NCCN Guidelines Panel: Multiple Myeloma

On behalf of Merck & Co., Inc., I respectfully request the NCCN Panel for Multiple Myeloma to review the enclosed information with KEYTRUDA (pembrolizumab), in reference to NCCN Guidelines V3.2017 for Multiple Myeloma.

Specific changes requested:

We respectfully request the panel to consider adding KEYTRUDA (pembrolizumab), in combination with pomalidomide and low-dose dexamethasone, for the treatment of patients with relapsed/refractory multiple myeloma.

FDA approval:

KEYTRUDA (pembrolizumab) is not approved for the treatment of patients with multiple myeloma. For additional information on FDA-approved indications, please see enclosed prescribing information (PI).1

Rationale:

In a single-center, phase II study, 48 patients with relapsed/refractory multiple myeloma (RRMM) received pembrolizumab 200 mg IV every 2 weeks, pomalidomide 4 mg orally daily for 21 days and dexamethasone 40 mg orally weekly; cycles were repeated every 28 days for 2 years and responding patients continued on monthly pembrolizumab with pomalidomide and dexamethasone. Patients had a median of 3 (range: 2-5) lines of therapy, median age 64 (range: 35-83) years and had received both immune modulatory agent and proteasome inhibitor; 73% were refractory to both; 31 patients had prior ASCT and 30 patients had high-risk cytogenetics.2 

Treatment-related adverse events grade 3 and higher occurred in 42% of patients, including neutropenia (42%), anemia (21%), lymphopenia (15%), hyperglycemia (21%) and pneumonia (15%). Autoimmune adverse events included pneumonitis (13%) and hypothyroidism (10%), mostly grade ≤2. Objective responses occurred in 60% of patients including: sCR/CR (8%), VGPR (19%) and PR (33%); median duration of response was 14.7 months (95% CI 7.9-17.5). At a median follow-up of 15.6 months, median progression free survival was 17.4 months (95% CI 11.7-18.8) and median overall survival was not reached (95% CI 18.9-NR). Pembrolizumab, pomalidomide and low-dose dexamethasone showed acceptable safety and durable responses in RRMM patients.2
The following resources are submitted to assist the committee with their review:

1. KEYTRUDA (pembrolizumab) prescribing information. Merck & Co., Inc.


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

Sincerely,

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