

Submitted by:
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Date of Request: April 8, 2016

Dear NCCN Multiple Myeloma Guidelines Panel Members:

On behalf of Celgene Corporation, we respectfully request that the NCCN Guidelines Panel for Multiple Myeloma review recently presented data on the use of POMALYST® (pomalidomide) in combination with dexamethasone and daratumumab in patients with previously treated multiple myeloma (MM).

Specific Changes: Recommend an update to the guidelines regarding previously treated MM to reflect results from a Phase Ib study of the triplet combination of pomalidomide/dexamethasone/daratumumab described herein.

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, 2015).

Rationale for Proposed Change:

The addition of triplet combinations to the treatment landscape for multiple myeloma has expanded the therapy options for patients with RRMM in later lines of treatment. Despite tremendous progress, there continues to be an unmet medical need in the treatment of RRMM.

The combination of pomalidomide, dexamethasone and daratumumab has demonstrated activity in an ongoing, open-label, multicenter Phase Ib study in 98 MM patients who received ≥ 2 prior therapies, including 2 consecutive cycles of lenalidomide and bortezomib, and who were refractory to their last line of therapy (Chari et al., 2015).

Patients received pomalidomide 4 mg on Days 1-21, daratumumab 16 mg/kg weekly for 2 cycles, every 2 weeks for 4 cycles and then every 4 weeks plus dexamethasone 40 mg (20 mg if >75 years) on Days 1, 7, 14 and 21 until disease progression. A high response rate (overall response rate [ORR], 71%; clinical benefit response [CBR], 73%) was observed at a median follow-up of 4.2 months. Response occurred early, after a median of 1.2 months, with 2.8 months until best response. Responses were also noted to deepen over time. At 6 months, two-thirds of patients remained progression-free (progression-free survival [PFS], 66%). Progression was also limited among responders (no progression, 89%). Infusion related reactions (IRR) were mainly Grade ≤ 2 ; Grade 3 (6%) IRR events were manageable with pre-medication and reduced infusion rates. Grade ≥ 3 adverse events (AEs) were most commonly hematologic, including neutropenia (60%), anemia (25%) and leukopenia (20%).

A copy of this study, recently presented at the American Society of Hematology Annual Meeting, is enclosed for your review.

Your consideration of this submission is greatly appreciated.

Sincerely,



Eulena Horne, PharmD
Associate Director, Global Medical information



Peg Squier
Vice President, US Medical Affairs

Cited References:

1. Celgene Corporation. Pomalyst (pomalidomide) [Package Insert]. Summit, NJ: Celgene Corporation. <http://www.pomalyst.com/>.
2. Chari A, Lonial S, Suvannasankha A, et al. Open-Label, Multicenter, Phase 1b Study of Daratumumab in Combination with Pomalidomide and Dexamethasone in Patients with at Least 2 Lines of Prior Therapy and Relapsed or Relapsed and Refractory Multiple Myeloma [Oral]. Oral presented at: 57th Annual Meeting and Exposition of the American Society of Hematology (ASH); December 5-8, 2015; Orlando, FL, USA.