

December 20, 2015

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NCCN Guidelines Panel: Non-Small Cell Lung Cancer

On behalf of Merck & Co., Inc., I respectfully request the NCCN Non-Small Cell Lung Cancer panel review the enclosed information for KEYTRUDA (pembrolizumab) on the NCCN Guidelines for Non-Small Cell Lung Cancer.

Specific changes requested:

I respectfully request that the NCCN panel update the guidelines to list pembrolizumab as recommended therapy (category 1) for patients with metastatic non-small cell lung cancer who have progressed on or after first-line chemotherapy.

Rationale:

Results of KEYNOTE -010 trial in patients with previously-treated, PD-L1 positive (defined as membranous PD-L1 staining in $\geq 1\%$ of tumor cells) advanced non-small cell lung cancer were published in the *Lancet* on December 19, 2015. In summary, pembrolizumab, compared with docetaxel, provided superior overall survival for patients with 1 or more prior treatment regimens for advanced non-small cell lung cancer and a tumor proportion score $\geq 1\%$.

The following resources are submitted in support of this proposed change:

1. KEYTRUDA (pembrolizumab) prescribing information, Merck & Co., Inc.
2. Herbst RS et al. Pembrolizumab versus docetaxel for previously treated, PD-L1 positive advanced non-small cell lung cancer (KEYNOTE-010): a randomized controlled trial. *Lancet*. 2015;doi: 10.1016/S0140-6736(15)01281-7.

Thank you for considering this request. Below is my contact information should you need to contact me for additional information.

Sincerely,



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