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NCCN Guidelines Panel: Melanoma

On behalf of Genentech, Inc., I respectfully request the NCCN Melanoma Guideline Panel to review the enclosed recent key presentation for Cotellic™ (cobimetinib) for the treatment of patients with previously untreated, unresectable locally advanced or metastatic melanoma with a BRAF V600 mutation:

Atkinson V, Larkin J, McArthur GA, et al. Improved overall survival with cobimetinib + vemurafenib in advanced BRAFV600-mutated melanoma and biomarker correlates of efficacy. Presented at the Society for Melanoma Research 2015 Congress in San Francisco, CA; 2015 November 18-21. SMR Oral Presentation.

Specific Changes:

Please consider the Atkinson V et al. presentation for your updating purposes.

FDA Clearance:

- Cotellic™ is FDA-approved for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. It is not indicated for the treatment of patients with wild-type BRAF mutation.

Please refer to the product prescribing information for the full FDA-approved indications and safety information.

- Full Cotellic™ prescribing information available at:
http://www.gene.com/download/pdf/cotellic_prescribing.pdf

Rationale:

- The pre-specified final analysis of overall survival, a secondary endpoint of the coBRIM study, was presented at the recent Society of Melanoma Research (SMR) meeting on November 17-21, 2015 in San Francisco, California. After a median follow-up of 18.5 months, the median OS for patients in the Cotellic plus Zelboraf group was 22.3 months vs 17.4 months in the placebo plus Zelboraf group (HR: 0.70; 95% CI: 0.55-0.90, P=0.005).
- The updated safety profile of Cotellic plus Zelboraf was tolerable and manageable. Treatment related grade 3-4 AEs were 57% in the Cobimetinib plus Zelboraf group and 50% in the placebo plus Zelboraf group.

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