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ASIA EDITION

Janssen seeks USFDA nod for Darzalex to treat ASCT multiple myeloma

14 March 2019 | News

Application supported by the Phase 3 MAIA study being reviewed under the FDA Real-Time Oncology Review pilot program

The Janssen Pharmaceutical Companies of Johnson & Johnson announced the submission of a supplemental Biologics License Application (sBLA) to the US Food and Drug Administration (FDA) seeking approval of Darzalex (daratumumab) in combination with lenalidomide and dexamethasone (Rd) for the treatment of patients with newly diagnosed multiple myeloma who is ineligible for autologous stem cell transplant (ASCT).

The sBLA, based upon data from the phase 3 MAIA (MMY3008) clinical study, is being reviewed by the FDA under the Real-Time Oncology Review (RTOR) pilot programme, which for certain applications allows the FDA to review data before the applicant formally submits the complete application. It aims to explore a more efficient review process to help ensure treatments are available as soon as possible for patients. Selection into the RTOR pilot programme does not guarantee or influence approvability of the supplemental application.

"We are pleased to complete the latest Darzalex submission based upon the Phase 3 MAIA study, which evaluated the efficacy and safety of this anti-CD38 monoclonal antibody as a combination regimen for newly diagnosed patients with multiple myeloma who are transplant ineligible," said Yusri Elsayed, MD, M.H.Sc., PhD, Vice President, Hematologic Malignancies Disease Area Leader, Janssen Research & Development, LLC. "We look forward to closely collaborating with the Agency throughout the expedited Real-Time Oncology Review process in support of this newly diagnosed, transplant ineligible multiple myeloma patient population for whom a combination treatment regimen with Darzalex may be useful."