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BEERSE, BELGIUM, December 19, 2014 - Janssen-Cilag International NV (Janssen) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the approval of VELCADE® (bortezomib) in combination with rituximab, cyclophosphamide, doxorubicin and prednisone, for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are unsuitable for haematopoietic stem cell transplantation.[1]

MCL is a rare and aggressive type of blood cancer that can be challenging to treat and is associated with a poor prognosis.[2,3] The positive opinion of the CHMP was based on data from the Phase 3 study, LYM-3002. In the European Union (EU), VELCADE is currently indicated for the treatment of multiple myeloma (MM), another rare blood cancer, either as monotherapy or in combination with of other treatment regimens.[4]

"At Janssen, we are committed to continuously developing therapeutic solutions to treat relevant, haematologic diseases like MCL," said Thomas Stark, Vice President, Medical Affairs, Janssen Europe, Middle East and Africa (EMEA). "This positive opinion brings us one step closer to offering additional treatment options with VELCADE for patients and physicians, and we are delighted with this recommendation."

Study Efficacy Results[5]

LYM-3002 was a randomised, open-label, active-controlled, multicentre, international, prospective Phase 3 study including 487 patients with newly diagnosed MCL who were ineligible, or not considered, for bone marrow transplantation.

The results showed significant benefits when treating newly diagnosed patients with MCL using a VELCADE-based combination (VR-CAP*), compared to a widely used standard of care combination not including VELCADE (R-CHOP?). The VR-CAP regimen significantly improved progression-free survival (PFS), the primary endpoint, and showed improvements across a range of secondary endpoints.[5] An independent review committee reported the increase in PFS to be 59 percent (median 24.7 vs. 14.4 months; HR 0.63; p