



Submitted by:
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Dear NCCN NSCLC Guidelines Panel Members,

This letter is in follow-up to prior correspondence regarding consideration for update of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines) to include albumin-bound paclitaxel in combination with carboplatin as first-line therapy for advanced non-small cell lung cancer (NSCLC).

In response to Dr. Ettinger's request of November 11, 2011, please find, the peer-reviewed article of the Phase III study entitled "Weekly *nab*-Paclitaxel in Combination With Carboplatin Versus Solvent-based Paclitaxel Plus Carboplatin as First-Line Therapy in Patients With Advanced Non-Small-Cell Lung Cancer: Final Results of a Phase III Trial" by Socinski et al. published ahead of print on April 30, 2012 in the *Journal of Clinical Oncology* (Reference 1).

1. Socinski MA, Bondarenko I, Karaseva NA, et al. Weekly nab-paclitaxel in combination with carboplatin versus solvent-based paclitaxel plus carboplatin as first-line therapy in patients with advanced non-small-cell lung cancer: Final results of a Phase III trial. *Journal of Clinical Oncology* 2012; 30(17): 2055-62.

Celgene would like to inform the Panel that these data from the Phase III Socinski et al. study were submitted in December 2011 to the US Food and Drug Administration (FDA) under a Section 505(b) (2) application for approval as first-line treatment of patients with advanced NSCLC. The study design was reviewed by the FDA in a special protocol assessment (SPA), indicating that the design, clinical endpoints, and statistical analyses were acceptable and mutually agreed upon a priori. Within this SPA, the FDA agreed to use overall response rate (ORR) as the primary endpoint (as determined by independent, central, blinded radiological review based on RECIST) and overall survival (OS) and progression free survival (PFS) as secondary endpoints for this randomized pivotal study in the first-line treatment of patients with advanced NSCLC.

The PDUFA date for this filing is October 12, 2012.

Additionally, please find attached the publication by Reynolds et al. which was inadvertently omitted in the original 2010 submission to the Panel (Reference 2) and 4 posters recently presented at the American Association for Cancer Research (AACR) and the American Society of Clinical Oncology (ASCO) (References 3-6).*

2. Reynolds C, Barrera D, Jotte R, et al. Phase II trial of nanoparticle albumin-bound paclitaxel, carboplatin, and bevacizumab in first-line patients with advanced nonsquamous non-small cell lung cancer. *Journal of Thoracic Oncology* 2009; 4(12): 1537-43.
3. Bertino EM, Villalona-Calero MA, Nana-Sinkam P, et al. Phase II Trial of *nab*-paclitaxel plus carboplatin for advanced NSCLC in patients at risk of bleeding from VEGF directed therapies [poster]. *Poster presented at: 103rd Annual Meeting of the American Association for Cancer Research (AACR)* 2012; March 31 - April 4; Chicago, IL; USA.
4. Hirsh V, Okamoto I, Hon JK, et al. Weekly *nab*-paclitaxel in combination with carboplatin as first-line therapy in patients with advanced non-small cell lung cancer (NSCLC): Analysis of patient-reported neuropathy and taxane-associated symptoms [poster]. *Poster presented at: 48th Annual Meeting of the American Society of Clinical Oncology (ASCO)* 2012; June 1-5; Chicago, IL; USA.
5. Renschler MF, Okamoto I, Hon JK, et al. Safety and efficacy analysis by histology of weekly nab-paclitaxel in combination with carboplatin as first-line therapy in patients with advanced non-small cell lung cancer (NSCLC) [poster]. *Poster presented at: 48th Annual Meeting of the American Society of Clinical Oncology (ASCO)* 2012; June 1-5; Chicago, IL; USA.
6. Socinski MA, Langer CJ, Okamoto I, et al. Weekly *nab*-paclitaxel in combination with carboplatin as first-line therapy in elderly patients with advanced non-small cell lung cancer (NSCLC) [poster]. *Poster presented at: 48th Annual Meeting of the American Society of Clinical Oncology (ASCO)* 2012b; June 1-5; Chicago, IL; USA.

*These enclosed publications and posters along with those previously submitted (on August 5, 2010 and November 11, 2011) represent the full body of data published evaluating the use of Abraxane with carboplatin in the first line treatment of NSCLC.

Thank you for your kind attention.

Sincerely,



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