Bristol Myers Squibb™

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NCCN Guidelines® Panel: Multiple Myeloma

On behalf of Bristol Myers Squibb, we respectfully request the Multiple Myeloma Panel to review recently published data in Lancet Oncology on June 01, 2021 regarding the use of POMALYST® (pomalidomide) in combination with DARZALEX® (daratumumab) and dexamethasone (DPd) versus pomalidomide and dexamethasone (Pd) in relapsed refractory multiple myeloma (RRMM) patients.

Specific Changes: Consistent with our December 11, 2020 submission, we respectfully request the panel's consideration of the enclosed data to update the inclusion of pomalidomide in combination with daratumumab and dexamethasone from Other Recommended Regimens (Category 2A) to Preferred Regimen (Category 1) for therapy for previously treated multiple myeloma [MYEL-G 3 of 3] and the respective discussion section [MS-33].

FDA Clearance: POMALYST® (pomalidomide) is a thalidomide analogue indicated, for the treatment of adult patients with multiple myeloma in combination with dexamethasone in patients 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. (Pomalyst® (Pomalidomide) [Package Insert], Celgene Corporation).

DARZALEX® (daratumumab) injection, for intravenous use is a CD38-directed cytolytic antibody indicated for the treatment of adult patients with multiple myeloma in combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor (Darzalex® (daratumumab) [Package Insert], Janssen Biotech, Inc).

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) injection, for subcutaneous use is not FDA approved for the treatment of adult patients with multiple myeloma in combination with pomalidomide and dexamethasone. (Darzalex FASPRO® (daratumumab and hyaluronidase-fihj) [Package Insert], Janssen Biotech, Inc).

Rationale:

These data are being submitted in response to a standing request from the NCCN® for new data.

The December 11, 2020 submission was based on the interim results of an open-label, randomized, Phase III clinical study (APOLLO) evaluating the efficacy and safety of subcutaneous daratumumab in combination with pomalidomide and dexamethasone (DPd) (n=151) compared to Pd (n=153) in patients with early RRMM with ≥1 prior line of therapy, including lenalidomide and a proteasome inhibitor that was presented as an oral presentation at the 62nd American Society of Hematology Annual Meeting and Exposition (ASH) 2020 Virtual Meeting. At a median follow up of 16.9 months (mo) the primary endpoint showed improved median progression free survival of 12.4 mo with DPd compared with 6.9 mo with Pd (Hazard Ratio [HR] 0.63; 95% Confidence Interval [0.47-0.85] p=0.0018). No new safety findings were identified with the combination of DPd. The enclosed full publication and supplementary appendix include additional efficacy and safety information such as additional insight on: overall survival, median time to subsequent antimyeloma

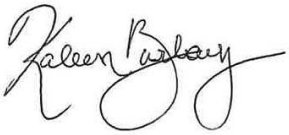
therapy, median time to first response, and most common adverse events stratified by age, weight, sex, race, renal and hepatic status, that were not included in the previously submitted presentation.

As part of the submission, the following resources are enclosed for your review:

- Dimopoulos MA, Terpos E, Boccadoro M, et al. Daratumumab plus pomalidomide and dexamethasone versus pomalidomide and dexamethasone alone in previously treated multiple myeloma (APOLLO): an open-label, randomised, phase 3 trial. Lancet Oncol. 2021 Jun;22(6):801-812. doi: 10.1016/S1470-2045(21)00128-5.
- Supplement to: Dimopoulos MA, Terpos E, Boccadoro M, et al. Daratumumab plus pomalidomide and dexamethasone versus pomalidomide and dexamethasone alone in previously treated multiple myeloma (APOLLO): an open-label, randomised, phase 3 trial. Lancet Oncol. 2021 Jun;22(6):801-812.

Thank you for your consideration of this request.

Sincerely,



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