

## NCCN Melanoma Guidelines V.3.2011 – Follow-up Teleconference – 04/01/11

Guideline Page and Request	Panel Discussion	References	Vote		
			YES	NO	ABSTAIN
<p><b>ME-3, ME-8</b></p> <p><b>Internal request:</b> Based on the recent FDA approval, review the data for peginterferon alfa-2b for inclusion in the Melanoma Guidelines as an option for adjuvant treatment of Stage III disease.</p>	<p>Based on the recent FDA approval and supporting data in the noted reference, the panel consensus was to add a new footnote “n” to the option of interferon alfa for the adjuvant treatment of stage III disease (sentinel node positive or clinically positive node[s]) that states, “Interferon alfa can be given as high-dose interferon for one year or peginterferon alfa-2b for 5 years.” Footnote n was also added to the option of interferon alfa for the treatment of nodal recurrence after complete lymph node dissection.</p>	<ol style="list-style-type: none"> <li>1. Eggermont AMM, Suci S, Santinami M, Testori A, et al. Adjuvant therapy with pegylated interferon alfa-2b versus observation alone in resected stage III melanoma: final results of EORTC 18991, a randomised phase III trial. <i>Lancet</i> 2008;372:117-126.</li> <li>2. Prescribing Information: <a href="http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103949s5153lbl.pdf">http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103949s5153lbl.pdf</a></li> </ol>	19	0	0
<p><b>ME-E</b></p> <p><b>Internal request:</b> Based on the recent FDA approval, review the data for ipilimumab for inclusion in the Melanoma Guidelines as a systemic therapy option for the treatment of advanced or metastatic melanoma.</p> <p><b>External request:</b> Submission from Bristol-Myers Squibb to add ipilimumab as systemic therapy for patients with unresectable or metastatic melanoma as a category 1 recommendation.</p>	<p>Based on the recent FDA approval and supporting data in the noted reference, the panel consensus was to add ipilimumab (category 1) as an option for the treatment of patients with advanced or metastatic melanoma. Corresponding footnote “2” that states, “Ipilimumab has the potential for significant immune-mediated complications. Participation in the risk evaluation and mitigation strategy (REMS) program and/or experience in use of the drug as well as resources to follow the patient closely are essential. Ipilimumab should be used with extreme caution, if at all, in patients with serious underlying autoimmune disorders,” was also added.</p>	<ol style="list-style-type: none"> <li>1. Hodi FS, O’Day SJ, McDermott DF, Weber RW, et al. Improved survival with ipilimumab in patients with metastatic melanoma. <i>N Eng J Med</i> 2010; 363:711-723.</li> <li>2. Prescribing Information: <a href="http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125377s0000lbl.pdf">http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125377s0000lbl.pdf</a></li> </ol>	19	0	0