

October 9, 2016

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NCCN Guidelines® Panel: Melanoma

Dear Panel Members:

On behalf of Bristol-Myers Squibb Company, I respectfully request the NCCN® Melanoma Panel to review the enclosed data on the use of YERVOY® (ipilimumab) monotherapy for the adjuvant treatment of fully resected Stage III melanoma. These data were presented at the 2016 European Society of Medical Oncology (ESMO) Congress.¹

Specific Changes: In section ME-4, I respectfully request you to consider recommending ipilimumab 10 mg/kg monotherapy as a Category 1 option for the adjuvant treatment of fully resected Stage III melanoma.

FDA Clearance: The FDA-approved YERVOY® (ipilimumab) on October 28, 2015 for the adjuvant treatment of patients with cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm who have undergone complete resection, including total lymphadenectomy.² Ipilimumab was also approved on March 25, 2011 for the treatment of unresectable or metastatic melanoma.

Rationale: This data is being submitted in response to a standing request from NCCN for new clinical data and include:

- Overall survival data from the registrational Phase 3 trial (CA184-029), for the adjuvant treatment of fully resected Stage III melanoma

The following resources are included for your review:

1. Eggermont A, Sileni V, Grob J et al. Ipilimumab vs Placebo After Complete Resection of Stage III Melanoma: Final Overall Survival Results From the EORTC 18071 Randomized, Double-blind, Phase 3 Trial. Presented at the European Society of Medical Oncology (ESMO) 2016 International Congress; Copenhagen, Denmark; 7-11 October 2016.
2. YERVOY Prescribing Information

Thank you for your consideration of this request.

Sincerely,



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