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Dear Dr. Garey;

March 4, 2015

By way of follow up to earlier submissions, attached please find prospective data from two independent randomized Phase III studies of afatinib regarding changes in patient reported outcomes (PRO) in Lux Lung 3 as well as the association between progression free survival and health-related quality of life in Lux Lung 6.

As before, my name, company affiliation and contact information are provided at the bottom of this correspondence.

Specifically, we are requesting a review of data relative to the first line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions (Del19) or exon 21 (L858R) substitution mutations.

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This placement is consistent with the FDA approved indication which reads as follows:

Indication and Usage

GILOTRIF is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions (Del19) or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

Limitation of Use

Safety and efficacy of GILOTRIF have not been established in patients whose tumors have other EGFR mutations.

In addition, the use in this indication is included in the NCCN treatment guidelines with a Category 1 recommendation.

The attached data demonstrate that treatment with afatinib in the Lux Lung 3 study was associated with significantly better control of two of the three pre-specified lung cancer-related symptoms and longitudinal global health status/QOL compared with cisplatin/pemetrexed. In addition, treatment with afatinib in the Lux Lung 6 study provided significant improvement compared with cisplatin/gemcitabine in Global Health Status/QoL score as well as physical, role and social functioning scales with longer time to deterioration and better mean scores over time, as detailed in the references cited below and attached:

1. Yang JC, Hirsh V, Schuler M, et al. Symptom control and quality of life in Lux Lung 3: A phase III study of afatinib or cisplatin plus pemetrexed in patients with advanced lung adenocarcinoma with EGFR mutations. J Clin Oncol 2013; 31: 3342–50.
2. Wu YL, Palmer M, Griebsh I and Lungershausen J. Evaluation of association between progression-free survival (PFS) with health-related quality of life (HRQOL) in lung cancer patients. ESMO 2014, Poster #1268P

Thank you in advance for your consideration of this data and please let me know of any additional information or level of detail that would be helpful in your evaluation.

Best regards,



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