



Submitted by:  
Kim Lee, PharmD  
Associate Director, Global Medical Information  
Celgene Corporation  
86 Morris Avenue  
Summit, NJ 07901  
Ph: 908-219-0777  
Email: [kilee@celgene.com](mailto:kilee@celgene.com)  
Date of Request: July 26, 2017

Dear NCCN Multiple Myeloma Guidelines Panel Members:

On behalf of Celgene Corporation, we respectfully request the NCCN Guidelines Panel for Multiple Myeloma review recently published data on the use of POMALYST<sup>®</sup> (pomalidomide) in combination with daratumumab and dexamethasone (DPd) in patients with relapsed/refractory multiple myeloma (rrMM).

**Specific Changes:**

We request addition to the guidelines information on the combination of POMALYST<sup>®</sup>, daratumumab and dexamethasone in a Phase Ib study (MMY1001) in 103 patients with rrMM to reflect the recent publication in Blood (Chari et al., 2017b).

**FDA Clearance:**

POMALYST is a thalidomide analogue indicated, in combination with dexamethasone, for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy (Celgene Corporation).

DARZALEX<sup>®</sup> (daratumumab) has been approved by the US Food and Drug Administration (FDA) in combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor (Janssen Biotech).

**Rationale for Proposed Change:**

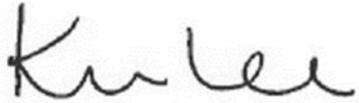
The open-label, multicenter, Phase Ib study (MMY1001) evaluated DPd in 103 patients with rrMM (Chari et al., 2017b). Patients included in the study were refractory to their last line of therapy, had received  $\geq 2$  prior lines of therapy, and were pomalidomide and daratumumab naïve. Patients had received a median of 4 prior therapies and median time from diagnosis was 5.13 years. Ninety-eight percent of patients had previously received a combination of lenalidomide and bortezomib.

The primary endpoint was safety and the secondary endpoint of overall response rate was 60%; stringent complete response 8%, complete response 9%, very good partial response 25%, and partial response 18%. Median progression-free survival was 8.8 months [95% Confidence Interval (CI), 4.6-15.4]. Median overall survival (OS) was 17.5 months (95% CI, 13.3-Not Evaluable, NE) and 12-month OS was 66% (95% CI, 55.6-74.8).

The most common ( $\geq 10\%$ ) Grade  $\geq 3$  AEs included neutropenia, anemia, leukopenia, thrombocytopenia, lymphopenia, fatigue, and pneumonia. Infusion-related reactions occurred in 50% of patients and were mainly Grade  $\leq 2$ .

A copy of the full publication of this study is enclosed for your review. Your consideration of this submission is greatly appreciated.

Sincerely,



Kim Lee, PharmD  
Associate Director, Global Medical Information



Thorsten Sperber, M.Sc.  
Executive Director, US Medical Affairs

## REFERENCES

1. Celgene Corporation. Pomalyst (pomalidomide) [Package Insert]. Summit, NJ: Celgene Corporation. <http://www.pomalyst.com/>.
2. Chari A, Suvannasankha A, Fay JW, et al. Daratumumab plus pomalidomide and dexamethasone in relapsed and/or refractory multiple myeloma. *Blood*. 2017b. <http://www.ncbi.nlm.nih.gov/pubmed/28637662>.
3. Janssen Biotech. Darzalex (daratumumab) [Prescribing Information]. Janssen Biotech. <https://www.darzalex.com/sites/www.darzalex.com/files/darzalex-prescribing-information.pdf>