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**Panel:** Non-small cell lung cancer

On behalf of Eli Lilly and Company, I respectfully request the National Comprehensive Cancer Network (NCCN) to review the enclosed recent publication for CYRAMZA® (ramucirumab) in reference to NCCN Guidelines V7.2019 for Non-Small Cell Lung Cancer (NSCLC):

> **Nakagawa K, Garon EB, Seto T, et al. Ramucirumab plus erlotinib in patients with untreated EGFR-mutated advanced non-small-cell lung cancer (RELAY): a randomised, double-blind, placebo-controlled, phase 3 trial. [published online October 4, 2019].** ***Lancet Oncol*****.**
> **https://doi.org/10.1016/S1470-2045(19)30634-5**

We are providing the full manuscript of previously submitted data from the RELAY study of ramucirumab and erlotinib in first-line metastatic epidermal growth factor receptor (EGFR) mutated NSCLC. RELAY is a global, randomized, double-blind, multi-center Phase 3 study of ramucirumab in combination with erlotinib versus placebo with erlotinib in previously untreated patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.

**Specific changes recommended**:
We request that the NCCN review the attached clinical evidence and include ramucirumab plus erlotinib following full FDA approval in the first line setting as a treatment option for patients with EGFR mutation-positive metastatic NSCLC.

**FDA Clearance:**
Ramucirumab in combination with erlotinib is not an FDA-approved first-line treatment option for patients with EGFR mutation-positive NSCLC. Please refer to the product prescribing information for the full FDA-approved indications and safety information. Full prescribing information is available at:

> http://pi.lilly.com/us/cyramza-pi.pdf

**Rationale:**
Results of the RELAY study were previously submitted following oral presentation at the Annual Meeting of the American Society of Clinical Oncology (ASCO): May 31-June 4, 2019; Chicago, IL. As previously reported, the combination of ramucirumab plus erlotinib resulted in a significant improvement in progression-free survival compared with placebo plus erlotinib with consistent benefit observed in prespecified subgroups, including exon 19 and 21 mutation types. No new safety signals were identified.

The recently published manuscript for this study is being submitted for your review.

Sincerely,

Jessie L. Fahrbach, MD
Vice President, Global Medical Affairs, Lilly Oncology