

March 4, 2015



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Dear Dr. Garey,

In follow up to submission by Dr. William Goeckeler on February 4, 2015 data from 2 independent, randomized, controlled phase III studies; please consider this additional submission in evaluating the pharmacoeconomic impact of treating metastatic non-small cell lung cancer (NSCLC) harboring common mutations for EGFR in the first line setting. My name and contact information are contained in this correspondence.

The wholesale acquisition cost (WAC) for recommended starting dose of Gilotrif® (afatinib tablets) 40mg is less expensive than recommended starting dose of Tarceva® (erlotinib) 150mg for metastatic NSCLC, as per Truven Health Analytics' Red Book (accessed – 02/01/2015). Additionally, market research data from Ipsos, US Oncology Monitor, November 2014, indicates the average daily dose of TARCEVA (stage IIIb/IV NSCLC) for first line is 145mg. GILOTRIF remains less expensive than the mean (mg) dose of TARCEVA in metastatic NSCLC.

Tarceva Average Daily Dose (Stage IIIb/IV NSCLC)

6 Months Ending November 2014

Source: Ipsos US Oncology Monitor

	All lines	1L	2L	3L+
Mean (mg)	141	145	135	128
Median (mg)	150	150	150	125

We are requesting a review of the previously submitted 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. 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 pateints 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.

Limitations 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.

Thank-you for your consideration of this additional data.

Best Regards,
Kelly Burgeson

Kelly Burgeson

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