Gilotrif® (afatinib) – Expanded indication

- On January 16, 2018, Boehringer Ingelheim announced the FDA approval of Gilotrif (afatinib), for the first-line treatment of 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.
    - Previously, Gilotrif was approved for EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.
    - This approval includes three additional EGFR mutations: L861Q, G719X and S768I.
    - Safety and efficacy of Gilotrif were not established in patients whose tumors have resistant EGFR mutations.
- Gilotrif is also approved for the treatment of patients with metastatic, squamous NSCLC progressing after platinum-based chemotherapy.
- The approval of Gilotrif for this expanded indication was evaluated in a pooled analysis of 32 patients with NSCLC harboring non-resistant EGFR mutations S768I, L861Q, and G719X enrolled in one of three clinical trials: LUX-Lung 2, LUX-Lung 3, and LUX-Lung 6.
    - The analysis showed that Gilotrif was active in the non-resistant EGFR mutations in confirmed responses and duration of response.
- The recommended dosage of Gilotrif for all indications is 40 mg orally, once daily until disease progression or no longer tolerated by the patient.

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