Alimta® (pemetrexed) – Expanded indication

- On June 5, 2018, Eli Lilly announced the FDA approval of Alimta (permetrexed) in combination with carboplatin and Keytruda® (pembrolizumab) for the initial treatment of patients with metastatic, non-squamous non-small cell lung cancer (NSCLC).
    - This indication is approved under accelerated approval based on tumor response rate and progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.
    - This indication was added to the Keytruda drug label in May 2017.

- Alimta is also indicated for the following:
    - In combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, non-squamous NSCLC
    - As a single agent for the maintenance treatment of patients with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy
    - As a single agent for the treatment of patients with recurrent, metastatic non-squamous NSCLC after prior chemotherapy
    - Initial treatment, in combination with cisplatin, of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.

- The expanded indication for Alimta was based on cohort G1 of the KEYNOTE-021 study, which included 123 patients who were previously untreated with metastatic, non-squamous NSCLC with no epidermal growth factor receptor or anaplastic lymphoma kinase aberrations and irrespective of PD-L1 expression. Patients received Keytruda and Alimta plus carboplatin (peme/carbo) or peme/carbo alone. The major efficacy outcome was objective response rate (ORR). Additional efficacy outcomes were progression free survival (PFS), duration of response, and overall survival (OS).
    - The ORR was significantly improved in the Keytruda and peme/carbo group vs. the peme/carbo group (55% [95% CI: 42, 68] vs. 29% [95% CI: 18, 41]; p = 0.0032).
    - There was significantly greater improvement in PFS in the Keytruda and peme/carbo group vs. the peme/carbo group (13 months vs. 8.9 months; HR = 0.53 [95% CI: 0.31, 0.91; p = 0.020).
    - Duration of response for ≥ 6 months was seen in 93% of Keytruda plus peme/carbo patients vs. 81% of peme/carbo patients.
    - OS data were not available at the time of analysis.

- The recommended dosage of Alimta when administered with carboplatin and Keytruda for the initial treatment of NSCLC in patients with a creatinine clearance (calculated by Cockcroft-Gault equation) of ≥ 45 mL/min is 500 mg/m^2 administered as an intravenous infusion over 10 minutes prior to carboplatin on day 1 of each 21-day cycle for 4 cycles.
    - Following completion of platinum-based therapy, Alimta may be administered as maintenance therapy, alone or with Keytruda, until disease progression or unacceptable toxicity.

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    - Keytruda should be administered prior to Alimta when given on the same day.
    - Consult carboplatin and Keytruda's drug labels for dosing recommendations.

- Consult Alimta's drug label for dosing recommendations for other indications.