

Submitted by:

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NCCN Guidelines Panel: Non-Small Cell Lung Cancer

On behalf of Boehringer-Ingelheim Pharmaceuticals, Inc., I respectfully request the NCCN Non-Small Cell Lung Cancer Guidelines Panel to review the enclosed data including the recent Supplemental NDA approval (January 12, 2018) from the FDA for GILOTRIF (afatinib) tablets. This approval broadens GILOTRIF's (afatinib) indication as a first-line treatment for patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test.

FDA initially approved afatinib in 2013 for the treatment of patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test and in 2016 for metastatic, squamous NSCLC progressing after platinum-based chemotherapy.

Specific Changes: The guidelines for treatment of EGFR mutation positive NSCLC should be updated to include first line treatment with afatinib for patients with non –resistant mutations.

Rationale:

Demonstration of durable responses in a subset of 32 afatinib-treated patients with metastatic NSCLC harboring non-resistant EGFR mutations (S768I, L861Q, and/or G719X) other than exon 19 deletions or exon 21 L858R substitutions enrolled in one of three clinical trials (LUX-Lung 2, LUX-Lung 3, and LUX-Lung 6).

The following articles are submitted in support of this proposed change.

Yang ,James Chih-Hsin ,et al. Afatinib versus cisplatin-based chemotherapy for EGFR mutation-positive lung adenocarcinoma (LUX-Lung 3 and LUX-Lung 6): analysis of overall survival data from two

randomised, phase 3 trials. (Lancet Oncol. 2015 Feb;16(2):141-51. doi: 10.1016/S1470-2045(14)71173-8. Epub 2015 Jan 12)

Yang JCH, et al, Clinical Activity of Afatinib in Advanced NSCLC Harbours Uncommon EGFR Mutations: Combined Analysis of LL 2, 3, and 6 (Lancet Oncol.2015 July 16(7):830-8. doi: 10.1016/S1470-2045(15)00026-1. Epub 2015 Jun 4.

GILOTRIF [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc, 2018.

Sincerely,

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