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Celgene receives positive CHMP opinion for lenalidomide and pomalidomide for multiple myeloma patients

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Celgene Corporation has announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted positive opinions for two triplet regimens based on Celgene's proprietary IMiD® medications, REVLIMID (lenalidomide) and IMNOVID (pomalidomide).

The CHMP recommended approval of an expanded indication of REVLIMID as combination therapy with bortezomib and dexamethasone (RVd) for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.

The committee also recommended approval of IMNOVID in combination with bortezomib and dexamethasone (PVd), for the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide.

The European Commission, which generally follows the recommendation of the CHMP, is expected to make its final decision in approximately two months.

"The CHMP positive opinions for our IMiD combinations, RVd and PVd represent very good news for patients with multiple myeloma in Europe," said Nadim Ahmed, President, Hematology/Oncology for Celgene. "We look forward to potential EMA approvals, which would make these new triplet regimens available to patients, as we aim to improve patient outcomes across multiple stages of their disease."

The CHMP positive opinion for REVLIMID was based on the data from SWOG S0777, a phase 3 trial evaluating the triplet combination of REVLIMID, bortezomib and dexamethasone (RVd) in adult patients with previously untreated multiple myeloma, without an intent for immediate autologous stem cell transplant (ASCT). Results from SWOG S0777 showed statistically significant progression-free (PFS) and overall survival improvements in patients treated with RVd compared to those treated with REVLIMID and dexamethasone alone (Rd). The choice of treatment in a first-line therapy setting is important as patients progressively become less responsive to therapy and experience shorter periods of remission at later lines of treatment.

The CHMP positive opinion for PVd was based on the data from OPTIMISMM, the first prospective phase 3 trial to evaluate an IMNOVID-based triplet regimen in patients who were previously treated with REVLIMID, and who were, in the majority (70 percent), REVLIMID refractory. This patient population represents a growing unmet medical need for which new treatment options are necessary. Results from OPTIMISMM showed that patients receiving PVd achieved a significantly longer PFS than those in the Vd treatment arm.

REVLIMID in combination with bortezomib and dexamethasone and IMNOVID in combination with bortezomib and dexamethasone are not approved for any use in any country.