know how to fully evaluate the benefits of Iressa given that certain subsets of patients appear to benefit more than others. (2) That it might be premature to pull Iressa from the market given that all of the phase IV data is not in yet and that no new safety concerns have developed since Iressa was granted accelerated approval. (3) That quality of life for advanced lung cancer patients must be considered given that few treatment options are available for patients. (4) That a number of biologic selection parameters such as FISH analysis, immunohistochemistry analysis and mutations analysis could prospectively be applied to ongoing trials and studies thereby providing additional data for furthering our understanding of how Iressa benefits patient subsets.

In our letter we asked that you not act hastily to pull Iressa – or any other drug that appears to be tolerated --- from the market so that doctors and patients can do what they have always done, consider the data and make the decision that is right for them.

We have also taken the opportunity to discuss with AstraZeneca similar concerns—that they work with the FDA and lung cancer community to develop a policy that will allow for doctors and lung cancer patients to continue to have access to Iressa if doctors and their patients determine it would be an important treatment option.

As indicated in our letter, The Lung Cancer Alliance is interested in speaking with you in person on these issues before any decisions are made on the fate of Iressa. I would also like to suggest that representatives from AstraZeneca join our discussion. Since we are receiving inquiries, would like to be able to provide patients with the most current and accurate information possible. Please contact me at our Washington, DC office, (202) 463-2080.

Thank you again for your attention on this very important issue.

Sincerely,

A handwritten signature in cursive script, appearing to read "Laurie Fenton".

Laurie Fenton
President
Lung Cancer Alliance

CC: Patty Delaney, Office of Special Health Issues, FDA
Mary Lynn Carver, Director, Oncology Public Affairs, AstraZeneca
Lung Cancer Alliance Board of Directors