

March 20, 2016

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### **NCCN Guidelines Panel: T-cell Lymphomas**

On behalf of Merck & Co., Inc., I respectfully request the NCCN Panel for T-cell Lymphomas to review the enclosed information with KEYTRUDA (pembrolizumab), in reference to NCCN Guidelines V2.2017 for T-cell Lymphomas.

#### Specific changes requested:

We respectfully request KEYTRUDA (pembrolizumab) to be considered as an anti-PD1 immunotherapy in patients with relapsed or refractory NK/T-cell Lymphoma after failing L-asparaginase regimens.

#### FDA approval:

KEYTRUDA (pembrolizumab) is not approved for the treatment of patients with NK/T-cell lymphoma. For additional information on FDA-approved indications, please see enclosed prescribing information (PI).<sup>1</sup>

#### Rationale:

In a retrospective, named-patient study in Hong Kong, Singapore and Seoul, seven patients with relapsed or refractory NK/T-cell lymphoma patients failing asparaginase-regimens were treated with pembrolizumab (2 mg/kg). Most had advanced-stage disease with widespread organ involvement; systemic hemophagocytic syndrome was present in five patients. All patients had failed SMILE or SMILE-like regimens, two patients had relapsed from allogeneic hematopoietic stem cell transplantation (HSCT) and the median number of prior regimens including allogeneic HSCT was 2. A median of 7 (2–13) cycles of pembrolizumab were administered and objective response was observed in every patient. After a median follow-up of 6 (2–10) months, 5 patients remained in complete response (CR); one (post-allogeneic HSCT) had G2 rash, consistent with acute graft-versus-host disease.<sup>2</sup>

The following resources are submitted to assist the committee with their review:

1. KEYTRUDA (pembrolizumab) prescribing information. Merck & Co., Inc.
2. Kwong YL *et al.* PD-1 PD1 blockade with pembrolizumab is highly effective in relapsed or refractory NK/T-cell lymphoma failing L-asparaginase. Blood First Edition Paper, prepublished online February 10, 2017; DOI 10.1182/blood-2016-12-756841

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

Sincerely,

A handwritten signature in black ink, appearing to read "Maria Rivas". The signature is fluid and cursive, with the first name "Maria" and last name "Rivas" clearly distinguishable.

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