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FDA expands Lilly's ALIMTA Label

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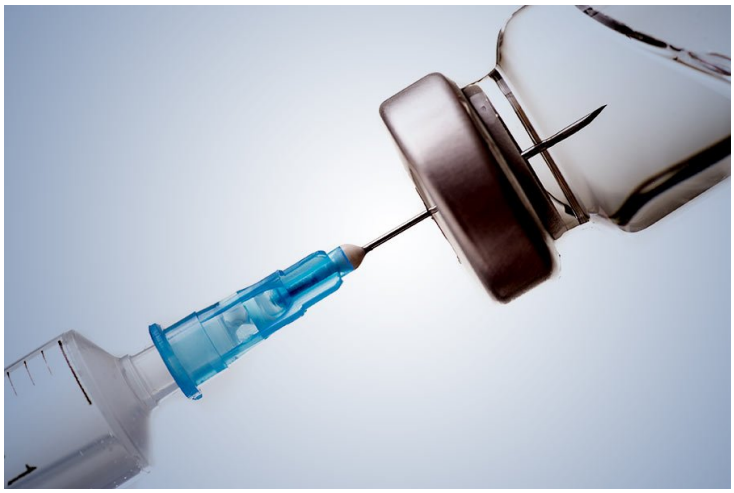

Eli Lilly and Companyhas announced that USFDA has granted approval for a new indication for ALIMTA® (pemetrexed for injection) in combination with KEYTRUDA® (pembrolizumab), developed and marketed by Merck, and platinum chemotherapy for the first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations.

This indication is approved based on data from Merck's Phase 3 KEYNOTE-189 trial. ALIMTA in combination with pembrolizumab and carboplatin was first approved in June 2018 under the FDA's accelerated approval process for the first-line treatment of patients with metastatic nonsquamous NSCLC, based on tumor response rates and PFS data from the Phase 2 study KEYNOTE-021 (Cohort G1).

As per the company statement, “In accordance with the accelerated approval process, continued approval was contingent upon verification and description of clinical benefit, which has now been demonstrated in the KEYNOTE-189 trial and has resulted in the FDA converting the accelerated approval to full (regular) approval.”

Anne White, president, Lilly Oncology said, "KEYNOTE-189 demonstrated an exceptional effect of the ALIMTA-pembrolizumab-platinum chemotherapy combination in the first-line setting, offering significantly improved survival in patients with metastatic nonsquamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations. This new indication reinforces Lilly's continued commitment to providing practice-changing treatment options that can make a meaningful difference for people living with lung cancer."

ALIMTA is indicated in combination with pembrolizumab and platinum chemotherapy for the initial treatment of patients with metastatic nonsquamous non-small cell lung cancer, with no EGFR or ALK genomic tumor aberrations.